

February 28, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Request for comments on the Medicare Program; Contract Year 2015 policy and technical changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, proposed rule.

Dear Ms. Tavenner:

The Medicare Payment Advisory Commission (MedPAC) is pleased to provide comments on the Centers for Medicare & Medicaid Services' (CMS's) January 10, 2014, Medicare Program; Contract Year 2015 policy and technical changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, proposed rule. We appreciate your staff's work on the notice, particularly given the competing demands on the agency.

Our comments focus on the following five policy changes in the proposed rule:

- drug categories or classes of clinical concern,
- medication therapy management programs under Part D,
- Part D tiered pharmacy networks,
- Limitation on the number of plans offered by sponsors of stand-alone prescription drug plans (PDPs), and
- enrollment requirements for prescribers of Part D covered drugs.

Drug categories or classes of clinical concern

Under Part D, plans are required to include on their formularies all or substantially all drugs in six classes—anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. The Patient Protection and Affordable Care Act of 2010 (PPACA) required that these protected classes remain in place until the Secretary established new criteria to identify drug categories or classes of clinical concern.

The “protected classes” policy is intended to ensure access to medications in those classes and prevent plan sponsors from designing formularies that substantially discourage enrollment by beneficiaries who take certain medications in those classes. However, because the policy essentially requires open coverage of drugs in those classes, CMS is concerned that it results in higher Part D costs by “substantially limit[ing] Part D sponsors’ ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes.” The agency is also concerned that the policy results in overutilization of these medications. Using the authority provided by PPACA, CMS proposes to use the following criteria to determine drug categories or classes of clinical concern:

- Hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and
- More specific CMS formulary requirements will not suffice to meet the universe of clinical drug- and disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

In other words, under the proposed rule, a drug class would not be given the protected status unless a delay in obtaining a medication is likely to result in serious health consequences and the clinical needs of patients treated with one or more medications in that drug class cannot be met unless all Part D drugs in that class are included in a plan formulary.

After reviewing the medications in the six protected classes, CMS determined that three classes—immunosuppressants for transplant rejection, antidepressants, and antipsychotics—do not meet both of the proposed criteria, and thus, could be removed from the list of drug categories or classes of clinical concern. However, for the benefit year 2015, the agency is proposing to change the formulary requirements for immunosuppressants and antidepressants, but not for antipsychotics because of the clinical risk associated with untreated psychotic illness and the agency wants to make certain there is not a need for additional transitional considerations.

In general, we support CMS’s approach in applying objective criteria to determine drug categories or classes of clinical concern, while balancing the goals of beneficiary access and welfare with Part D plans’ tools to manage the drug benefit and appropriately constrain costs. We too have concerns about antipsychotics and support CMS’s move to proceed slowly. In addition to the concern raised by the agency about the potential for adverse clinical outcomes, we are also concerned, based on our work, that the current exceptions and appeals process may not consistently provide meaningful protection for beneficiary access to antipsychotics. CMS audit also found that many plans had difficulty meeting the program requirements in the area of Part D coverage determination, appeals, and grievances.

Although the Commission shares the Agency’s concern about the overutilization of drugs in these classes, we expect the proposed changes in the formulary requirements to have little impact in

addressing overuse. We believe that both CMS and MedPAC need to focus on inappropriate use of medications, generally, with particular attention paid to drug classes such as antipsychotics where inappropriate use can not only increase Part D costs, but cause harm to the beneficiary. We provide further comments on this issue below.

Medication therapy management programs under Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs) to implement medication therapy management programs (MTMPs) to improve the quality of pharmaceutical care high-risk beneficiaries receive. To be eligible for the program, a beneficiary must have multiple chronic diseases, take multiple covered Part D drugs, and be likely to incur annual costs exceeding a level designated by the Secretary. Neither the legislation nor subsequent CMS regulations provided much guidance on how these programs should be designed or implemented. Consequently, plan MTMPs differed on the number and type of chronic conditions and prescriptions a beneficiary must have to be eligible, how eligible beneficiaries are identified and enrolled, the kinds of interventions provided to enrollees, and the outcomes that drug plans measure.

Since 2010, CMS has been tightening requirements for plan programs: reducing the number of chronic conditions and Part D covered drugs beneficiaries must have, lowering the estimated annual cost threshold to be eligible for MTM, requiring specific MTM services, and requiring plans to use an opt-out method to enroll eligible plan beneficiaries. However, enrollment rates remain low, at 8 percent of all Part D enrollees. CMS suggests that eligibility criteria prevent access to enrollees who might benefit from the program.

This year CMS proposes to broaden access by requiring plans to permit beneficiaries with two or more chronic conditions, taking two or more Part D covered drugs, and with a projected annual cost of \$620 to enroll in MTMPs. CMS estimates that 55 percent of Part D enrollees will be eligible for MTM using these criteria. CMS also proposes requiring plans to make stronger efforts to contact and enroll eligible beneficiaries.

Although the Commission supports CMS's goal of improving medication management, we question whether applying these new criteria to the current program are the most effective way to achieve this goal. AS CMS notes, plans are unable to contact many eligible beneficiaries and many beneficiaries refuse the service. In addition, physicians may be reluctant to accept recommendations from drug plans with which they have no direct relationship. Most importantly, the cost of expanding the program to meet the new criteria may be excessive when there is little evidence that Part D MTM programs have been effective for enrolled beneficiaries.

After seven years, it may be time to question whether MTM programs offered through PDPs – without the cooperation and coordination of a beneficiary's care team – have the capacity to significantly improve beneficiaries' drug regimens. Plans have little incentive to offer MTM programs. Physicians participating in MedPAC focus groups have said they are not receptive to advice from patients' insurers, and patients have not been induced to participate. Further, even

within MA-PDs, which do have a financial incentive to engage in MTM-like activities, other care management programs or tools may have greater potential to improve outcomes for beneficiaries.

With respect to PDPs, better medication management might be achieved through programs offered by ACOs, medical homes, and other team-based delivery models. Although this type of program would be limited to beneficiaries receiving care through these systems, it could result in more effective medication management for those enrollees who do participate. Providers working within these care models have more incentive to improve their patients' medication regimens.

Encouraged by their physicians and pharmacists, eligible patients may be more likely to participate in MTM programs and follow the advice they receive.

Part D tiered pharmacy networks

In our most recent March report to the Congress,¹ we reported an increase in sponsors' use of tiered pharmacy networks that distinguish between preferred and nonpreferred pharmacies among the pharmacies that are classified as in-network. Cost sharing (copayments and/or coinsurance) for beneficiaries is less at preferred pharmacies than at nonpreferred pharmacies, with varying degrees of cost-sharing differentials across plans.

The proposed rule reminds Part D sponsors that, although the use of lower cost sharing at some pharmacies is permitted, such cost sharing reductions are permissible only if the reductions do not increase CMS payments to these plans. CMS found that unit costs observed among some preferred pharmacies that offered lower cost sharing were higher than those at nonpreferred pharmacies. This finding may suggest that these plans are in violation of this requirement. Thus, the agency is proposing several changes that affect the contractual arrangements between Part D sponsors and pharmacies.

We appreciate the agency's concern and agree that the competition created by preferred pharmacy networks should result in lower costs for the program and for Part D enrollees. The Commission shares those objectives and believes that the use of tiered pharmacy networks could be beneficial for the program and its enrollees if price concessions plan sponsors obtain are reflected in prices at the pharmacies and/or used to lower premiums. However, we do not agree with CMS's proposed approaches. Instead, we suggest making several programmatic changes to ensure that the use of tiered pharmacy networks do not increase Medicare costs and do not harm beneficiaries.

First, we agree that any price concession plan sponsors obtain from pharmacies should be transparent and be used to lower negotiated prices at the point-of-service and/or used to lower costs of providing the benefit. We strongly encourage CMS to require plan sponsors that use tiered pharmacy networks to ensure that the prices net of all price concessions obtained from preferred pharmacies do not exceed those obtained from nonpreferred pharmacies.

¹ Medicare Payment Advisory Commission. 2013. Report to the Congress: *Medicare payment policy*. Washington, DC: MedPAC.

Second, we believe that actuarial equivalence should be met with the level of cost sharing offered at nonpreferred pharmacies so that a beneficiary who does not live within a reasonable distance from a preferred pharmacy is not receiving a benefit that is less generous than the defined standard benefit.

Finally, we encourage CMS to consider requiring an access standard for preferred pharmacy networks. For example, CMS may want to consider setting a pharmacy access standard that is based on the standard used for TRICARE, which is the standard currently used for the overall pharmacy network adequacy under Part D. The standard should not be so stringent as to discourage the use of tiered pharmacy networks but sufficient to allow the majority of beneficiaries enrolled in such plans to take advantage of the lower prices offered at those pharmacies if they choose to do so. And in so doing, plans must continue to meet the overall network adequacy requirement.

Given the rapid increase in the number of plans that use tiered pharmacy networks, the Commission will continue to monitor the effects of this trend to ensure that program costs and beneficiary access are not adversely impacted.

Limitation on the number of plans offered by sponsors of stand-alone prescription drug plans

Currently, a sponsor of a stand-alone prescription drug plan (PDP) is permitted to offer up to two enhanced benefit plans once it has offered one basic benefit plan in a given region. Enhanced benefit plans must be able to meet the “meaningfully different” standard as measured by enrollees’ expected out-of-pocket costs. This standard is intended to ensure that an enhanced benefit plan provides a more generous coverage than the basic benefit plan offered by the same sponsor. Similarly, if a plan sponsor offers two enhanced benefit plans, the second enhanced benefit plan must be more generous than the first, and include some coverage in the gap. Under this rule, a PDP sponsor with more than one Part D contract in a region can offer up to three plans per contract.

For the 2015 benefit year, CMS is proposing to allow PDP sponsors to offer only one contract per region and limit the number of plans they may offer to a total of two plans per contract, a basic benefit plan and an enhanced benefit plan. CMS believes that the phase-out of the coverage gap that began in 2011 will result in a narrowing of the difference between the two enhanced benefit options such that they do not meet the “meaningfully different” standard. Further, CMS is concerned that some plan sponsors are offering multiple enhanced benefit plan options to avoid low-income subsidy (LIS) enrollees and engage in risk segmentation

On the one hand, we agree with CMS that risk segmentation could be a concern for the program, particularly if it involves avoiding LIS enrollees. If a plan sponsor is able to systematically attract healthier enrollees in one of their enhanced benefit plans, it may result in a higher premium for its basic benefit plan due to worse risk selection for that plan than it otherwise would have been. If that basic plan qualifies as an LIS benchmark plan, it could increase the amount Medicare pays for the low-income premium subsidy.

On the other hand, there has not been sufficient time to analyze the impact of this policy on costs to the enrollees and the program. We are particularly concerned about the effects this policy could have on enrollees' plan options and premiums, and competition among plan sponsors. Given these uncertainties and the short time frame between when the rule is finalized and when plan sponsors must submit their bids for the 2015 benefit year, we strongly encourage CMS to delay making this change for 2015. In the meantime, we encourage CMS to use its authority to reject plan bids that discriminate against certain groups of beneficiaries based on LIS status and/or health status.

Enrollment requirements for prescribers of Part D covered drugs and improper prescribing practices

CMS is proposing to make two changes to address issues related to Part D program integrity: inappropriate payment for drugs and improper prescribing that increases program costs and raises patient safety concerns.

Under Part D, a valid prescription must be written by qualified prescribers, meaning prescribers who have an active professional health care license that conveys prescribing privileges to them under applicable state laws. In 2012, CMS implemented a requirement that every Prescription Drug Event record submitted by a Part D sponsor to CMS contain an active and valid individual prescriber national provider identifier (NPI), further ensuring that prescriptions covered under the program are written by qualified prescribers. The change also allowed CMS to more effectively identify and monitor prescribers in the Part D program. However, as CMS acknowledges in the preamble, NPI is not a practitioner credentialing system, and is based on self-reported information by the applicant. This has contributed to inappropriate payments for drugs ordered by individuals who do not meet the definition of qualified prescribers as documented by the OIG (OEI-02-09-00608).

In this proposed rule, CMS addresses the issue of qualified prescribers and the excess spending and patient risk imposed by unqualified prescribers in two ways. First, the Secretary would invoke the authority granted her under PPACA and require that only physicians or eligible professionals who are enrolled in the Medicare FFS program or have a valid opt-out affidavit on file with Medicare can write prescriptions for Medicare beneficiaries enrolled in Part D. In addition, CMS proposes to strengthen the existing requirement that Part D claims must include an NPI, by specifically instructing plan sponsors to deny any claim for a Part D drug, including at the point of sale, if the claim does not contain an active and valid physician or eligible professional NPI. A plan sponsor must also deny any claim for a Part D drug if the prescriber is not enrolled in Medicare or have a valid opt-out affidavit on file with Medicare.

The second set of changes CMS is proposing would grant CMS the authority to revoke a physician or eligible professional's Medicare enrollment if:

- the prescriber's Drug Enforcement Administration Certificate is suspended or revoked,
- the prescriber has a suspended or revoked license under the applicable administrative body in the state where the prescriber practices, or

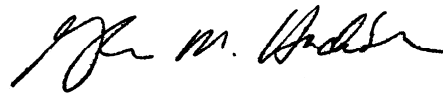
- the prescriber shows a pattern or practice of prescribing Part D drugs that is abusive and represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements.

In the proposed rule, CMS does not define what would constitute “abusive” prescribing or a pattern of prescribing that posed “threat to the health and safety of Medicare beneficiaries.” Instead, CMS proposes to consider various factors in determining instances of a pattern or practice of prescribing that is abusive and a threat to the health and safety of beneficiaries.

The Commission strongly supports both of the proposed changes, which reflect CMS’s continued efforts to protect the program from inappropriate payments for prescription drugs and to promote patient safety without inadvertently harming prescribers who engage in reasonable prescribing activities. In addition to reducing the program’s vulnerability to abusive or fraudulent prescribing, these changes will allow for more effective monitoring of improper prescribing behaviors. Inappropriate prescribing can result in overutilization of medications that increase program costs without providing any health benefit, or potentially harm the beneficiaries. The Commission plans to focus on this issue going forward.

If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC’s Executive Director.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth".

Glenn M. Hackbarth, J.D.
Chairman