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Comment On: CMS-2008-0141-0001

Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations in 42 CFR, Sections 484.55, 484.205, 484.245, 484.250 (CMS-R-245)

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VA

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SUBMITTER

General Comment

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January 13, 2009

Centers for Medicare & Medicaid Services
 Office of Strategic Operations and Regulatory Affairs
 Attention: Document Identifier CMS-R-245
 Room C4-26-05
 7500 Security Boulevard
 Baltimore, MD 21244-1850

Re: Comments on Medicare and Medicaid Programs OASIS Collection
 Requirements as part of the CoPs for HHAs and Supporting Regulations in
 42CFR, Sections 484.55, 484.205, 484.245 and 484.250

The National Pressure Ulcer Advisory Panel (NPUAP) would like to take this opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the latest draft of the OASIS C assessment tool for home health care agencies.

NPUAP is an independent, not-for-profit organization dedicated to the prevention and management of pressure ulcers through education, research and public policy. Formed in 1987, the NPUAP Board of Directors is comprised of leading authorities representing various disciplines, including medicine, nursing, occupational and physical therapy, nutrition, biomedical engineering, research and education.

Section by Section Comments:

(M1310) Current Number of Unhealed (non-epithelialized) Pressure Ulcers at Each Stage d.1 Unstageable: Suspected deep tissue injury in evolution

NPUAP Comment:

We recommend the following additional wording be included to assist in defining Suspected Deep Tissue Injury:

Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

(M1314) Pressure Ulcer Width: Width of the same pressure ulcer, greatest width measured at right angles to length | ____ | ____ | . | ____ | (cm)

NPUAP Comment:

We recommend two additional questions for this section:

1. Is there evidence of undermining of the wound?
2. Is there evidence of wound tunneling?
 - a. If yes, indicate tunneling length

(M1326) Pressure Ulcer Intervention: Are moisture retentive dressings specified on the physician-ordered plan of care?

NPUAP Comment:

The term "moisture retentive dressings" needs to be further defined in order to differentiate from saline soaked gauze which is often incorrectly thought to be moisture retentive. Also, exudate management dressings such as foam and alginate dressings are often not thought to be moisture retentive as they wick excess moisture away from wounds. These dressing categories may be appropriate nonetheless for certain wound types as they maintain a moist wound environment.

We recommend the following wording:

Are dressings supportive of the principles of moist wound healing* on the physician-ordered plan of care? (*Dressings that retain enough moisture to stimulate healing yet not cause maceration or irritation.)

(M1350) Does this patient have a Skin Lesion or Open Wound, excluding bowel ostomy, other than those described above that is receiving assessment and/or intervention by the home health agency?

NPUAP Comment:

We recommend the following wording for clarity:

Does this patient have a Skin Lesion or Open Wound, other than pressure ulcer(s), stasis ulcer(s) or surgical wound(s) that require assessment and/or intervention by the home health agency? (Excludes ostomy for bowel/bladder elimination.)

(M1360) Diabetic Foot Care Plan: Does the physician-ordered plan of care include regular monitoring for the presence of skin lesions on the lower extremities and patient education on proper foot care?

NPUAP Comment:

We recommend the addition of the word "caregiver" following "patient". The new wording would be as follows:

Does the physician-ordered plan of care include regular monitoring for the presence of skin lesions on the lower extremities and patient/caregiver education on proper foot care?

(M1365) Diabetic Foot Care Plan Follow-up: Since the previous OASIS assessment, was the physician-ordered plan of care regarding regular monitoring for the presence of lesions on the lower extremities and patient education on proper foot care followed?

NPUAP Comment:

We recommend the addition of the word "caregiver" following "patient". The new wording would be as follows:

Since the previous OASIS assessment, was the physician-ordered plan of care regarding regular monitoring for the presence of lesions on the lower extremities and patient/caregiver education on proper foot care followed?

* * * * *

NPUAP appreciates the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on the OASIS C assessment tool for home health care agencies. We would welcome an on-going dialogue with CMS on this tool as it continues to develop.

Sincerely,
Catherine R. Ratliff, PhD
Chair, Public Policy

Diane K. Langemo, PhD, RN, FAAN
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Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations in 42 CFR, Sections 484.55, 484.205, 484.245, 484.250 (CMS-R-245)

Comment On: CMS-2008-0141-0001

Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations in 42 CFR, Sections 484.55, 484.205, 484.245, 484.250 (CMS-R-245)

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VA

Submitter Information

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Organization: American Physical Therapy Association

General Comment

On behalf of the American Physical Therapy Association, I am submitting the attached comments for consideration.

Attachments

CMS-2008-0141-0077.1: VA



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CMS, Office of Strategic Operations and Regulatory Affairs
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Attention: Document Identifier/OMB Control number 0938-0760
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7500 Security Boulevard
Baltimore, MD 21244-1850

**RE: Title of Information Collection – Medicare and Medicaid Programs OASIS
Collection Requirements as Part of the COPs for HHAs and Supporting
Regulations in 42 CFR, § 484.55, 484.205, 484.245, and 484.250**

Dear Sir or Madam:

On behalf of our 70,000 member physical therapist, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) respectfully submits comments regarding the recently released revisions to the home health assessment instrument termed OASIS C.

Physical therapy is an integral component of patient care in the home health setting. In the home health setting, physical therapists are responsible for providing physical therapy services to patients who have impairments, functional limitations, disabilities, or changes in physical function and health status resulting from injury, disease, or other causes through a plan of care. Physical therapists thoroughly examine a patient which includes evaluation of therapeutic, rehabilitative, and functional status in order to develop a comprehensive plan of care designed to optimize outcomes. The physical therapist also instructs patients and caregivers in risk reduction and in the use and performance of therapeutic exercises, functional activities and assistive devices, including prosthetics and orthotics.

Physical therapists provide specific examinations (tests and measures) for evaluation of falls risk through assessment of patient balance, strength, and endurance, along with gait, transfers, and vertigo. Physical therapists also evaluate components of patient cognition and patient and caregiver's safety. Physical therapists modify home and living environments and provide adaptive equipment and assistive devices to allow individuals to function safely in their homes and communities. Physical therapists interact and practice in collaboration with a variety of health care professionals to optimize patient outcomes.

Therefore, we are very interested in the revision of OASIS, and we are excited to work with CMS to ensure that OASIS C is revised in a manner that ensures quality

The Science of Healing. The Art of Caring.

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and other providers, as well as, bolsters increased collaboration between clinicians thus creating a more favorable environment for interdisciplinary care. Lastly, the use EHRs will help improve the accuracy and consistency of the data collected which leads to improved patient care.

APTA is committed to advancing the use of electronic health records and has made several strides over the years to promote the use of health information technology, and we are currently exploring how to use these tools to advance the delivery of physical therapy and to effectively measure patient outcomes. Therefore, we strongly urge CMS to implement policies and guidance that maximize the utilization of electronic health records and other forms of health information technology within the home health setting.

Comments on Specific Items within OASIS C

(M1012) List each Inpatient Procedure and the associated ICD-9-CM procedure code

APTA would like more clarification on the inclusion of this item. Specifically, we inquire about how this information will be used and how it will translate to payment (i.e. HHRGs, risk-adjustment, the home health prospective payment system, etc). Secondly, we are concerned about which healthcare professional will be responsible for providing this information.

If adopted in the final version of OASIS C, we strongly urge that CMS actively encourage home health agencies to provide educational opportunities to nurses and therapists on how to accurately document such information. In addition, we ask that CMS fully consider the issues related to disparities in access to information, particularly for small independent agencies. Lastly, we request that CMS fully consider the timeliness of the collection of this data and whether it can be completed accurately within the timeframe allotted for the assessment of the home health patient.

Ultimately, we believe that this item does not add any value to the collection of information and that the administrative burden of completing this item outweighs the anticipated benefit.

(M1032) Frailty Indicators: Which of the following signs or symptoms characterize this patient as at risk for major decline or hospitalization?

We believe that this item is too subjective. Therefore, we request that CMS provide definitions for the terms used within the assessment tool. We believe that this change will lead to greater accuracy and consistency of information among home health agencies. With respect to an individual patient's baseline, we request that CMS provide a space by "other" in which the clinician is asked to list the specific indicator.

(M1038) Guidelines for Physician Notification: Does the physician-ordered plan of care establish parameters (limits) for physician notification of changes in vital signs and other clinical findings?

We request that CMS give further explanation of what is meant by "other clinical findings".

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(M1242) Has the patient had a formal Pain Assessment using a standardized pain assessment tool (appropriate to the patient's ability to communicate the severity of pain)?

We request that CMS add definitions of "severe pain" as well as provide examples of "standardized pain assessments" that would be acceptable to satisfy this item. Some examples of pain assessment instruments are:

- Pain Drawings and Pain Maps
- Pain Numerical Rating Scale
- Pain Tactile Tests
- Pain Verbal Rating Scales
- Pain Visual Analog Scales
- Faces Pain Scale (FPS)¹

In addition, the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has pain assessment and management standards that should be considered as examples.

Integumentary Status (M1300 –M1365)

APTA would like to emphasize that physical therapy intervention is highly effective in wound care treatment. When evaluating patients with chronic wounds, a physical therapist reviews the reason for referral and any relevant medical records. The patient's medical history is taken, and an examination is performed that includes a systems review and tests and measures that include examination of the wound. The wound examination includes the evaluation of the wound characteristics - location, size, shape, depth, necrotic and viable tissue characteristics, peripheral tissue edema, periwound characteristics (e.g. erythema, edema, and maceration), and pulses. In addition, physical therapists will look for signs of infection or inflammation and examine wound characteristics such as bleeding, drainage, necrosis, undermining, contraction, tunneling and odor. A physical therapist will review activities and postures that may aggravate the wound, or those that relieve trauma to the wound.

Based on the examination and evaluation of the findings, the therapist will develop a plan of care and determine the patient's prognosis and the anticipated outcomes of treatment. The plan of care considers the clinical implications of the severity, complexity, and acuity of the patient and the wound including any impairment, functional limitation, and/or disability secondary to the wound or any underlying pre-existing or co-morbid conditions. The physical therapist will establish goals, including the expected outcome of treatment and its impact on the patient's function in daily life.

One important aspect of the standard care for chronic wounds is treatment interventions that address restoration of mobility and function. Physical therapists are experts in this area. They address the impairments and functional limitations associated with injury, disease and other causes associated with the integumentary, musculoskeletal, neuromuscular and cardiovascular systems or any combination. Improving the patient's mobility and functional status will have a positive impact on their general health as well as that of the wound.

¹ American Physical Therapy Association: *Guide to Physical Therapist Practice with Catalog of Test and Measures*, Ed. 2, Alexandria, VA, 2001.

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APTA strongly encourages CMS to provide guidance, within OASIS to home health agencies that physical therapists are and should be permitted to perform all wound care interventions legally mandated by state licensure and defined by the education curriculum of the physical therapist. This would include the coverage of interventions such as: dressings (wound coverings, hydrogels, vacuum-assisted closure), including wet-to-dry dressings, wet-to-moist dressings, wet dressing, enzymes, and physical agents and mechanical modalities; oxygen therapy (topical and supplemental); debridement, both nonselective and selective, including sharp debridement, pulsed lavage, debridement with other agents (e.g. autolysis), and enzymatic debridement; topical agents (e.g. ointments); physical agents and mechanical modalities; electro therapeutic modalities, including electrical stimulation by way of direct current, alternating current, pulsed current, pulsed electromagnetic induction; orthotics, protective and supportive devices; and assistive and adaptive devices.

Cardiac Status (M1500 Symptoms of Heart Failure: Since the previous OASIS assessment, did the patient exhibit symptoms of heart failure indicated by clinical heart failure guidelines (including dyspnea, orthopnea, edema, or weight gain) at any point? and M1510 Heart Failure Follow-up: Since the previous OASIS assessment, what action(s) has (have) been taken to respond to each instance of heart failure?)

APTA applauds CMS on the addition of these items as cardiac is the largest diagnostic group in home health. In addition, we would like to emphasize that physical therapists are more than competent to complete the information needed for these items. Physical therapists are an integral part of a cardiac care as they provide individualized therapeutic exercise, and promote increased function.

Physical therapists evaluate patients' needs by gathering data on medical history and other relevant factors such as health habits and co-morbidities, and then identify risk factors and behaviors that may impede optimal functioning. In the case of patients recovering from a heart valve replacement, angioplasty, bypass, heart failure or a heart or lung transplant or those patients sent home with a left ventricular assist device (LVAD), physical therapists develop a plan of care that is tailored for these specific conditions. This plan is established in collaboration with the patient, caregivers, and other health care practitioners and is based on data from the patient's history, systems review, specific tests and measures (including body mass analysis and endurance testing), diagnosis and co-morbidities.

In designing the plan of care, the physical therapist analyzes and integrates the clinical implications of the severity, complexity, and acuity of the pathology/pathophysiology (disease, disorder, or condition), the impairment, functional limitation, and the disabilities to establish the prognosis and predictions about the likelihood of achieving anticipated goals, expected outcome, and optimal function in the patient's daily life. Appropriate follow up ensures patient safety and adaptation as physical status, caregivers, tasks demand, and environment change.

Therefore, we strongly encourage CMS to provide guidance to home health agencies that physical therapists are well-trained in cardio-vascular conditions and should be able to initiate care for these items and coordinate with other appropriate health care practitioners when needed.

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Neuro/Emotional/Behavioral Status (M1710) When Confused (Reported or Observed); (M1720) When Anxious (Reported or Observed) and (1730) Depression Screening: Has the patient been screened for depression, using a standardized depression screening tool?

APTA suggest that CMS consider the use of the PHQ-9 Depression Scale Form in order to harmonize home health assessment information with data collected in other settings (i.e. MDS in the skilled nursing facility setting). Secondly, PHQ-9 has been previously tested and validated and is a recognized tool among behavioral health experts.

(M1860) Ambulation/Locomotion: Ability to walk safely, once in standing position, or use a wheelchair, once in a seated position, on a variety of surfaces.

We request that CMS provide more clarification of what is meant by the statement "climb stairs". We believe that this statement should include the ability of the patient to ascend and descend as both are needed to be functional in a multi-level home without elevators. Are patients considered to have met this requirement if there able to reach the top of the stairs with assistive technology such as a stair lift?

In addition, we request that the following choice be added to this item, following choice number (1), "With the use of a one-handed device, able to walk alone on level surface and/or requires human supervision or assistance to negotiate stairs or steps or uneven surfaces".

(M1930) Has this patient had a multi-factor Fall Risk Assessment (such as falls history, use of multiple medications, mental impairment, toileting frequency, general mobility/transferring impairment, environmental hazards)?; (M1940) Falls Risk Intervention: Does the current physician-ordered plan of care include intervention(s) to mitigate the risk of falls?; and (M1945) Falls Risk Intervention: Since the previous OASIS assessment, have fall prevention steps in the physician-ordered plan of care been implemented?

Physical therapists are well-versed in falls risk assessment. Falls are a major health concern among older adults. Falls are the leading cause of injury deaths, the most common cause of non-fatal injuries, and the most common reason for hospital admission due to trauma in older adults. Physical therapists can use a number of tests and measures to determine a patient's risk of falling. It is important to match the correct tool with the correct patient and environment to aptly measure falls risk. This may require using more than one tool to take into account the multiple factors that may contribute to the patient's falls risk.

Within the examination, include tests that focus on range of motion, muscle strength, and sensory integrity. Foot and ankle deficits in tactile sensitivity, ankle flexibility, and toe strength are important factors in balance and functional ability in older adults. Weakness around the knee and ankle relate to increase incidence of falls.

Therefore, we strongly recommend that CMS, in its accompanying guidance to this assessment instrument, reflect the importance of the role of the physical therapist in falls risk assessment and the utilization of multiple tools to accurately determine falls risk.

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Medications

(M2000) Potential Adverse Effects/Reaction: Does a complete drug regimen review indicate potential clinically significant adverse effects of drug reactions, including ineffective drug therapy, side effects, drug interactions, duplicate therapy, omissions, dosage errors, or noncompliance?; (M2010) Patient/Caregiver Drug Education: Has the patient/caregiver received instruction on high-risk medications (such as hypoglycemics and anticoagulants) including monitoring the effectiveness of drug therapy, potential adverse effects, and how and when to report problems that may occur?; and (M2015) Patient/Caregiver Drug Education Intervention: Since the previous OASIS assessment, was the patient/caregiver instructed to monitor the effectiveness of drug therapy and potential adverse effects, and how and when to report problems that may occur?

APTA would like to point out that the physical therapist is more than capable of completing this item. It is within the scope of the physical therapist to perform a patient screen in which medication issues are assessed even if the physical therapist does not perform the specific care needed to address the medication issue. The physical therapist is competent and qualified to serve a case manager and facilitate coordination of care with physicians and nurses.

APTA has a position statement adopted by its House of Delegates which states:

"Physical therapist patient/client management integrates an understanding of a patient's/client's prescription and nonprescription medication regimen with consideration of its impact upon health, impairments, functional limitations, and disabilities. The administration and storage of medications used for physical therapy interventions is also a component of patient/client management and thus within the scope of physical therapist practice."

Physical therapy interventions that may require the concomitant use of medications include, but are not limited to, agents that:

Reduce pain and/or inflammation

Promote integumentary repair and/or protection

Facilitate airway clearance and/or ventilation and respiration

Facilitate adequate circulation and/or metabolism

Facilitate functional movement"

In addition, within the Normative Model of Physical Therapist Professional Education: Version 2004, Pharmacology is a primary content area and includes:

Pharmacokinetic principles

Dose-response relationships

Administration routes

Enhancement of transdermal drug absorption

Absorption and distribution

Biotransformation and excretion

Factors affecting pharmacokinetics

Potential drug interactions

Pharmacodynamics

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Also, within the Guide to Physical Therapist Practice² (included in the Patient/Client Management Model), medications are gathered from the patient/client history. This includes: medications for current condition; medications previously taken for current condition; and medications for other conditions.

Therefore, APTA strongly urges CMS to duly note and recognize the role of the physical therapists in OASIS items as they relate to medication management (i.e. screening, evaluation, collection of information, identification of adverse events/reactions, and education). APTA is more than willing to work with CMS to ensure that all home health Medicare policies reflect the appropriate role of physical therapists in medication management.

It is also important to note that there is great variance among the tools or resources used to determine potential adverse effects or reactions. There may also be significant difference in the discipline or practitioner who may have been involved in completing the item and the different times (i.e. day or week) in which patient care is provided. For example, a computer-based point of care with drug interaction database/tool would allow clinicians to standardize ways to process this item immediately. But, all home health agencies do not have access to such technology and will need to depend more heavily upon an interdisciplinary team approach and agency support to accurately complete this item. In addition, physicians and pharmacologists may be needed for accuracy in completing. Therefore, CMS' OASIS guidelines should duly note the variability in resources, timing, and access.

Equipment Management (M2110) Types and Sources of Assistance

APTA applauds CMS for the inclusion of this item. M2110 helps to harmonize the home health assessment instrument with information collected utilizing the CARE tool. This item first helps to identify valuable information regarding caregiver availability from the beginning to the end of the home health care episode. In comparison, the CARE tool helps to identify caregiver expectations across settings and may help to distinguish areas of inconsistency which could lead to improvement in quality of care.

(M2310) Reason for Emergent Care: For what reason(s) did the patient receive emergent care (with or without hospitalization)?

APTA is concerned that the issue of risk adjustment is not fully assessed within this item. We would like to highlight the fact that the success or failure of this measure does not solely lie within the scope of care delivered by the home health agency or its health care providers. Specifically, the scope of physical therapists and home health agencies encompass a broad array of patient cases that include impairments of the musculoskeletal, neuromuscular, cardiovascular, pulmonary and integumentary systems. As a result of these impairments, the patient experiences varying limitations in functional activities and participation. Considering the wide range of patient cases and the complicated interrelationships among impairment, and limitations in

² American Physical Therapy Association: *Guide to Physical Therapist Practice*, Ed. 2, Alexandria, VA, 2001.

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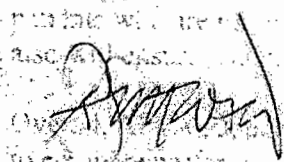
activities and participation, researchers have recommended the use of multiple and different measures in determining the effectiveness of physical therapy interventions.

It is critical that risk adjustment be sufficient so that providers are not penalized for treating patients who are more clinically complex with multiple co-morbidities. Adequate risk adjustment also will ensure that providers do not have incentives to avoid treating complex patients.

Overall, APTA supports the inclusion of this item, but believes that before applying this measure to compare performance among clinicians, it is imperative that the measure be adequately risk adjusted. As stated earlier, home health agencies treat a wide variety of patients with many different conditions. There are many factors, which are interdependent, that must be considered when determining the reason for emergent care. We are concerned that physical therapists and home health agencies that have worse outcomes because they are treating sicker patients may be penalized for conditions and characteristics of their patients that are outside of their control.

In conclusion, APTA thanks CMS for the opportunity to comment on the Medicare and Medicaid Programs OASIS Collection Requirements - Revisions, and we look forward to working with the agency to craft patient-centered policies that reflect quality health care for all Medicare and Medicaid beneficiaries. If you have any questions regarding our comments, please contact Roshunda Drummond-Dye, Associate Director of Regulatory Affairs, at (703) 706-8547 or roshundadrummond-dye@apta.org.

Sincerely,



R. Scott Ward, PT, PhD
President, American Physical Therapy Association

In conclusion, APTA thanks CMS for the opportunity to comment on the Medicare and Medicaid Programs OASIS Collection Requirements - Revisions, and we look forward to working with the agency to craft patient-centered policies that reflect quality health care for all Medicare and Medicaid beneficiaries.

If you have any questions regarding our comments, please contact Roshunda Drummond-Dye, Associate Director of Regulatory Affairs, at (703) 706-8547 or roshundadrummond-dye@apta.org.

patient care and fosters the adoption of best practices. The following comments are for your consideration.

General Comments

Alignment with the development of the CARE tool: In the *Federal Register* solicitation for comments, CMS states that, "adopting measures of efficient and high-quality care is central to the direction that CMS would like to take in its Quality Initiative. In concordance with long-standing federal objectives, CMS ultimately plans to create a standard patient assessment instrument that can be used across all post-acute care settings. The revision of the OASIS instrument is an opportunity to consider various components of quality care and how patients might be better served as they (and information about them and their care) move among health care settings. For this reason, the OASIS C includes process items that support measurement of evidence-based practices across the post-acute care spectrum that have been shown to prevent exacerbation of serious conditions, can improve care received by individual patients, and can provide guidance to agencies on how to improve care and avoid adverse events."

APTA agrees with this statement and strongly urges CMS to fully analyze and compare the information contained within OASIS C with the current development of the CARE tool. CMS specifies that the CARE tool will be used to 1) standardize program information on Medicare beneficiaries' acuity at discharge from acute hospitals; 2) document medical severity, functional status and other factors related to outcomes and resource utilization at admission, discharge and interim times during post-acute treatment; and 3) understand the relationship between severity of illness, functional status, social support factors and resource utilization. The CARE instrument will be used in the Post-Acute Care (PAC- Payment) Reform Demonstrations Program and will ultimately be used to develop a setting neutral post-acute care payment model.

APTA supports the concept of having a uniform assessment tool and agrees that patients should be placed into the appropriate setting to meet their needs based on their individual clinical characteristics/presentation.

Educational outreach to home health providers: Since the implementation of OASIS, educational outreach efforts by CMS such as the guidance on OASIS and sessions offered by professional associations and private companies has attributed to the home health community's increased accuracy in coding and the use of the OASIS assessment instrument. Due to the significant nature of these revisions, APTA strongly encourages the continuation of such activities that aid providers in understanding the OASIS C revisions and how to accurately complete the assessment instrument. This educational effort should include regional workshops, open door forums, and national informational sessions. APTA is willing to collaborate with CMS on these outreach efforts so that information can be widely disseminated to the physical therapy community.

Encouraging the use of health information technology: APTA would also like to emphasize the importance of using electronic health records to collect data in the home health setting. Electronic health records (EHRs) are vitally important to the future progression of quality health care. APTA believes that EHRs promote fluidity of information among home health agencies