



American Society of Consultant Pharmacists

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Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
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Dear Dr. McClellan:

The undersigned organizations, which represent long-term care residents, facilities, and health professionals, seek your immediate assistance on an urgent matter affecting the transition to Medicare Part D for residents of nursing homes and other long-term care facilities. Long-term care facilities and residents are facing a crisis from numerous problems that serve as obstacles to long-term care residents receiving medications under Medicare Part D.

We appreciate the hard work undertaken by the Centers for Medicare and Medicaid Services (CMS) to implement Medicare Part D. Despite these efforts, problems have become apparent during the first few weeks of the new drug benefit program. CMS staff have been responsive and cooperative in addressing many of the problems that have arisen. This assistance has generally focused on dealing with problems involving specific Part D plans.

The focus of this letter is the impact of Medicare Part D on long-term care residents and facilities and the physicians and pharmacies that serve these facilities. We write to seek policy changes that are urgently needed to prevent a major crisis of access to medications in long-term care.

Shown below are the broad policy issues that present major problems for long-term care facilities and residents.

1. The formulary restrictions and utilization management tools of Medicare Part D plans are inconsistent with the provision of quality care, resident safety, and efficient operations for long-term care residents, facilities, physicians, and pharmacies.

Medicare Part D plans used by long-term care residents have limited formularies and extensive use of prior authorization and step therapy requirements. Reimbursement for many drugs can only be obtained through restrictive and inhibitory requirements designed by the Part D plans that are inconsistent with nursing home requirements and practices.

These plan policies fail to consider the realities of long-term care operations:

- Physicians are not on-site at the nursing facility. They typically visit the facility only once per month to see their patients.
- Physician orders in long-term care require three-way communication – the pharmacy and long-term care facility must both have the current physician order so that the same medication is both dispensed and administered to the resident.
- Physicians generally do not have medical records for their nursing facility residents at their offices. They rely on nursing staff at the facility to provide them with the information required to make medical decisions between visits to the facility.

If the Part D plan requires the physician to call them to discuss the patient, the physician in most cases will not have the information available to make sound decisions about the appropriateness of changing the patient to a different medication, or to discuss patient details that the plan might want to obtain from the physician.

Requiring physicians to make decisions about changing medications when the physician does not have access to the patient's clinical record jeopardizes patient safety. An alternative medication will likely have a different profile of adverse effects, contraindications, or drug interactions. Without the patient record, it is not possible for the physician to make an appropriate judgment about changing medications. The Part D plan also does not have access to the patient's full clinical profile and thus is no position to advise the physician about the appropriateness of any medication change.

Part D plans have widely varying procedures and forms related to formulary exceptions processes and prior authorization. Each plan is different and many plans have multiple prior authorization forms, with different forms for different

drugs. Some plans require the physician to call them to discuss the patient, even though the physician does not have the clinical record of the patient accessible.

The policies and practices of the Part D plans are not consistent with quality care, resident safety, or efficient operations for long-term care residents, facilities, physicians, or pharmacies. This is especially true when facilities have their residents randomly scattered among more than a dozen different Part D plans.

2. The Medicare Part D program, and the policies of Part D plans, have the potential to conflict with the Conditions of Participation for long-term care facilities and with good clinical care.

Although the transition period is still in effect, it is becoming increasingly clear that policies of many of the Medicare Part D plans place long-term care facilities at risk of violating regulatory and survey requirements that apply to these facilities.

Long-term care facilities already have in place numerous provisions and protections related to appropriate use of medications for residents. These protections include:

- CMS regulations and survey guidance related to “unnecessary drugs” and “pharmacy services”
- Periodic dose reduction requirements on psychotropic medications
- Restrictions on use of “Beers criteria” medications (medications generally considered inappropriate for use in the elderly)
- Annual survey of the facility by the state health department
- State health department surveys prompted by complaints about the facility from residents, family members, ombudsmen, or others
- Monthly drug regimen review by the consultant pharmacist
- Drug utilization review and medication screening by the long-term care pharmacy provider
- Continuous monitoring and oversight of the resident by facility nursing staff and aides
- Medical director oversight of quality of care provided to facility residents, including drug therapy issues
- Review of quality of care provided to residents, including medication use, by the facility Quality Assessment and Assurance Committee

Virtually all the Part D plans have almost all “Beers criteria” medications on Tier 1 of their formularies, even though these medications are not recommended for use in the elderly. There have already been anecdotal reports of Part D plans asking physicians to substitute chloral hydrate for zolopidem tartrate and

clozapine for olanzapine. Chloral hydrate is a “Beers criteria” medication and clozapine requires expensive and invasive blood monitoring. These substitutions would save money for the plan, but could also have adverse consequences for the beneficiary and put long-term care facilities at risk of survey deficiencies and fines from health departments. Surveyors will not accept poor quality care from facilities, even if Part D plans refuse to pay for the appropriate medications.

3. The Medicare Part D program is built on the faulty assumption that physicians are able to donate their time to comply with Part D plan administrative requirements that serve as barriers to access to medications.

Medicare Part D was designed to follow the commercial model of drug benefit programs. In this model, pharmacy benefit managers and insurance companies limit access to medications through the use of formularies and a variety of utilization management tools. The tiered formulary, which shifts an increasing amount of the drug cost to the patient as the drug cost increases, is the most commonly used tool in commercial insurance programs. Prior authorization, step therapy, and quantity limits are also sometimes used.

Because low-income individuals are unable to pay more than a nominal co-pay for prescription drugs, Congress imposed stringent limits on cost-sharing for low-income Medicare beneficiaries. As a result, the use of prior authorization and step therapy is far more prevalent in Medicare Part D than in commercial insurance programs. These latter tools require intervention from the patient’s physician, or other primary care provider such as nurse practitioner or physician assistant, for the patient to have access to the medication.

The widespread use of restrictive formularies, prior authorization, and step therapy, especially in Part D plans designed for low-income Medicare beneficiaries, combined with the high volume of medications used by dual eligibles, places an administrative burden on physicians that is untenable and for which there is no compensation. Physicians do not have sufficient time available to respond to pharmacist or patient requests for medication changes, or to call or fax Part D plans to explain why the patient needs the medication.

In the long-term care setting, pharmacists are already beginning to notify physicians about medications that will not be covered by the Part D plans. Anecdotal reports indicate that some physicians are so overwhelmed by the volume of these requests that they will not be able to cooperate with all the requests being received. Although the program is currently in the transition period, we are concerned that this volume of bureaucratic workload on

physicians and pharmacists will soon create an unsustainable impediment to care of long-term care residents.

The long-term care industry is already challenged to recruit qualified physicians. The increased burden imposed by Part D plans to assist with obtaining payment for medications for their patients may cause many physicians to simply stop caring for residents of nursing homes. This would increase the burden on remaining physicians, producing a vicious cycle. Facilities in rural areas are at especially high risk of losing adequate physician support to care for their residents.

4. Some Part D plans are imposing prior authorization requirements on entire categories of medications, preventing a physician from prescribing any of these medications without following the plan's designated requirements for the physician to call or fax the plan.

Some plans require physician intervention to secure payment for all medications used to treat Alzheimer's disease. Medications used for prophylaxis or treatment of influenza are also restricted by many plans. These category restrictions leave the physician with no choice of agent within that therapeutic class that can be provided without restriction. CMS should require all plans to offer at least one agent in each therapeutic class that can be obtained without restriction.

That CMS would allow plans to impose prior authorization requirements on influenza medications is especially troubling. When needed, these medications must be administered promptly to be effective. When an outbreak occurs in a long-term care facility, there is no time for physicians to call multiple Part D plans to seek permission to have these medications paid for.

The Centers for Disease Control and Prevention has recently issued a Health Advisory recommending that the two older agents, amantadine and rimantadine, should no longer be used for influenza prophylaxis or treatment in the United States. CMS should issue a directive to plans that the two agents recommended by the CDC for use in treating influenza, oseltamivir and zanamivir, must be made available to prescribers without restrictions. This is especially important in long-term care settings.

5. In the long-term care environment, if the Part D plan refuses to pay for a medication, the long-term care facility must still provide it to the resident.

Nursing facilities are legally obligated to provide any medication included on the resident's plan of care, regardless of whether the drug benefit provider pays for the medication.

In the community setting, if the patient can not pay for the medication, or get an outside party to pay, the patient will usually go without the medication. If a nursing facility resident needs a medication, and the resident or another party can not pay, the nursing facility becomes the default payer. Medicare Part D plans are perfectly free to refuse to pay for a medication. If the plan requires the physician to fill out a form or call the plan to get the medication covered, and the physician does not do so, the plan will simply reject the claim. Once the transition period has expired, this could leave the nursing facility with financial exposure for any uncovered medications. It was not the intention of Congress to force nursing facilities to pay for medications.

6. Current CMS policies are resulting in blocked payments for injectable medications and certain other medications that are frequently used in long-term care settings.

Congress required that Medicare Part A and Part B payment for medications should remain the same, and Part D should only pay for medications not covered by Medicare A or B. Over 600 medications can be covered by either Medicare Part B or Part D, depending upon diagnosis, site of administration, or other factors. CMS has chosen to restrict Part D plans from approving a claim for any of these medications until proof is provided that Medicare Part D is the applicable payer. The result of this policy is that many medications that are commonly used in the long-term care setting are being blocked from payment through the prior authorization process.

Delays in payment for these medications can sometimes result in transfer of the resident to the hospital for treatment. When a resident needs an intravenous infusion to treat dehydration, or an injectable antibiotic to treat pneumonia, delays of even a few hours are unacceptable. Some of these medications are quite expensive, but hospitalizing the beneficiary to receive the medication is far more expensive.

Procedures are needed to clarify the proper payer. There is no reason, however, that a post-authorization process can not be used. Because the vast majority of the claims submitted by long-term care pharmacies will be properly billed to Part D, a post-dispensing audit should be used to confirm proper billing rather than blocking all claims at the time of dispensing. If an audit shows it should have been billed to Part B, the pharmacy can reverse the claim and re-bill.

7. CMS policy has resulted in tremendous variability among the dozens of Medicare Part D plans.

CMS has chosen to allow Medicare Part D plans to have freedom to choose their own paths in offering the Medicare drug benefit. These Part D plans all have different approaches, forms, or requirements related to areas such as:

- Formularies
- Injectable medications and intravenous infusion solutions
- Prior authorization procedures
- Quantity limit requirements
- Initial fill policies
- Transition policies related to new admissions, hospital transfers, etc.
- Customer service hours of operation and call volume capacity
- Payment policies for emergency box medications, leave medications, medication doses that are dropped by the nurse or spit out by the resident, etc.

CMS guidance to the Part D plans in these areas is generally couched as recommendations or requests, rather than as specific requirements with deadlines to comply and penalties for failure to comply. The problem with this approach became very clear when the Part D program was launched and many plans were not honoring established transition policies and were unable to respond to telephone calls from beneficiaries and pharmacists.

When the lives of Medicare beneficiaries are at stake, the level of government oversight should be sufficient to protect these vulnerable beneficiaries. CMS should develop and apply uniform minimum standards across all the plans to ensure that all Medicare beneficiaries, especially dual eligible individuals and long-term care residents, have access to critically needed medications. These standards should be developed in partnership with long-term care facilities and pharmacies. Without these minimum standards, and active government oversight and enforcement of the rules, lives are in jeopardy.

8. The tremendous variability among Part D plans creates obstacles to providing quality care to long-term care residents.

A recent Institute of Medicine report on medical error [To Err is Human – Building a Safer Health System, 2000; pp. 170–3] noted that simplifying key processes and standardizing work processes are key strategies to enhance patient safety. When the same task must be completed in numerous ways to achieve the same outcome, the risk of error is greatly increased. Long-term care facilities are

held responsible for achieving quality outcomes in areas such as timely administration of medication and minimizing medication errors, among others. Yet facilities are also required to allow their residents to be randomly dispersed among perhaps dozens of Medicare Part D plans.

Because of the number of plans and the variability among plans, facilities are hindered in efforts to achieve consistent quality outcomes. Efficiency is also hindered, which increases costs and takes staff away from other resident care duties to contend with administrative requirements of Part D plans.

Recommendations

When the transition period is over, the most important obstacles to long-term care residents receiving medications are the non-formulary and prior authorization (including step therapy) requirements imposed by Medicare Part D plans. As discussed previously, long-term care physicians can not follow the procedures required by most Part D plans to ensure that claims for these medications are paid by the plans. Many of these procedures, such as requiring the physician to call the plan, are entirely inappropriate in the long-term care setting. The tremendous variety of forms and procedures used by these plans also prevents physicians from navigating obstacles to ensure their patients receive the appropriate medication for their particular need.

We therefore offer the following recommendations to help ensure long-term care residents have access to needed medications:

- Part D plans should be prohibited from requiring physicians to call them to discuss non-formulary and prior authorization requests; a form should be used for this purpose instead.
- CMS should develop or authorize standard procedures and forms for non-formulary and prior authorization requests. This should include a universal prior authorization form that must be honored by all the Part D plans for all their medications.
- In accordance with the CMS initial fill policy, Part D plans should be prohibited from imposing formulary restrictions or prior authorization requirements at the time of initial fill, allowing long-term care residents access to medications while the long-term care pharmacy and physician work to complete plan requirements for payment of subsequent fills of the medication.
- Plans should be prohibited from imposing prior authorization requirements on entire categories of medication. At least one medication in each category should be readily accessible to the physician without need for completion of prior authorization procedures.

- Part D plans should be required to recommend formulary alternatives to non-formulary medications, or those requiring prior authorization, during the prescription claim transaction.
- Part D plans should be required to make all their prior authorization criteria for individual medications available to physicians and pharmacists.

Until such time as these recommendations can be implemented, Part D plans should be prohibited from applying non-formulary or prior authorization restrictions. We recommend that CMS create a task force to evaluate these issues and develop uniform plan policies and forms that are appropriate for the long-term care setting. We welcome the opportunity to participate in such a task force.

A fundamental source of major operational challenges, and a risk to quality care for long-term care residents, is the random scattering by CMS of dual eligible long-term care residents among multiple Part D plans with such diverse policies and formularies. CMS must introduce as much consistency as possible in the drug benefit program for Medicare beneficiaries who reside in long-term care facilities.

If CMS believes that legislation is needed to secure any of these requested changes, we would appreciate receiving this feedback promptly so that legislators can be made aware of this need. We are confident that Congress does not intend for the Medicare Part D program to produce the adverse consequences in long-term care that are sure to ensue without these policy changes.

We appreciate your attention to these issues, and your consideration of our recommendations. We are available to meet with you to discuss further strategies to improve the interaction between long-term care facilities and Medicare Part D.

For additional information, or questions about these comments, please contact me or Thomas R. Clark, RPh, MHS, ASCP Director of Policy and Advocacy; Telephone: 703-739-1316 x123; E-mail: tclark@ascp.com.

Thank you.

Sincerely,

John Feather
Executive Director

On behalf of:

American Association for Geriatric Psychiatry

American Geriatric Society

National Association of Directors of Nursing Administration in Long-Term Care