Much has been written about the potential positive and negative sequelae of the Medicare Modernization Act (MMA) of 2003. The prescription drug benefit has been the most publicized and maligned. However, the impact on consumers who need complex, high-end seated positioning and wheeled mobility systems and on the practitioners and suppliers who serve them is significant.

The MMA calls for competitive acquisition—national competitive bidding—on seating and wheeled mobility products by the year 2007. On the commodity side of durable medical equipment (DME) and supplies, competitive bidding may make sense. Competitive acquisition is not appropriate, however, for high-tech seating and wheeled mobility systems. By nature, the provision of these products falls to companies that have a unique business model that involves a high level of personal involvement between the provider and consumer and the integration of licensed healthcare professionals throughout the process. The products provided are uniquely configured for the individual consumer based on diagnosis, prognosis, and lifestyle. Moreover, while products may be classified (for competitive bidding) in the same national Healthcare Common Procedure Coding System (HCPCS) code, they are not equal in regard to their capabilities to meet the medical and functional needs of a consumer.

Competitive acquisition will result not only in suppliers reducing services to people with disabilities but also in consumers receiving products that are selected based on cost and not on medical and functional appropriateness. Such a reduction in services, or limitation of products based on price alone, will have a severe negative impact on clinical outcomes associated with the provision of high-tech rehabilitation and assistive technology.

Even though Congress has mandated the implementation of a system of competitive acquisition for certain items of DME, they have recognized the need to differentiate among different products. Language contained in Section 302(b) of Public Law 108-173 of the MMA also gives the Secretary of Health and Human Services, through the Centers for Medicare and Medicaid Services (CMS), the authority to exempt certain products when competitive acquisition “is not likely to result in significant savings.” This is certainly the case with complex, high-end seating and wheeled mobility products, which make up a miniscule part of Medicare expenditures. In addition, the provision specifies that in implementing this competitive acquisition authority, “the Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.” Congress recognized that while product may be classified in the same HCPCS code, they are not necessarily equal in regard to their capability to meet beneficiaries’ medical needs. Congress therefore authorized the Secretary to carefully analyze whether individual products within broad product classifications have sufficient clinical benefit to be treated differently than other items in that code, that is, to be excluded from competitive acquisition. This language serves to document the intent of Congress that the Secretary uses competitive acquisition judiciously after careful reflection, study, and analysis, and that price should not take precedence over medical best practice.

There is a clear course of action that should be followed to assure that consumers receive the appropriate seating and wheeled mobility systems in light of competitive bidding requirements. To determine the relative therapeutic benefit of seating and wheeled mobility items, the Secretary should immediately impanel a working group consisting of—

- Physicians with training and experience in the rehabilitation of persons with significant disabilities requiring complex, high-tech seating and wheeled mobility products.
- Experienced, credentialed occupational therapists and physical therapists.
• Manufacturers and suppliers of high-tech rehabilitation and assistive technology products and services.

This panel should—

• Develop a definition of “therapeutically advantageous,” complex, high-tech seating and wheeled mobility products under competitive acquisition that can be applied to manufactured items and reflected on claims with the use of a modifier or other alpha-numeric marking when specifically prescribed by the consumer’s physician.

• Assist CMS in reexamining complex, high-tech seating and wheeled mobility products, including establishing a definition, perhaps based on International Classification of Diseases, Ninth Edition (ICD-9) codes, of persons considered to be eligible consumers of complex, high-tech seating and wheeled mobility products.

• Develop minimum standards as part of broader DME quality provisions under Section 302(a) for providers of complex, high-tech seating and wheeled mobility technology, including minimum qualifications and certification for the people involved in the various activities associated with providing the appropriate products and services.

The work of this panel of experts will provide a foundation upon which appropriate public policy can be written that—

• Ensures Medicare beneficiaries will receive the appropriate products and services to meet their clinical needs.

• Ensures that the people involved in providing high-tech seating and wheeled mobility technology and services are properly trained and credentialed and actively participate in ongoing continuing education programs.

• Establishes high professional standards and a clear definition of what constitutes high-tech seating and wheeled mobility technology products, which will make providing these products difficult for those individuals who perpetrate fraud.

Along with the issues associated with the MMA, people with disabilities are faced with two additional, and more immediate, problems that limit their access to needed seating and wheeled mobility products. These are two of the eligibility criteria that Medicare applies to determine if consumers qualify for wheeled mobility equipment.

The first addresses CMS’s definition of nonambulatory that is the basis of eligibility for wheeled mobility systems. Wheeled mobility systems are covered only for consumers who are nonambulatory; that is, the consumer would be bed- or chair-confined without the wheeled mobility device. This places unrealistic limitation on a consumer’s independence within his or her home environment and potentially creates danger of injury caused by falls and the inability to leave the home in emergency situations.

CMS should adopt a standardized, objective, and inclusive definition of nonambulatory. According to CMS’s definition, “if a patient can bear weight to transfer from a bed to a chair or wheelchair, the patient is considered nonambulatory. However, if the patient is able to walk either without any assistance or with the assistance of an ambulatory aid, such as a walker, the power wheelchair is denied as not medically necessary.” Conversely, when describing the information needed to determine a medical necessity, the policy mentions the need to provide documentation on the “distance the patient can walk (1) independently and (2) with the assistance of a walker or other ambulatory aid.” These represent clear contradictions that cause confusion and delays in providing needed technology.

An objective and inclusive definition of ambulatory versus nonambulatory is needed. For example, the Social Security Administration (SSA) in its Disability Evaluation Under Social Security (Blue Book, January 2003) has its definition for “ambulating effectively.” It states the following:

“b. What we mean by inability to ambulate effectively.

Definition. Inability to ambulate effectively means an extreme limitation of the ability to walk; i.e., an impairment(s) that interferes very seriously with the individual’s ability to independently initiate, sustain, or complete activities. Ineffective ambulation is defined
generally as having insufficient lower extremity functioning (see 1.00J) to permit independent ambulation without the use of a hand-held assistive device(s) that limits the functioning of both upper extremities. (Listing 1.05C is an exception to this general definition because the individual has the use of only one upper extremity due to amputation of a hand.)

To ambulate effectively, individuals must be capable of sustaining a reasonable walking pace over a sufficient distance to be able to carry out activities of daily living. They must have the ability to travel without companion assistance to and from a place of employment or school. Therefore, examples of ineffective ambulation include, but are not limited to, the inability to walk without the use of a walker, two crutches or two canes, the inability to walk a block at a reasonable pace on rough or uneven surfaces, the inability to use standard public transportation, the inability to carry out routine ambulatory activities such as shopping and banking, and the inability to climb a few steps at a reasonable pace with the use of a single hand rail. The ability to walk independently about one’s home without the use of assistive devices does not, in and of itself, constitute effective ambulation.”

The second issue is Medicare’s coverage policy stating that seating and wheeled mobility technology, as well as DME products, is limited to items that are necessary for use within the home. In 1984, Congress defined DME in Section 1861(n) of the Social Security Act to require use of DME, including wheelchairs, “in the patient’s home,” for an individual to qualify for reimbursement under Part B of Medicare. Specifically excluded from such reimbursement is DME that is used in a hospital or skilled nursing facility. Congress’ intent to restrict payment for DME was limited to excluding hospitals and skilled nursing facilities. Congress did not otherwise impose a geographical limit on use of DME; for example, there is no restriction to the four walls of the home for wheeled mobility systems for an individual to qualify for reimbursement under the “in the patient’s home” clause. The application of the “in the patient’s home” requirement for an individual to qualify for Medicare coverage has been applied in an overly restrictive manner by both CMS and the Durable Medical Equipment Regional Carriers (DMERC).

CMS should incorporate a consistent principles medical review policy as exemplified in the Congressional and Executive mandates, including Section 1861(n) of the Social Security Act; the Home Health Care Protection Act of 2000, which is contained in the Benefits Improvement and Protection Act of 2000 and defines “homebound”; and President Bush’s New Freedom Initiative that is designed to enhance the independence of people with disabilities through increased access to the community and the workforce.

The restriction of access to needed technology caused by CMS policy and regulation is not limited to consumers with Medicare coverage. The effects trickle down to the state level where consumers of all ages and disabilities are negatively impacted. Private insurance companies are also adopting similar policy and access restrictions. It is time that CMS and members of Congress realize that well-intentioned legislation and regulation have unintended effects on people with disabilities nationwide.

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