

THE AMERICAN GERIATRICS SOCIETY

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LINDA HIDDEMEN BARONDESS
Executive Vice President

December 22, 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

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 submit comments on the “Medicare Modernization Act Formulary Guidelines – CMS Strategy for Affordable Access to Comprehensive Drug Coverage”.

The AGS is pleased with the direction of the strategy laid out by CMS in the paper. The fundamental purpose of the Guidelines is the protection of Medicare beneficiaries. We believe the Guidelines are of sufficient breadth and granularity to assure that Medicare beneficiaries, and specifically certain categories of needy beneficiaries, are not discouraged from enrolling because of the nature of the formulary of the PDP or the provider and beneficiary protections offered by the PDP. In short, our letter focuses on three general areas.

First, we are pleased with the statement of principle that requires use of best practices to select drug benefits for seniors. The AGS supports the use of an evidence-based approach that captures common geriatric syndromes

Second, the Guidelines note that CMS will work to ensure appropriate access to drugs addressed in widely accepted treatment guidelines, such as those for behavioral health and psychological disorders. CMS notes that, “in some cases, widespread industry practice and widely used treatment guidelines require all or substantially all drugs in particular class to be covered.” We ask that CMS extend this protection to the frail

elderly population as well. We note that while all Medicare beneficiaries are at risk from restricted access to medications, those beneficiaries at the greatest risk are the 6 million dual eligibles (those with both Medicare and Medicaid coverage), the 4 million frail elderly (those age 85 and over), and residents of nursing homes and assisted living communities, numbering approximately 3 and one-half million. These individuals frequently take eight or more medications and have multiple chronic conditions.

Frail elderly individuals and long-term care residents need access to a wide variety of medications and dosage forms to appropriately manage their multiple chronic conditions and medical problems. AGS believes that if seniors do not have access to the most commonly utilized medications that seniors will be forced to change to inappropriate medications resulting in costly adverse effects. This can be accomplished by allowing for physicians to authorize for the dispensing of nonformulary medications in those cases where the formulary medications are determined by the prescribing physician to be inappropriate. This allowance is the only mechanism to assure that those with special needs will receive the individualized medications that are required given their frailty and comorbidities.

Third, the Guidelines discuss the membership of the pharmaceutical and therapeutic (P & T) Committee. 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 or 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.

Examples of some of the objective measures of special and demonstrable training in geriatrics include the following:

- Physicians with Geriatric Board Eligibility / Certification
- Physicians with Fellowship training in Geriatrics
- Physicians who are Fellows of the American Geriatric Society Fellowship
- Certified Medical Director (designation by American Medical Director Association)
- Pharmacists with advanced residency or fellowship training in geriatrics
- Pharmacists who are Board Certified Pharmacotherapy Specialists (BCPS)
- Pharmacists who are Certified Geriatric Practitioners (CGP)

Thank you for the opportunity to provide comments on this important issue. If you have questions or comments, please contact Susan Emmer in the AGS Washington office at 301-320-3873.

Sincerely,

A handwritten signature in black ink, appearing to read "Meghan Gerety". The signature is fluid and cursive, with the first name "Meghan" being more prominent than the last name "Gerety".

Meghan Gerety, MD, AGSF
President
American Geriatrics Society