

# THE AMERICAN GERIATRICS SOCIETY

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October 4, 2004

The Honorable Mark McClellan, MD, PhD.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8012  
Baltimore, MD 21244-8012

Attention: CMS-4068-P

Dear Dr. McClellan:

The American Geriatrics Society (AGS), an organization of nearly 7,000 geriatric health care professionals who are specially trained in the management of care for frail, chronically ill older patients, appreciates the opportunity to provide comments on the proposed Medicare prescription drug benefit, also known as the Part D regulations. Our comments on the proposed rule are below.

- 1) S 423.50 Marketing and Enrollment Forms. The rule explains that a prescription drug plan (PDP) may not accept enrollment forms in providers' offices. This appears to prohibit a physician from taking an enrollment form from a patient and assisting with the enrollment process. We suggest that in certain limited circumstances, such as for dual eligible or frail elderly patients with special health or social needs, providers should assist or facilitate with the enrollment process.
- 2) S 423.120 Formulary requirements for P & T Committee. If a plan uses a formulary, it must use a pharmaceutical and therapeutic (P&T) committee to develop and review the formulary. The Centers for Medicare and Medicaid Services (CMS) has requested comments on their interpretation of the law that a P & T Committee decision regarding the plan's formulary are binding on a plan. The AGS proposes further review beyond the P & T Committee. Specifically, we recommend, as frequently is current practice, that a quality assurance committee approve the P & T committee recommendations.

- 3) S. 423.120 P & T Committee Design. The P & T committee will be involved in designing formulary tiers and any clinical programs designed to encourage the use of preferred drugs (e.g., prior authorization; step therapy, generics programs). The majority of the P & T committee would be required to be practicing physicians and/or practicing pharmacists. At least one of each would need to be expert in care of elderly and disabled individuals. Geriatricians and other health care professionals with special training in geriatrics – such as geriatric pharmacists – have special training in pharmacology and specifically in areas involving medical contraindications. For this reason, the AGS suggests that the P & T Committee include at least one health care provider with special and demonstrable training in geriatrics.

Furthermore, CMS requests comment on their decision to strengthen the regulation by requiring that more than just one pharmacist and one physician is independent and free of conflict. The AGS strongly supports this requirement, which will lead to meeting the best needs of the patient.

- 4) USP Model Guidelines. The US Pharmacopeias (USP) will develop a model set of guidelines that consists of a list of drug categories and classes that may be used by PDP sponsors and MA orgs to develop formularies, including therapeutic categories and classes. The AGS submitted a comprehensive comment letter on the proposed guidelines and has met privately with members of the USP expert guideline committee. In short, the AGS is concerned that the medications needed to appropriately treat frail elderly populations, those Medicare beneficiaries with multiple chronic conditions or functional limits (1) will not be included in the proposed formulary and (2) will not be readily available through the formulary over-ride process. In addition, the proposed guidelines reliance on the ICD-9 code approach does not adequately capture common geriatric syndromes.
- 5) Treatment Protocols. The rule states that plans would be required periodically to evaluate and analyze treatment protocols and procedures related to their formularies to ensure that their plan members are receiving the best care. CMS seeks comments on the minimum timeframes for periodic evaluation and analysis of protocols and procedures. The AGS believes that a quarterly review initially and every 6 months thereafter would suffice as an adequate amount of time for periodic evaluation and analysis of protocols. Identifying problems dictated by a change in practice standards or when the FDA approves a new drug with benefits for older patients and having those addressed early during program implementation would be beneficial. As programs mature, CMS could reduce monitoring of plans to an annual review.
- 6) Appropriate Notice. The Medicare Modernization Act (MMA) also requires “appropriate notice” to CMS, enrollees and prescribers regarding: 1) removing a drug from its formulary and 2) making any change in the preferred or tiered cost-sharing status. The regulation defines appropriate notice as at least 30 days prior

to such change taking effect during a given contract year. The AGS would recommend a longer notice period of 60-90 days. Beneficiaries may need to see their primary care provider before making changes and this may not be feasible in a 30-day period.

Furthermore, the regulation also only requires notice to be given to those enrollees taking that drug – not to all plan enrollees. The AGS believes that plans should notify all providers since other beneficiaries may be thinking of switching medications and may be in discussions with physicians about making these changes. Such changes would be impacted by PDP decisions in this area.

- 7) Prior Authorization. PDPs can include use of prior authorization; step therapy; tiered cost-sharing; and other tools. CMS seeks comments on whether these should be under the direction and oversight of a P & T committee to ensure balance between clinical efficacy and cost-effectiveness and if they should involve quality assurance and medication therapy management. In general, evidence based clinical guidelines for medication treatments should be followed. The guidelines that the P & T Committee has chosen should be accessible to beneficiaries and physicians online, and subject to the same notification principles as a change in formulary.

The AGS objects to prior authorization and step therapy as it interferes in the practice of medicine and inappropriately second guesses the physician. Tiered cost sharing is acceptable provided it is not structured in such a manner that it inhibits the appropriate use of medications

- 8) S 423.153 Cost Effective Utilization Management. The Part D regulations require each plan to provide a program to include incentives to reduce costs when medically appropriate. This should not come to simply mean “switching,” in which one branded drug product is switched with another similar branded drug product, referred to as therapeutic substitution. Therapeutic substitution would always require explicit prescriber notification and approval. We oppose independent therapeutic substitution. In addition, we find the notification and approval procedures burdensome and ineffective for physicians.
- 9) Medication therapy management – Provider Types, Reimbursement & Eligibility. The Part D regulations require plans to establish medication therapy management programs (MTMP). Targeted beneficiaries include individuals with multiple chronic diseases; taking multiple Part D drugs; and are like to incur high annual costs, CMS seeks comments on which types of physicians and pharmacists should provide these services, which reimbursement mechanisms are appropriate for these services and how to define multiple chronic diseases and multiple Part D drugs.

MTMP requires a willing provider – the primary care provider – who is available to collaborate. In addition, the pharmacist should have experience or additional

training to provide consulting pharmacist services for nursing homes, such as a special certification and/or membership on an interdisciplinary team. Finally, the physician should be a geriatrician or other primary care provider with demonstrated geriatric experience. This experience is especially significant when there are important potential medication-disease interactions.

The AGS believes that the frail elderly is an excellent target population for the MTMP. We believe there are numerous ways to target this population. Multiple chronic illnesses do not fully capture this population. Instead, we would suggest a patient base that has multiple comorbidities, which includes functional status limits, as well as some other limiting factor, such as inability to self-manage these conditions, high health utilization costs and/or dementia. Effective medication therapy management requires the willingness of the beneficiary and their primary care physician to participate in the process.

- 10) Medication therapy management – Range of Services. The MMA allows plans to establish a broad range of services under the MTMP. CMS envisions a “range of services, ranging from simple to complex” and defines this very broadly. All prescriptions for medications in the modified Beers criteria drugs for potentially inappropriate use in the elderly should be reviewed. The services should review the patients total medication regimen – current prescription medications, herbal and supplements, and over the counter medicines. Services should also include drug regimen simplification, selection and monitoring, and implementation and management of a therapeutic plan following diagnosis.
- 11) S 423.564 Grievances, Coverage and Appeals. Plans must maintain grievance procedures for making timely coverage determinations; exceptions to a tiered cost-sharing structure; and handling exceptions to a formulary. Under the exceptions process, a nonpreferred drug could be covered as a preferred drug if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective or would have adverse effects or both. An enrollee or prescribing physician may request that a coverage determination be expedited. The enrollee or physician either must submit an oral or written request directly to the plan sponsor; physician may provide oral or written support for an enrollee’s request. CMS should make this process as simple as possible. Physician office staff should be allowed to place calls if calls are required. Plans should have standardized forms that can be completed quickly and faxed and should be required to provide a response in a timely manner, such as 48 hours.
- 12) Exceptions to formularies. PDP sponsors must also establish a formulary exceptions process. Formulary use includes the application of a dose restriction that causes a drug not to be covered for the number of doses prescribed, or a step therapy requirement that causes a drug not to be covered until the requirements of the sponsor’s coverage policy are met. The process must address coverage of drugs that are not covered; continued coverage of a drug that sponsor is

discontinuing on the formulary; and exception to the policy that causes a drug not to be covered until the step therapy requirement is satisfied.

The procedures must include a description of the criteria a sponsor uses to evaluate physician's determination; a process for comparing applicable medical/scientific evidence on safety and effectiveness of non-formulary drug with formulary drug; a description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug; if the sponsor covers a non-formulary, and if the cost incurred by the enrollee for that drug is treated as included in meeting the annual out of pocket threshold. An enrollee, representative or physician may file an exception.

The plan may require a written certification from a physician because a drug is medical necessary, because there is not a drug on the formulary to treat the disease or medical condition that is an acceptable clinical alternative; because the alternatives for step therapy have been ineffective in the treatment of the enrollee's disease, based on evidence and known characteristics of the enrollee and the drug, is likely to be ineffective, or the number of doses have been ineffective.

Finally, the plan may require that the written certification may include: enrollee's name; contract number; patient history; primary diagnosis; the reason the formulary drug is not acceptable; why the drug required for step therapy not acceptable; why the available number of doses is not acceptable; why the drug is needed; any other information reasonably necessary.

We have several concerns with the exceptions process. Physicians must go through two separate processes to ensure their patients receive nonpreferred drugs and drugs that are not on the formulary. We object to these processes due to their interference in the practice of medicine/second guessing physician. In addition, the written certifications are extremely burdensome. Finally, the AGS specifically objects to the diagnosis being included on the certification.

- 13) Independent Review Entity (IRE). The regulations establish an IRE for enrollees who are dissatisfied with re-determinations. The IRE does not occur automatically; an enrollee must request review. The IRE must seek views of prescribing physician. In order for an enrollee to request an IRE reconsideration, the physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition are not as effective for the individual, has adverse effects for the individual, or both. This process is highly burdensome for both the physician and the beneficiary.
- 14) Transition Issues. Under the Part D regulations, the Medicaid drug benefit ends as of January 1, 2005, but the auto-enrollment does not begin until May 15, 2006. Consequently, dual eligibles that do not enroll in a plan would be without drug coverage until May or June. AGS is concerned about this provision for several

reasons. "Duals" have complex medical and social needs. Many duals have multiple chronic conditions, functional limits and/or dementia and are particularly in need of ongoing medications, many of these specialized. Gaps in coverage or confusion surrounding auto enrollment procedures would particularly harm this population.

In order to protect the most vulnerable beneficiaries, CMS should incorporate the following protections. CMS should require Part D plans to reimburse current pharmacies for current medications for the first 6 months of the new benefit. This will allow a smooth transition for all parties and allow prescriptions to be switched to formulary medications and allow everyone to switch to in-network pharmacies in a manner that does not endanger health. CMS should also allow States to obtain federal financial participation for any wrap-around medication until July 1, 2006. Alternatively, the automatic enrollment of dual eligible individuals should occur on December 31, 2005.

- 15) Special Enrollment Periods (46640) 423.36 – Under the Part D regulations, if an enrollee resides in the community with a PDP plan and moves into the nursing home, there is currently no special enrollment period to allow the beneficiary to change plans upon entry into a nursing home. In comparison, there is such a provision under the discount card program. The AGS recommends comparable treatment under the prescription drug program for this vulnerable and special need's population. In addition, the AGS would recommend that nursing home eligible seniors that are non-institutionalized also have access to this SEP. Given the move for this frail population to enter community based programs it is important to develop all opportunities based on the beneficiaries needs rather than location of care.

### Conclusion

We hope to work with CMS on the development of the final rule on the Part D program. If you should have questions or comments on this letter, please contact Susan Emmer in our Washington office at (301) 320-3873.

Sincerely,



Meghan Gerety, MD, AGSF  
President  
American Geriatrics Society