Testimony of Michael B. Clark
Chief Administrative Officer and General Counsel
The SCOOTER Store, New Braunfels, Texas

Before the US Senate, Special Committee on Aging
On

"*Eliminating Waste and Fraud in Medicare: An Examination of Prior Authorization Requirements for Power Mobility Devices*"

September 19, 2012 @ 2:00pm

Ranking Member Corker, Members and staff of the Senate Special Committee on Aging, my name is Mike Clark. I am the Chief Administrative Officer and General Counsel for The SCOOTER Store, a nationwide supplier of durable medical equipment (DME), including Power Mobility Devices (PMDs)[1] to the disabled and elderly who rely on this equipment to conduct their activities of daily living in the home. Based in New Braunfels, Texas, The SCOOTER Store started as a small family business in 1991 and now employs roughly 2300 individuals throughout the country.

Our company is committed to regulatory compliance and providing our fellow citizens with the finest quality health care products and services. TSS maintains accreditation from an independent, third party, the Accreditation Commission for Health Care ("ACHC"). ACHC is nationally recognized for helping companies meet customer and regulatory requirements, and continually enhancing their employee skills and efficiencies for promulgating quality management systems and processes against those standards.

I would like to thank the Committee for holding this very important and timely hearing to discuss Prior Authorization for PMDs and the Medicare Demonstration that began on September 1st in seven States that cover nearly half of all Medicare beneficiaries.

Power Mobility Devices Are Essential to Address Heath Care Needs of the Nation's Elderly and Disabled, and Their Use Generates Health Care Savings

PMDs allow people to retain or regain their independence in the home, and complete their activities of daily living safely and with dignity. Innovative technology has made PMDs more usable by allowing the equipment to maneuver in tight spaces. Ultimately, this keeps people in their home and out of nursing homes and hospitals.

PMDs enhance the lives of untold thousands of people who would otherwise be left either bed or chair bound and unable to live their lives in dignity. Without the use of

[1] PMDs include both power wheelchairs (four-wheeled motorized vehicles with steering operated by an electronic device or joystick to control direction and turning) and power-operated vehicles ("POVs")(three or four-wheeled motorized vehicles operated by a tiller) used in the home.

this equipment, seniors would be more likely to incur significant injuries simply trying to get from room to room.

PMDs help prevent people from falling. The Centers for Disease Control and Prevention (CDC) identifies falls as the leading cause of injury and/or death in people 65 or older.[2] We also note that an April 1, 2000 Report written by George F. Fuller and published by the American Academy of Family Physicians, entitled *Falls in the Elderly*, concluded that "falls are the leading cause of injury-related visits to emergency departments in the United States and the primary etiology of accidental deaths in persons over the age of 65 years."[3] At the time, George F. Fuller was the White House physician and deputy director for clinical operations. Studies estimate the direct costs of non-fatal falls in those 65 and older to be at least $19 billion annually.[4]

Power mobility equipment not only improves the lives of our fellow citizens, but it also saves health care dollars by preventing worse injuries.

Medicare Rightfully Requires a Face-to-Face Examination Prior to Payment For a Power Mobility Device

Congress, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), established the physician/ treating practitioner as the gatekeeper when dealing with power wheelchairs covered by Medicare. Specifically, Congress set forth that payment may not be made for a motorized or power wheelchair unless a physician, a physician assistant, nurse practitioner, or a clinical nurse specialist "has conducted a face-to-face examination of the individual and written a prescription for the item." *The face-to-face examination is the event established by Congress to determine whether a beneficiary is qualified for a power wheelchair*.

In 2004, the Centers for Medicare and Medicaid Services (CMS) convened an Interagency Wheelchair Working Group (IWWG) comprised of physicians, occupational therapists, physical therapists, researchers, and policy specialists from different federal agencies including the Veterans Administration, National Institutes of Health, Food and Drug Administration, and Department of Education. IWWG recommended that CMS replace the wheelchair "bed and chair confined" standard with a new *functional* standard.

On June 3, 2005, CMS modified the Medicare National Coverage Determination Manual, replacing the National Coverage Determinations ("NCDs") for PMDs, power operated wheelchairs (§ 280.1) and power operated vehicles (§ 280.9), with a new

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[2] *Falls Among Older Adults: An Overview,* Centers for Disease Control and Prevention, *available at* http://www.cdc.gov/homeandrecreationalsafety/falls/adultfalls.html (referencing data found in the CDC's Web-based Injury Statistics Query and Reporting System, as accessed on November 30, 2010).
[3] George F. Fuller, Falls in the Elderly, 61 American Family Physician 2159-2168 (2000).
[4] *See e.g.*, JA Stevens, et al., *The costs of fatal and non-fatal falls among older adults,* 12 Injury Prevention, 290-295 (2006).

Mobility Assistive Equipment[5] ("MAE") NCD (§ 280.3). Effective for claims with dates of service on or after May 5, 2005, the MAE NCD establishes that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home.[6] This standard is thus based on the beneficiary's present abilities and condition at the time he or she is evaluated and equipment is prescribed and is not diagnosis dependent. These determinations can only be made during the face-to-face evaluation required by law.

CMS regulation makes clear that a physician or treating practitioner must conduct "a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity."[7] In the preamble to the final PMD rule issued April 5, 2006, entitled "*Medicare Program; Conditions for Payment of Power Mobility Devices (PMD), Including Power Wheelchairs and Power-Operated Vehicles,*" CMS declared that no format is required to document the face-to-face examination[8] and the information recorded at the face-to-face examination will generally be sufficient.[9]

The congressionally mandated face-to-face examination properly places the physician/treating practitioner in charge of patient care. TSS fully supports this requirement and applauds Congress for emphasizing the role of the medical professional when assessing power mobility needs.

Congress and the Centers for Medicare and Medicaid Services Have Instituted Significant Fraud and Abuse Safeguards Governing the Power Mobility Benefit

As a taxpayer, I want to know that money used toward any government program is properly administered and dispensed. TSS applauds efforts to combat fraud and abuse. Toward that end, we have supported efforts by Congress and CMS to increase program integrity requirements in recent years including the following:

- Accreditation for all DME suppliers.
- CMS' issuance of new PMD billing codes.
- Increased supplier standards for PMDs
- Surety Bond requirement for DME suppliers.
- Face-to-Face examination
- Seven element prescription
- Detailed product description

[5] "Mobility assistive equipment" includes: canes; crutches; walkers; manual wheelchairs; power wheelchairs; and scooters. Medicare National Coverage Determination Manual, § 280.3 (eff. May 5, 2005).
[6] Medicare National Coverage Determination Manual, § 280.3.
[7] 42 C.F.R. § 410.38(c)(2) (emphasis added).
[8] 71 Fed. Reg. 17021, 17028 (2006).
[9] *Id.* at 17023.

- Home Assessment

These measures help ensure that only law abiding companies participate in the Medicare program and that only necessary equipment is reimbursed by the federal government.

TSS offers additional recommendations that we believe would target real fraud and abuse in the industry:

- *Mandated Equipment Serial Number Tracking System.* Rationale: Industry adoption would allow CMS and its contractors to verify that all claims submitted by suppliers represent supplier deliveries of real equipment obtained from authorized manufacturers.

- *Real Time Auditing of High-Volume Physicians* who have prescribed over 50 PMD units in a 12 month period. Rationale: Industry data indicates that most physicians prescribe two (2) or fewer PMDs per year. Use of physician NPI numbers on claims will help identify abnormalities in the Medicare program.

We look forward to working with this Congress and CMS on these initiatives.

Reimbursement Cuts

There have been a number of legislative and regulatory measures that have impacted the power mobility benefit.

- November 15, 2006 - CMS updated PMD codes (65 codes) resulting in a 27% Medicare reimbursement reduction.
- January 1, 2009 – Comprehensive 9.5% reimbursement reduction due to delay in National Competitive Bidding program;
- January 1, 2011 – all standard power wheelchairs became rental items pursuant to the Patient Protection and Affordable Care Act;
- January 1, 2011 – Round 1 of the Durable Medical Equipment Prosthetics Orthotics and Suppliers (DMEPOS) National Competitive Bidding (NCB) program began in nine of the largest Metropolitan Statistical Areas (MSAs) resulting in a 26% average reimbursement reduction;
- Round 2 of NCB scheduled to start in 2013 in 91 additional cities;

All of these measures contribute to a benefit that has been subject to much regulatory and legislative oversight, significantly reducing the ability of those that might want to defraud the Medicare program.

We note that Medicare power wheelchair utilization has dropped significantly. By our estimates, overall national reimbursements of standard power units declined by 20,157 units in the first half of 2011 representing a 23.5% drop from the first half of 2010. Total

allowed reimbursement for the first half of 2011 delivered units fell nearly $200 million from the same period in 2010, a 65.5% reduction in CMS allowed reimbursements.

TSS Compliance Process

In addition to the legislative and regulatory measures impacting the power mobility benefit, TSS has instituted numerous safeguards to ensure that appropriate claims are submitted to Medicare as well as other payers. The following are some important procedures established by our company.

Our company has an extensive Medicare compliance program, headed by a Corporate Compliance Officer and implemented by a Compliance Department comprised of 128 people. Through its compliance efforts, TSS seeks to ensure that its employees follow the procedures and policies that govern its business. TSS previously hired Steve Ortquist, a nationally renowned compliance expert with the Aegis Compliance and Ethics Center, LLP, to review TSS's procedures to be sure they are the most rigorous in the health care industry.

As part of its compliance department, TSS employs 57 full time Clinician (nurses) and Quality Review (QR) personnel who review and assess claims independent from any sales channel.

TSS also performs a Pre-Delivery In-home Assessment by Mobility Managers, who conduct a thorough in-home assessment for purposes of ascertaining potential or real equipment and safety issues. The Mobility Manager has full authority to cancel the potential delivery, should any irresolvable issues be uncovered, or should they discover for any reason that the customer does not qualify.

*As a result of the policies and procedures and extensive screening process instituted by our company, only **13** percent of beneficiaries who contact us for power mobility equipment have their claims submitted to Medicare.* The fact that 87 percent of the persons who seek power mobility products from TSS under their Medicare benefits are disqualified by the company's screening process is powerful evidence of the company's commitment to ensuring that only legitimate claims are submitted to Medicare.

Error Rate Reporting Does Not Tell the Whole Story

Medicare error rates for PMDs are presented to the public but the whole story is often not told. Based on prior history, Medicare contractors deny nearly all PMD audited claims (80-90 percent) only to have a significant amount of these denied claims overturned during a lengthy and costly Medicare appeals process. The contractor error rates never take into account the denied claims overturned at the redetermination, reconsideration and Administrative Law Judge levels of appeal.

A July 2011 Report issued by the Department of Health and Human Services Office of Inspector General Report, entitled Dep't of Health and Human Serv., Office of Inspector Gen., OEI-04-09-00260, *Most Power Wheelchairs in the Medicare Program Did Not*

Meet Medical Necessity Guidelines (Report), analyzed Medicare claims for power wheelchairs submitted in 2007.[10] The Report did not uncover fraud but rather involved the second guessing by an auditor of a medical determination made by treating physicians.

While the Report suggested that 61% of claims reviewed in the first half of 2007 were medically unnecessary or lacked sufficient documentation to determine medical necessity, only 9% of the total claims were deemed to be medically unnecessary. The Report determined that a vast majority of beneficiaries within this "medically unnecessary" group needed a different type of power wheelchair. In many cases, beneficiaries needed a more expensive power wheelchair.[11] Further, the Report did not take into account that a large number of claims originally denied by a Medicare contractor are overturned during the appeals process, a process that often takes over eighteen months to complete.

The Current Prior Authorization Demonstration Program For PMDs Has Numerous Issues That Need To Be Addressed

I now turn to the prior authorization demonstration project underway September 1, 2012. This demonstration project, representing the first time the agency has required prior authorization for DME, would apply to all Medicare power mobility device claims in the states of California, Florida, Illinois, Michigan, New York, North Carolina, and Texas (roughly 50% of Medicare PMD claims nationwide). Prior authorization would require a provider or supplier to submit a claim to a CMS contractor and obtain approval prior to delivery of the equipment to the Medicare beneficiary.

As of the date of this testimony submission, every prior authorization claim we have submitted has been denied. A 100% denial rate. Several denials are related to technical issues unrelated to medical necessity where the Medicare contractor missed a date that was on a fax stamp.

One denial was for medical necessity and is especially troubling. A female patient with a significant progression in the decline of her *resting* O2 saturation rates (over a 7 month period the doctor documented O2 Sat rates at 3 liters declining from 97% to 83% on the date of the Face-to-Face exam) was denied because the doctor did not conduct an O2 saturation rate test at *exertion*. It would appear that this reviewer was merely following some type of check list. Clearly the reviewer did not have the medical background required to know that requiring the patient to take an exertion test when her resting O2 saturation rate is 83% would have placed the her health at significant risk. Since the Medicare contractors have placed arbitrary constraints upon what constitutes the patient's medical record, this patient may have difficulty getting approved for a PMD without yet another trip to the doctor for a second face-to-face exam. Specifically, the Medicare contractors will not consider Attestations or Letters of Medical Necessity

[10] Dep't of Health and Human Serv., Office of Inspector Gen., OEI-04-09-00260, *Most Power Wheelchairs in the Medicare Program Did Not Meet Medical Necessity Guidelines* (July 2011).
[11] *Id*. at 20.

written by the doctor to explain his/her opinion.[12] Moreover, there is not clear guidance as to what entry to a chart note will be accepted if the entry occurs after the face-to-face exam. These types of denials, coupled with the constraints on the medical record, clearly place the reviewer between the doctor and the patient, detracting from the primary task of determining whether the patient needs the equipment.

Although TSS believes a Prior-Authorization process "done right" can be useful, we have several concerns about the program as currently structured:

- *First, we believe that any prior authorization demonstration must be significantly smaller. Simply put, this is a "bet the benefit" proposal. By placing roughly 50% of the nation's Medicare PMD utilization into a prior authorization model with no defined "phase in," CMS has ensured that if ANYTHING goes wrong, the results will be catastrophic. There is absolutely no logical or justifiable reason for the initial demonstration to have a potentially negative impact on hundreds of thousands of Medicare beneficiaries who may need PMDs to perform activities of daily living.*

- *Under the current CMS claims processing system, a beneficiary is provided his or her PMD after the physician performs the face-to-face examination. Medicare contractors routinely conduct audits and initially deny nearly all the claims (80-90 percent). A substantial amount of these denied claims are overturned during a lengthy and costly appeals process. The appeals process occurs after the patient receives the PMD.*

- *Under the prior authorization demonstration project, the 80-90 percent denial rate will move to the front end of the process, meaning that beneficiaries will no longer have access to the PMD while awaiting the decision of the Medicare contractor. With no formal appeals process in place to challenge a Medicare contractor's prior authorization denial, beneficiaries will be denied access to PMD's up front, and legitimate law abiding health care companies will simply go out of business.*

- *Based on our company's experience, the proposed prior authorization demonstration is different than other established prior authorization models developed by managed care companies and state Medicaid systems. Unlike other models, the proposed demonstration project (i) does not have a face-to-face examination template and (ii) de-emphasizes the documentation generated from the face-to-face examination, putting the government between the doctor and the patient.*

[12] In a guidance document entitled *Power Mobility Device (PMD) Demonstration Operational Guide*, provided on CMS' website, the agency states "physician attestation letters (e.g. Letters of Medical Necessity), are deemed not to be part of a medical record for Medicare payment purposes. Review contractors shall NOT consider this type of documentation when making a coverage/coding determination." A*vailable at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Downloads/PMDDemonstrationOperationalGuide_v11_08282012.pdf.

- *A face-to-face examination template must be part of any prior authorization program. Information recorded by a physician/treating practitioner during the face-to-face examination should be presumed to be valid and sufficient to determine medical necessity.*

The Size of the Prior Authorization Demonstration is Too Large and Should Be Reduced

Traditionally, a CMS demonstration project tests a payment model on a small segment of the Medicare population across a limited geographic area in order to ensure beneficiaries are not adversely impacted on a broad scale. For example, CMS conducted a **two location** durable medical equipment competitive bidding demonstration project, starting in Polk County (Florida) and then proceeding on to San Antonio. After studying the results, Congress initiated the next phase of the bidding program in nine (9) Metropolitan Statistical Areas (MSAs) starting in 2011. After 3 years, the next phase of the bidding program is set for 2013.

Sen. Rockefeller, in a July 2012 letter to Secretary Sebelius also expressed great concern over the unprecedented size of a proposed Coordinated Care Demonstration Project for dual eligible, stating that "this [demonstration] would greatly exceed the size of any previous CMS demonstration changing the way Medicare beneficiaries receive care, even though this demonstration is extremely complex. While it is clearly important to have an adequate sample size in order to evaluate demonstration programs, these changes appear to go far beyond what is necessary or appropriate...".[13]

If a smaller segment were tested initially, then the problems could be vetted and addressed without putting many beneficiaries and suppliers at risk.

A Face-to-Face Examination Template Is Necessary and Proper Weight Must Be Given To Such Template

A face-to-face clinical examination template is necessary to educate the physician/treating practitioner, supplier and beneficiary as to the exact information CMS believes is needed to properly document the face-to-face examination.

The physician/treating practitioner's professional medical judgment is essential to ensure that our nation's elderly and disabled receive appropriate medical care. Toward that end, a face-to-face examination Clinical Template should be designed to be comprehensive and sufficient to determine medical necessity. The prescribing physician/treating practitioner should be given the presumption that his/her medical judgment determined during the face-to-face exam is valid. Only when a reviewer finds clear and convincing evidence to rebut any documented face-to-face examination findings of a physician or treating practitioner should a claim be denied.

[13] Letter from John D. Rockefeller IV, Senator from West Virginia, to Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services (July 10, 2012).

The use of a Clinical Template is absolutely consistent with the documentation practices of our nation's healthcare professionals. Physicians/treating practitioners routinely use forms/templates to include as part of their medical records. The American Academy of Family Physicians (AAFP), for example, has provided many examples of forms for use by physicians. A website promoting these forms states, in part, that "[i]f you write progress notes by hand, you may find that the forms save you time as well as improve your documentation and coding by helping ensure that you capture the relevant information in an easily retrievable format."[14] Various medical record forms are also available to physicians from professional groups as well as private document/form companies that publish and sell such forms.[15] Similarly, many Medicaid programs currently require forms as the means to satisfy coverage for mobility items.

We note that CMS has developed a "*Suggested Electronic Clinical Template Elements of a Progress Note Documenting a Face-to-Face PMD Evaluation" (Clinical Template)*.[16] While we applaud the agency for taking this first step, this clinical template has not been finalized to coincide with the beginning of the prior authorization demonstration project for PMDs.[17] CMS recently informed the Office of Management and Budget of the following:

> *CMS does not believe that a prior authorization request form is necessary for this demonstration.*[18]
>
> *CMS does not believe that a template for documenting the existing face-to-face encounter is necessary to conduct this demonstration*.[19]

We respectfully disagree. A face-to-face examination Clinical Template, designed to determine and establish medical necessity, is necessary to establish clarity and consistency in the claims processing system and to ensure access to quality health care for our nation's elderly and disabled. Moreover, such a template will be important in an environment of electronic health records as more physicians move away from paper toward the health care system of the future.

<u>Beneficiaries Must Be Afforded An Appeal Right</u>

Under the current proposed demonstration, CMS has indicated that the beneficiary may resubmit the claim after receiving an initial prior authorization denial. At that point the reviewer will have at least 20 days to review the resubmitted claim. If denied again, it appears the beneficiary's only remedy is to keep resubmitting the claim to the same

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[14] American Academy of Family Physicians, available at http://www.aafp.org/fpm/2006/0900/p63.html
[15] *See, e.g.*, DocumForms: Innovative Podiatric Forms, available at http://www.dpmforms.com.
[16] *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/Downloads/SuggestedPMDElectronicClinicalTemplate.pdf.
[17] The current CMS version of the proposed electronic clinical template spans seven printed pages with detailed questions requiring collection of a vast amount of information. Surely, improvements could be made to benefit physicians/treating practitioners, suppliers, beneficiaries and the Medicare program.
[18] *CMS-10421 Response to 60-day public comments,* Centers for Medicare and Medicaid Services at 11-12 (May 30, 2012).
[19] *Id.* at 12.

Medicare contractor that has denied them access to care in previous instances. This process places decisions regarding the beneficiaries' access to care solely in the hands of a government contractor with no right of redress at a higher level.

CMS has not developed an appropriate appeals process that will ensure proper safeguards for Medicare beneficiaries. Under the proposed demonstration, a prior authorization denial would leave the beneficiary with no right to appeal to a separate independent body, thus making the initial contractor the ultimate and only arbiter. Beneficiaries and suppliers must retain appeal rights in any system proposed by CMS. This includes appeals to a Qualified Independent Contractor, Administrative Law Judge, Departmental Appeals Board and judicial review should the beneficiary and/or supplier choose to pursue this course.

Prior Authorization Recommendations

The American Medical Association (AMA) offered significant input in a June 2011 document entitled "*Standardization of prior authorization process for medical services white paper*".[20]

In their white paper, the AMA highlighted the enormous burden associated with prior authorization and the resulting "detrimental health consequences for patients."[21] The AMA offered the following recommendations: (1) The development of a standard uniform prior authorization form that can be submitted to and accepted by all payers; (2) Transparency, accessibility and consistent application of prior authorization requirements and restrictions, including a standard definition, are needed; (3) Transparency, accessibility, and consistent application of utilization review criteria and clinical expectations are needed; (4) There should be practical limits on medical record requests, which should in any event be reserved to those cases when there is difficulty determining medical necessity; (5) Consistent response times and processes with respect to prior authorizations or adverse determinations in non-urgent circumstances are needed to achieve administrative simplification; and (6) Industry consensus efforts should be aggressively pursued to automate the prior authorization processes on behalf of patients and physicians to reduce unnecessary costs.[22]

We believe the common sense recommendations of the AMA, as well as the other recommendations offered in this statement, should be fully implemented prior to starting any prior authorization program.

I appreciate the opportunity to provide this information to the Committee, and we look forward to keeping you informed as the prior authorization demonstration progresses.

[20] American Medical Association (June 2011) *available at* http://www.ama-assn.org/resources/doc/psa/standardization-prior-auth-whitepaper.pdf.
[21] *Id.* at 4.
[22] *Id.* at 10-12.