



RAMP

Restore Access to Mobility Partnership

American Association
for Homecare

Invacare Corporation

Mobility Products Unlimited

Pride Mobility Products
Corporation

Sunrise Medical

The MED Group

November 22, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

VIA ELECTRONIC MAIL:

[DMEPOS Quality Standards Public Comments@cms.hhs.gov](mailto:DMEPOS_Quality_Standards_Public_Comments@cms.hhs.gov)

**Re: Comments on Draft Quality Standards for DMEPOS
Suppliers**

Dear Dr. McClellan:

RAMP is pleased to provide comments on the “Draft Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services” (“Draft Quality Standards”) prepared by Abt Associates Inc for CMS. RAMP, a coalition representing power wheelchair providers and manufacturers, is committed to ensuring that Medicare beneficiaries with medical need have access to appropriate mobility products.

In general, we support establishing quality standards for DMEPOS suppliers. As an organization composed of members committed to delivering quality care to Medicare beneficiaries, we believe that universally applicable quality standards can serve a number of positive functions. First, if properly implemented, they reduce the risk that a Medicare beneficiary will be victimized by an unscrupulous provider. Accrediting entities will act as a private validation of a provider’s business processes, policies and actions.

Second, the standards can serve as an important compilation of federal requirements for DMEPOS suppliers. Third, they create the opportunity for providers to improve their service to beneficiaries and efficiency of their operations.

We also believe that the Draft Quality Standard's bifurcated structure under which certain standards apply to all suppliers and other standards are directed at specific service areas makes sense. DMEPOS covers a wide spectrum of services which both pose varying levels of risk to the Medicare program and beneficiaries and varying levels of intensive service needs. For the most part, the Draft Quality Standards strike an appropriate balance between general requirements and the specific standards applicable to categories of services.

That being said, there are two overarching and related concerns we have with the Draft Quality Standards. First, preparing for accreditation is a very intensive and time consuming process. Smaller suppliers will be disproportionately impacted because they are less likely to have the personnel to dedicate to the task. In many instances, the Draft Quality Standards impose requirements that do not reflect the reality of small business operations or would create particular hardship for small businesses.

Second, in many instances, the Draft Quality Standards take an encyclopedic approach to enumerating standards that will bind suppliers. While taken individually, many of these standards are not objectionable, their separate delineation will have the effect of requiring separate documentation during the accreditation process. Consequently, where possible, CMS should reduce the number of standards and make them more general. In the more specific discussions below, we will identify particular concerns and suggest alternative solutions.

It should also be recognized by CMS that this proposal will significantly increase the standards by which all businesses will be required to operate if they wish to participate in the Medicare program. The aggregate cost of all standards included in this proposal will significantly increase the cost of doing business with Medicare at a time when CMS is looking for ways to reduce its overall reimbursement rates for DME products. This must be taken into consideration as CMS compares its pricing schedule to other payors as it sets future fee schedules.

Although not directly addressed in the draft standards, CMS needs to make its intentions clear that it will grandfather previously accredited suppliers. Currently, there is no requirement that suppliers be accredited, and once the quality standards are published and accrediting organizations named, there will be a significant bottleneck for the accrediting agencies. We believe that CMS needs to establish a grandfathering policy sooner rather than later.

A clear policy statement from CMS on this issue favors all stakeholders and will encourage providers to seek accreditation now, promoting a smooth transition later when the standards are final. CMS should allow providers who are currently accredited to be

“grandfathered” under the new standards at least until the provider’s next survey by the accrediting body.

Generally Applicable Business Quality Standards

In this section, we provide comments on the general business standards. The numbering of the sections below corresponds to the numbering in the Draft Quality Standards.

ADMINISTRATION

3. *Procurement and testing of quality DME equipment and supplies:*

This standard establishes a burden which is beyond the purview of most suppliers. Manufacturers are the entities responsible for meeting FDA, ANSI, RESNA or other quality standards. Suppliers do not have the knowledge or resources to verify independently whether or not the manufacturers have met their obligations. At most, it might be reasonable for suppliers to require manufacturers to certify that they have met applicable regulatory requirements. However, even this requirement would not do much to protect the program if manufacturers are in violation of their obligations. With the objective of eliminating standards that do not meaningfully add to program protection or improve quality, we suggest that this standard be dropped.

4. *Delivery of quality services to beneficiaries*

This standard imposes a requirement that suppliers have staff available for telephone customer service for after hours emergency services. While we recognize the impetus for this particular standard, it should not be applied universally across all suppliers or product categories in the same way. Many suppliers deal only in devices for which a “failure” would not constitute an emergency. For instance, if a supplier only deals in mobility aids such as canes, walkers, manual wheelchairs, power wheelchairs and scooters, even if a device ceased working, it would not usually constitute an emergency. Rather, the mechanical failure could be addressed the next business day. In this context, it might be reasonable for the supplier to have an answering service, but not paid staff, to take messages so that they can be addressed the next business day.

However, within a specific product category code all suppliers should be required to adhere to the same level of standards so the regulatory environment does not favor certain sized suppliers.

By contrast, we recognize that with respect to other types of DME, mechanical failure can be life threatening. For instance, the failure of an oxygen system would not only require that the supplier have a 24/7 live emergency response line but also a mechanism to either provide back up service or emergency support.

Given the different types of equipment and consequences of equipment failure, we recommend that this provision be transferred from the general standards to the device specific standards and tailored accordingly.

Further, Medicare supplier standards require that a company operating retail establishments in different locations must obtain a supplier number for each location. In this context, the Quality Standards need to clarify that even where some after hours communication system is appropriate, this system can serve the entire corporate network of retail sites rather than having each site maintain a separate communications mechanism. For instance, if a supplier maintains a 24/7 helpline for its patients, that helpline should be allowed to serve the needs of all operating divisions or subsidiaries regardless of whether or not they have or are required to have separate supplier numbers.

RAMP also believes that the proposed standard with respect to mail order services should be not be generally applicable to all suppliers. RAMP acknowledges that it would not be acceptable to use mail order or drop shipment for power wheelchairs or oxygen systems for instance, but does not see why this standard would necessarily apply to other DMEPOS products across the board.

5. *Supplier Requirements*

Subsection (c) should clarify that only supplier retail and/or corporate locations are required to be accredited. Many suppliers maintain separate warehouse facilities to store inventory and transportation vehicles and are not open to the public. These non-retail locations should not be subject to separate accreditation procedures. However, RAMP acknowledges that these facilities will be governed by the accreditation standards for the retail facilities they support and may be inspected as part of the accreditation process for the retail stores.

6. *Compliance Plan*

RAMP supports the idea that suppliers must be in compliance with applicable federal and state regulatory standards and implement programs to ensure compliance. While we do not object to the concept of having a compliance plan obligation, we are quite concerned with how this standard will be evaluated and measured in the accreditation process.

Without incorporating a concept of “scalability,” this proposed standard will disproportionately affect smaller companies. This requirement must be scalable according the size and resources of the company. We do not believe that it is appropriate to provide accrediting entities unfettered discretion in how to evaluate a supplier’s performance on this standard. Rather, we encourage CMS to provide additional guidance on how scalability might be achieved.

For instance, the OIG’s Compliance Guidance for Individual and Small Group Physician Practices indicates that it may not be necessary for small physician practices to

comprehensively document all areas that might touch upon compliance. Rather, they are encouraged to focus initially on areas of greatest risk. Further, unlike guidance given to larger providers, small physician practices are encouraged to begin their compliance efforts with auditing and monitoring first, and then turn to creating policies and procedures. There is also a recognition that the implementation of a compliance plan may not occur all at once, but may occur over time as time and resources permit. We believe that similar concepts need to be incorporated in the final measurements of any compliance plan requirement. While we support a compliance standard for all suppliers, we strongly encourage CMS to provide greater detail in this area so that both suppliers and accrediting entities have advance assurance that compliance is not a “one size fits all” obligation.

FINANCIAL MANAGEMENT

The financial management standards demonstrate that the writers of the Draft Quality Standards do not understand the business operations of small DMEPOS suppliers. The accounting standards would, at a minimum, impose a significant burden on small suppliers and, at worst, be insurmountable.

One fundamental concern is that many suppliers keep their books on a cash basis rather than an accrual basis. Generally Accepted Accounting Principles (“GAAP”) require an entity to keep their books on an accrual basis. The proposed financial management standards create a number of issues based on its presumption of accrual-based accounting.

As a preliminary matter, we do not believe that CMS has the legal authority to require accrual based accounting through quality standards. While most of the standards contained in the Draft Quality Standards are restatements or extensions of existing regulatory or policy guidance, CMS has never required suppliers to keep their books on an accrual basis. This proposed standard would establish a major new requirement for suppliers and the transition from a cash-based to an accrual-based accounting system would be burdensome for suppliers. Under the Administrative Procedures Act (“APA”), this new requirement would have to be subject to notice and comment rulemaking. Further, we question whether CMS has the legislative authority to impose this requirement even if APA rulemaking procedures were followed.

Even if these legal points are addressed, we question whether imposing such a requirement is advisable. We are not aware of any evidence that suggests that similarly sized entities that keep their books on a cash basis create any more risk to the Medicare program than entities that keep their books on an accrual basis. However, we are certain that requiring suppliers to switch their accounting systems will be burdensome. Because small suppliers are more likely to use cash-based accounting systems, they would be disproportionately affected by this standard.

The GAAP standard raises other issues as well. For instance, GAAP creates standards for the reporting of historic income and liabilities. It does not create standards

for budgeting procedures. In this context, the requirement that “A financial management plan [include]...an annual operating budget according to generally accepted accounting principles” makes no sense. Certified Public Accountants looking at that requirement would have no idea what it means or how to implement it.

The proposed auditing standard creates both related and unrelated issues. First, because GAAP only applies to accrual-based accounting systems, an outside auditor could never prepare an unqualified opinion that a supplier that keeps its books on a cash basis meets GAAP standards. However, second, and more importantly, the requirement that financial statements are audited by accounting personnel to ensure financial propriety creates a new, unfunded mandate on suppliers. Even for the smallest of suppliers, it could be expected that obtaining an audit letter would cost \$10,000. This expense would impose a significant burden for small suppliers.

However, all suppliers should be required to adhere to the same level of standards so the regulatory environment supports a level playing field for all suppliers regardless of size.

Finally, the requirement that the supplier provide notice to CMS and accrediting organizations of potential adverse financial conditions is objectionable for a number of reasons. First, there is the issue of what constitutes "adverse financial condition." RAMP does not support CMS, or any other government entity going down the road of defining an "adverse financial condition" and requiring suppliers to notify CMS in the event that occurs. There are multiple reasons suppliers may experience "adverse financial conditions," most of which suppliers work through with no adverse impact on their clients. Business conditions change, reimbursement changes, payor mix changes, there are multiple unanticipated types of changes that businesses constantly must adjust to; and suppliers typically work through these times. It is unreasonable to have the government notified in these instances, primarily because they do not typically have an impact on patient care and services. Finally, we question what the government would do with this information. We cannot understand any meaningful use for this information might have for the government as it pertains to quality.

HUMAN RESOURCE MANAGEMENT

We appreciate that the Draft Quality Standards recognize the professional services rendered by DMEPOS suppliers. As part of the continuum of care, suppliers have a responsibility to ensure that individuals delivering services to patients have the appropriate credentials and training to enable them to accomplish the requisite tasks. When certain activities require licensure, we agree that the supplier should be responsible for ensuring the applicable individual has and maintains licensure. However, in certain instances, there are no professional licensure or credentialing standards applicable for certain categories of personnel. For instance, delivery techs are an important part of a patient's service team, but there are no licensure requirements applicable to this personnel class. We believe that the standards need to be more clear that all individuals need to be properly licensed or certified when such license or certifications are available

and applicable. Otherwise, personnel need to be properly trained to accomplish their job function.

2. *Criminal Background Checks*

We are confused about the standard addressing criminal background checks on all employees in compliance with state and federal laws. The current Medicare supplier standards already require that suppliers be in compliance with all local, state and federal laws and regulations. Where the state of licensure has requirements regarding criminal background checks, the suppliers should already be in compliance with those requirements. We are not aware of any *general* laws that would require all employees of a DMEPOS supplier to be subject to a criminal background check. Even OIG compliance guidance does not suggest that a criminal background check would be necessary for all employees (consider janitors or receptionists).

On the other hand, we do understand that it may be appropriate to have criminal background checks performed on people in key administrative positions or who deal directly with beneficiaries. We think a better way to restructure this standard would be to require criminal background checks on all individuals who come into contact with beneficiaries and to have the supplier identify positions involving substantial operational discretion or in key positions of trust to also be subject to criminal background checks.

We also believe that it would be helpful to define the obligations here more precisely. In this context, we suggest that for employees who have direct patient contact, criminal background checks be done in every state in which the employee will have patient contact. For employees who do not have direct patient contact but hold key administrative positions, the background check should be done in the state in which the employee resides.

BENEFICIARY SERVICES

2. *Providing information to beneficiaries*

This section contains a requirement that suppliers must provide “defined and guaranteed estimates for the time needed to ship items.” First, we do not understand what a “guaranteed estimate” would be in this context, and how can an “estimate” be “guaranteed”? Second, we want to clarify that this particular bullet point only applies to shipped items rather than delivered items.

3. *Coordination of Services*

The Draft Quality Standards include a statement that the supplier should consult with the treating physician and other healthcare team members to obtain pertinent beneficiary healthcare information that may have an impact on the use of the prescribed equipment followed by a laundry list of items. The structure of this proposed requirement implies that each item must be obtained by the supplier in all instances. Yet, none of these standards would be applicable to all suppliers in all instances. For

example, the requirement with respect to the frequency of visits would not inherently apply to a supplier of power mobility devices. Similarly, the pharmacy providing glucose testing strips would not necessarily need to gather information regarding safety measures to protect against injury. We believe it would be better to eliminate the enumerated list in this section. To the extent that individual standards are not already contained in Medicare reimbursement or coverage policies applicable to a specific category of DMEPOS, then it might be reasonable to include those standards in the specialized section provided later in the Draft Quality Standards.

PERFORMANCE MANAGEMENT

We appreciate the function of quality improvement programs in encouraging healthcare providers to continuously upgrade their performance. However, as drafted, this section is too detailed and will be burdensome on small suppliers. Usually in institutional providers, at least one individual is designated to be the quality improvement officer. That person is trained in general quality improvement strategies and techniques. However, DMEPOS suppliers generally do not have the capacity to employ an individual, especially for that person, or to acquire the rather robust set of skills necessary to conduct quality improvement activities. In this context, as drafted, this section is overly broad and overly burdensome.

By way of example, Item No. 2 creates a duty for the supplier to conduct a root-cause analysis of adverse effects. The concept of a root-cause analysis is a term of art in quality improvement and requires a rather specific and elaborate assessment of a host of factors that may have contributed to the adverse outcome. It is unlikely that this requirement will be easily understood by smaller entities.

Similarly, the trends analysis requirement may require a significant investment in information systems to track the data for small *or* large entities. This may require a supplier to invest in new capital equipment as well as software to provide the appropriate data analysis.

In sum, we do not object to some form of a quality improvement program. However, as compared to the institutional providers, the structure of such a program needs to be simplified so it can be easily understood and implemented by non-institutional organizations. . However, all suppliers should be required to adhere to the same level of standard so the regulatory environment supports a level playing field for all suppliers regardless of size.

EQUIPMENT AND SAFETY

For the most part, we agree that suppliers should be held accountable to the proposed standards in this section. However, expectations regarding the requirements contained in Section 5 need to be clarified and possibly transferred to the specialized sections later on in the Draft Quality Standards. Certain suppliers may never come into contact with a patient's home. For instance, a pharmacy providing the drugs or glucose monitoring testing strips would have no need to perform an environmental safety

evaluation of a patient's home. Even suppliers that deliver items to a patient's home may not need to evaluate factors such as emergency power. By way of example, a supplier that provides a patient with a cane or a walker probably should not be held accountable for evaluating the patient's ongoing condition or treatment plan, or determining how the patient would use the cane or walker in the home in the event of a power shut-down. By contrast, we recognize the importance of having that sort of evaluation with other items, such as CPAP or BiPAP or oxygen delivery services.

Finally, if a supplier is required to evaluate the power system in a patient's home, this evaluation needs to be quite limited. Suppliers of power wheelchairs should only be required to determine if there is an outlet readily available that is appropriate for charging the wheelchair's battery. Suppliers should not be responsible for conducting an independent evaluation of the wiring of the patient's house or apartment building or be required to determine what emergency power sources might be available.

BENEFICIARY RIGHTS AND ETHICS

Although we agree that a supplier should have policies addressing after hours and emergency coverage, this should not presume that all suppliers will provide 24/7 after hours live telephone response systems or 24/7 emergency services. For many types of supplies, a malfunction does not, in the short term, create an immediate health risk. In this context, these policies should be tailored to the nature of the supplier's business.

INFORMATION MANAGEMENT

2. *Computer Systems*

Many of the features currently contained in the Draft Quality Standards are beyond the current technological capacities of most suppliers. For instance, many suppliers will use Microsoft Access or a similar database product to manage information. These systems do not enable electronic time stamping for entries or prevent entries from being changed after initial input. We believe it would be reasonable for suppliers to implement policies preventing changes and requiring time of entry to be contained in the database. However, we do not believe that the Quality Standards can be used to require the wholesale replacement of electronic records systems.

6. *Collecting Beneficiary Service Data*

Fundamentally, we do not understand what is required by this provision and how a supplier would evidence compliance with this standard. Absent a more detailed explanation of what is trying to be achieved here, we suggest that the provision be removed.

Marketing Materials

Embedded in this section is a requirement that the supplier have a toll-free telephone number for direct beneficiary communications to service staff. Many suppliers operate entirely locally. If a supplier only serves patients within a local telephone service area, we do not understand the need for a toll-free number. In this context, the provision should be clarified to indicate that a supplier would be required to have a toll-free number if a beneficiary would need to incur long distance charges to communicate with the service staff. The same concerns previously iterated regarding 24/7 live response systems also applies here.

APPENDIX A

Service Plan

In the context of power mobility, we are unclear what a “service plan” would be. For general use mobility devices (as compared with rehab mobility devices), a power wheelchair supplier works with the physician’s office to obtain a prescription and then fill the order based on the physician’s instructions. After set up, there would be no formal “service plan” for the supplier. The supplier would respond to appropriate requests for repair, but those contacts would be unplanned. We do not believe that the “service plan” concept translates well into this part of the DMEPOS industry. As with other areas, the issue of whether there should be a service plan and what it looks like needs to be addressed in the product-specific appendices.

Delivery and Setup

RAMP fully understands that a power mobility device should be clean when delivered. However, this is a product, like canes and walkers, where the industry standard would not require sterility. The sterility language in this section should be eliminated.

Further, RAMP believes that the proposed standard that the supplier “supply any follow-up service” needs to be clarified to indicate that this duty extends to the initial placement of the power mobility device and does not extend in perpetuity.

The Draft Quality Standards contain a provision that the supplier provide a “written estimate” to the beneficiary of the cost and time required for any repair work. Unfortunately, due the lack of “real time” adjudication of Medicare claims, it often impossible for the supplier to give a patient an accurate estimate of cost. A patient may not have met his or her annual deductible. He or she may have secondary insurance that may cover a part or all of his co-insurance. He or she may have had same or similar equipment and has failed to inform the supplier of that history. All of these factors mean that the supplier is not well positioned to provide an accurate estimate of the patient’s out-of-pocket cost. Further, if suppliers took the tact of providing the patients with a statement of cost and proclaiming that Medicare and secondary payers may not cover the product, that would be a violation of the prohibition on blanket advance beneficiary

notices. Because claims processing infrastructure is insufficiently evolved, this provision should be struck.

Further, this section would require the supplier to advise the patient on Universal Precautions. Universal Precautions are not needed in the context of patient use of power mobility devices. This section should be removed and transferred as applicable to product-specific appendices.

Condition of the Home

As stated previously, there should be a limitation on what sort of evaluation a supplier must conduct on the adequacy of electricity. There cannot be an expectation that the supplier will be responsible for identifying more than a power source that safely operates the equipment in question. In most states, a home safety evaluation would be outside the scope of practice of DMEPOS suppliers.

Follow-up

In many instances, power mobility suppliers return to patient homes to make minor adjustments to a patient's chair or to replace a battery. For these minor and routine services, we do not believe that it would be necessary or appropriate to inform the patient's treating physician. In fact, the physician would likely be annoyed by such contacts. The standard should be changed to require communication with the treating physician to the extent that information sharing is necessary to shape the physician's future treatment of the patient, to protect the patient, or to obtain medical guidance for the supplier.

APPENDIX F

Intake

This standard does not reflect current practice for either general use power wheelchairs or rehab power wheelchairs. For both types of products, the physician would prescribe the general contours of the product being ordered. With respect to a general use chair, the supplier would determine what brand and other features would best meet the patient's needs within the scope of the physician's order. For rehab chairs, the specifics would be determined by other professionals, such as an RTS or a physical therapist or occupational therapist. These constitute "best practices" because physicians have insufficient knowledge of all the features, advantages and disadvantages of specific products and features. Consequently, physicians rely on the judgment of other professionals to fill their orders. The quality standards should be modified to reflect this practice.

Service Plan

The appropriateness of the proposed requirement that the supplier “assess the beneficiary’s planned use for the wheelchair relative to durability and style of wheelchair” depends on the outcome of a number of issues still under consideration by CMS. More specifically, CMS is considering revisions to the power wheelchair codes, and RAMP has been notified that one option CMS is strongly considering is downcoding product to the least expensive chair that will meet the patient’s need in the home. If this is the coding and payment policy decision made by CMS, then suppliers should not be held accountable for how beneficiaries would like to use the power wheelchair outside the home. To the extent that Medicare is going to permit prescribing specifically coded chairs for patient lifestyle choices outside the home, *and is going to pay for them*, then a consideration of those choices in determining the correct product would be appropriate.

Power Wheelchair

This section serves as an example of a series of requirements that, except as noted otherwise, are largely acceptable. However, taken in its entirety as an accreditation requirement will create an extreme burden with respect to documentation. In practice, requirements such as these would be reflected on internal checklists, which, when taken in combination with the section on training, would lead to a multi-page document that would slow down the delivery of product, frustrate patients and not meaningfully add to quality. This section should be restructured to require that the placed equipment is functioning, clean and adjusted to the patient’s needs. This level of specificity is not appropriate for an accreditation standard.

Further, the section creates standards that seem to conflate what might be appropriate for new versus used equipment. For instance, if the patient is being provided new product, then the supplier should not need to check wheelchair components for wear.

Some of the components of this section are not applicable to all wheelchair products. For instance, the Power Seating System Options would not be applicable to most general use products. Even the products that have elevating leg rest systems are generally adjusted manually. It may be necessary to develop separate standards for rehab chairs.

Training/Instruction to Beneficiary and Caregiver

If implemented as written, this section in particular would create an enormous documentation burden on suppliers and serve as an irritant to most patients. Simply put, this section represents an attempt to micromanage the training process without taking into account the patient or caregiver’s needs or desires. For instance, given that in order to qualify for a power wheelchair a beneficiary cannot have significant upper body strength, if the patient does not have a caregiver, he or she would never be able to manipulate the product directly. Consequently, they would not need or want training on how to remove armrests or on the removal and/or replacement of anti-tip devices. Similarly, some

wheelchairs are not designed for transportation in a personal vehicle; in other words it does not readily collapse for transport. If the patient does not intend to use the wheelchair outside the home, or utilizes van transport, then there should be no requirement that the supplier train the patient on how to prepare the wheelchair for transportation (where this can even be achieved).

The level of detail here is beyond anything typically seen in other accreditation processes. It is inappropriate for standards of this type to micromanage every possible issue that might arise with a beneficiary. For instance, requiring suppliers have to warn patients about the dangers of driving a power wheelchair and using a cell phone is ludicrous. Given that the equipment is for in-the-home use, how is a cell phone different from any other telephone that is wireless and used in the home? Apparently the drafters of the standards *assume* outside use of the equipment otherwise why would they also require suppliers to warn about the danger of alcohol use?

The supplier's responsibility should be to educate the patient regarding how the product works, how to care for and maintain the equipment, how to use it within the home, what is covered by the warranty, and who to contact in case of problems.

From the perspective of developing quality standards, the proper strategy here would be to require the supplier to document how they train delivery personnel regarding patient and caregiver education and then have a standard requiring suppliers to properly train patients on the use of their equipment.

Some of the specific items in this section create separate problems. First, under "Safety Review", the Draft Quality Standards would have the supplier train patients on how to go up and down curbs. Medicare only pays for power wheelchairs for use in the home, although it allows patients to use the device elsewhere. Suppliers should not be responsible for patient use outside the home, especially with respect to potentially hazardous activities like going up and down curbs. We ask that this particular requirement be removed because it encourages dangerous behavior.

Second, under the "General" section, there is a standard "When and who to contact if wheelchair no longer meets the beneficiary's medical needs or requires modification." If the wheelchair has been purchased and is outside the warranty period, it should be clear that the supplier has no duties in this regard.

* * *

RAMP is happy to serve as an on-going resource as these standards are modified. If you have questions or need further information, please contact Rob Falk at rfalk@pogolaw.com or 202-624-7318.