

Submitter : Mr. Paul Diaz
Organization : Kindred Healthcare, Inc.
Category : Health Care Provider/Association

Date: 07/12/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachement

Issue

Issue

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Wage Index Data

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Proposed Refinements to the Case-Mix Classification System

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Case-Mix Adjustment and Other Clinical Issues

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Implementation Issues

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Proposed Revisions to the SNF PPS Labor Market Areas

see attachement

CMS-1282-P-104-Attach-1.DOC



July 12, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1282-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments of Kindred Healthcare, Inc. on the proposed rule on the Medicare Prospective Payment System for Skilled Nursing Facilities for FY 2006 70 Federal Register 29070, May 19, 2005 (CMS-1282-P)

Dear Dr. McClellan:

Kindred Healthcare, Inc. welcomes this opportunity to comment on the proposed rule captioned above that would adopt changes to the Medicare Prospective Payment System (PPS) for skilled nursing facilities for FY 2006. Kindred Healthcare is a leading healthcare services company that through its subsidiaries operates 73 hospitals, 249 nursing centers, 36 institutional pharmacies, and a contract rehabilitation business in 38 states. As a member of the Alliance for Quality Nursing Home Care and the American Health Care Association (AHCA), Kindred Healthcare is devoted to our mission of providing high quality patient centered care as evidenced through our commitment to Quality First, a covenant for healthy, affordable, and ethical long term care.

While our association and other coalition partners will be submitting detailed comments and recommendations addressing concerns relative to several components of the proposed rule, Kindred Healthcare would like to take the opportunity to briefly highlight a number of issues that are of major importance to our organization and the patients and residents we care for in our facilities. To this end, Kindred Healthcare is respectfully submitting these comments to the proposed rule.

The net impact of the new RUG-53 system represents drastic cuts in reimbursement.

Kindred Healthcare supports the concept of RUG refinement, but we believe that the impact of this particular proposal needs to be reevaluated because research conducted by both the Alliance and AHCA concludes that payments for FY 2006 will be significantly lower than the proposed rule estimates. CMS should review its data methodology to ensure that the proposed rule meets the stated goal of zero net impact.

The SNF market basket has been significantly understated.

The SNF market basket index factor proposed in the May 19, 2005 NPRM is inadequate because it is based on outdated, inaccurate, and non-representative data. Outdated weights understate cost increases and misrepresent the true cost of labor, which over time, will erode strides made in quality improvement threatening access to long term care services. As a result, CMS should update the SNF market basket with the same frequency as the hospital market basket, which should, over time, reflect a SNF specific wage price index.

A SNF specific Area Wage Index is needed to avoid dramatic swings in reimbursement.

Changes to the Area Wage Index included in this NPRM are budget neutral in the aggregate, but states such as Arizona, Georgia, Idaho, and Utah for example, will see dramatic swings in reimbursement rates due to the changes in the index. To allow for a less dramatic transition, CMS should develop a rural floor for the wage index and allow for a 4-year phase in period allowing providers to make appropriate adjustments to their operations.

Eliminating the 14-day look-back period will negatively impact patient care.

The elimination of the MDS's 14-day look-back provision has both clinical and financial implications. Understanding that the primary rationale for proposing the elimination of the look-back period is based on financial concerns, it is important to note that doing so will negatively impact the patient assessment process, the appropriate transition of care, and will degrade strides made in quality improvement. The flexibility allowing the reevaluation of patients created through the look-back period ensures continuity and stability in care delivery and as such should not be eliminated.

Eliminating or limiting grace day periods associated with the assessment process will negatively impact patient care.

The current system allowing grace periods during the assessment process is working well. It allows needed flexibility that permits smoother administration of required evaluation and reevaluation of varied patients, which promotes quality patient care and favorable outcomes. Moving forward, CMS should not reduce or eliminate grace day periods.

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The 3-day inpatient hospital stay requirement should be changed to better reflect current medical practice.

By definition, patients in an observation status are considered outpatient for hospital billing purposes. Because observation days are now prevalent in hospitals, the observation period, prior to an inpatient admission, should be combined with the inpatient stay to meet the 3-day hospital stay requirement necessary to qualify for skilled nursing facility services.

Expanding consolidated billing exclusions.

CMS identified codes for exclusion from PPS consolidated billing. These excluded services were characterized by high cost and low probability in the SNF setting and represented recent medical advances. Kindred Healthcare has provided comments to AHCA regarding specific additional HCPCS code recommendations for exclusions which meet both of these criteria. Among these recommendations are drug exclusions which should be expanded to include other chemotherapy drugs, antineoplastics, antiemetics and supportive care drugs as well as oral chemotherapy agents currently in the Medicare Replacement Drug Demonstration Project which will be available as a covered service beginning January 2006. Most drugs recommended for exclusion are used in conjunction with chemotherapy due to the negative medical side effects of the chemotherapy agents. To exclude chemotherapy from consolidated billing without excluding the drugs and biologicals needed in conjunction with this treatment is to place a financial burden on SNFs, as their costs far exceed the payment received under the PPS. Also, new drugs that have been approved for coverage but have not been assigned a HCPCS should be excluded. These drugs, due to their high cost are eligible for pass-through status in the outpatient hospital setting which would mean additional reimbursement for the hospital, an advantage not available to the SNF. Other recommendations for exclusion due to their high cost and low probability in the SNF setting are radioisotope drugs, additional MRI HCPCS and hyperbaric oxygen therapy.

Other recommendations to CMS focused on site of service and represents recent medical advances in other care settings. CMS should examine current medical practice and modify its policy of permitting certain services to be excluded only if provided in a hospital and permit these same exclusions if services are provided suitably and appropriately in sites other than hospitals, chiefly freestanding clinics. CMS originally recognized that some services that patients could receive while in a SNF Part A stay were outside the scope of SNF services. These were, according to CMS, "intensive diagnostic or invasive procedures that are specific to the hospital setting." However, in order to be excluded from PPS, the services must be provided in a hospital. If they are provided in a

freestanding clinic, they are not excluded. However, medical practice has changed, and the services in question are no longer exclusively within the purview of hospitals.

Pay-for-Performance programs must not disrupt the delicate balance of payments.

While Kindred Healthcare endorses the concept of linking Medicare reimbursements to measurable quality indicators, we request that CMS continues to partner with nursing homes to develop pay-for-performance measures similar to those proposed in the *Medicare Nursing Facility Pay for Performance Act*, or other programs that provide meaningful incentives for nursing homes to continue to improve quality care in a way that does not unfairly impact a nursing home's revenue stream.

Moving toward the development of an integrated post-acute payment and delivery system is important but must be done cautiously. Kindred Healthcare believes that CMS's policy should be guided by four overriding principles.

Each provider in the post-acute sector plays a critical and distinct role in meeting the needs of the Medicare patient population. Post-acute facilities have few similarities and many differences. Although post-acute facilities tend to be categorized together, each setting is unique and CMS should maintain distinctive definitions that support the clinical care each type of facility is organized to deliver. CMS policy should seek clear definitions of these distinct roles but should recognize that a certain amount of overlap is inevitable and necessary to ensure continuity of patient care across settings.

Kindred Healthcare supports CMS' efforts to explore and evaluate development of a comprehensive post-acute assessment tool. Development of such an instrument is an important prerequisite to integrating care, and possibly payment, across the post-acute setting. We caution CMS, however, that the development of a common instrument is a complicated and important task. The range, depth, and content of clinical information necessary to evaluate and treat LTCH patients is more comprehensive than is captured in the assessment instruments used by other post-acute providers. Accordingly, policy makers should proceed carefully in developing a common instrument and ensure active participation by clinicians involved in treating patients across the post-acute continuum.

Kindred Healthcare supports the principle that patients should be cared and paid for in the most appropriate setting. While determination of appropriate setting is a complicated decision requiring extensive input from treating physicians in consultation with patients, Kindred Healthcare agrees with the premise of MedPAC's recommendation that the decision should be made based on patients' clinical characteristics and needs.

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Patients who can be safely and effectively cared for in SNFs should not be treated and paid for in LTCHs or IRFs. Conversely, severely ill, medically complex patients with multiple co-morbidities should have access to the intensive interventions only available in LTCHs.

Again, from a clinical perspective, these determinations are not always clear. Policy should allow for some flexibility so that clinical judgement can be effectively exercised in the best interest of patients. MedPAC's recommendations and CMS' current research on revised certification criteria for LTCHs should help achieve this goal.

As noted by MedPAC, CMS policy should also require not only that patients be placed in the appropriate setting, but that providers in the post-acute sector have the capacity to meet the needs of the patients. Staffing levels, staff skill mix, availability of diagnostic tests, sophistication of technology and intensity of service vary significantly across post-acute settings. While tempting for CMS policy-makers to encourage patients to be placed in the least intensive and least costly setting, this decision must be made in light of patient needs and quality of care, as measured by the providers' capacity to effectively treat patients with certain clinical conditions.

Kindred Healthcare is prepared to accept modifications to the Medicare PPS that promote patient centered care, quality improvement, and customer satisfaction. The reductions in the proposed rule however, represent too drastic a cut and may, if uncorrected, result in a repeat of the financial meltdown that the long term care community experienced immediately following the implementation of the PPS in 1998. We are available to work with CMS in whatever capacity you deem necessary and thank you for your continued support.

Sincerely,



Paul J. Diaz
President and Chief Executive Officer

Submitter :

Date: 07/12/2005

Organization : AARP

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1282-P-105-Attach-1.DOC



July 12, 2005

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1282-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-1282-P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006; Proposed Rule
42 CFR Part 424: May 19, 2005

Dear Dr. McClellan:

Thank you for the opportunity to comment on the qualifying three-day inpatient hospital stay requirement, approaches that support higher quality post-acute care, and pay for performance programs for the skilled nursing facility setting.

Qualifying Three-Day Inpatient Hospital Stay Requirement

We commend CMS for accepting comments on whether the time that patients spend in observation status should count toward meeting the skilled nursing facility (SNF) benefit's qualifying three-day prior hospital stay requirement. This requirement has been in existence since the creation of the Medicare program, when observation status did not exist in clinical practice.

Medicine and the standards of patient care have changed since the creation of the Medicare program in 1965. For example, care that may have been provided during a three-day hospital stay in 1965 may now be provided during observation status and possibly in the emergency room, as well as during an inpatient stay. In addition, patients may often be held in observation status due to the lack of available inpatient hospital beds.

Whether a beneficiary's acute hospital stay satisfies arbitrary administrative requirements, such as whether an inpatient bed is available, should not be the focus of this rule. Beneficiaries who require acute hospital care that involves a

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three day stay, whether technically admitted as a hospital inpatient or merely held in observation status, should not affect whether they qualify for SNF care. Since the three day rule was adopted, other criteria have been put in place through the SNF patient assessment process and other requirements to assure that beneficiaries are not inappropriately admitted for SNF care.

As CMS states in the preamble, Congress intended for the SNF benefit to cover a short-term, relatively intensive convalescent stay as a continuation of an acute hospital stay. We believe that SNF admissions following three days of acute hospital care that includes inpatient care, observation care, and/or emergency care are consistent with CMS' statement of congressional intent.

The arbitrary administrative nature of the distinction between formal inpatient admission and observation status has unfair and serious consequences for Medicare beneficiaries and their families who may only learn of the three-day stay requirement after they are transferred to a SNF and fail to meet the SNF benefit's prior hospital stay requirement.

For these reasons, we support counting a patient's time spent in observation status toward meeting the three-day stay requirement. Liberalizing the application of the three day rule could have the beneficial effect of reducing the need for rehospitalization in the case of beneficiaries who are unable to qualify for SNF care but who still need institutional care. We note that, while liberalizing the three day stay rule may have financial implications, we would not anticipate any negative consequences in terms of the impact on quality of SNF or other beneficiary care. Of course, the primary impact would be enormously positive by improving access to SNF care for beneficiaries who would not otherwise qualify. In any case, Congress did not establish this rule merely as a budgetary measure but to assure compliance with its overall intent that the SNF benefit not be used to cover custodial care that does not require prior acute hospitalization.

Approaches that Support Higher Quality Post-Acute Care and Pay for Performance in SNF Settings

AARP is pleased that CMS has taken steps to receive comments on the relative advantages and disadvantages of the various policies affecting the support for higher quality post-acute care.

We support efforts that allow CMS to closely monitor the impact of Medicare payment policies on the quality of and access to post-acute care and the appropriateness of care in various settings. We also support efforts that will allow Medicare to improve payments in post-acute payment settings.

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Furthermore, AARP supports efforts that allow CMS to take strong steps to ensure the quality of post-acute care and promote quality improvements where necessary. AARP places particular priority on working with quality improvement organizations to improve quality of care provided in post-acute settings and, improving methods of coordinating care among multiple providers, while maintaining or enhancing beneficiaries' choice of providers and access to needed care. CMS should work with MedPAC and all interested stakeholders as it examines changes in post-acute care payments.

Regarding using pay for performance systems in SNF settings, we believe that CMS should take a careful, thoughtful, and deliberate approach to this issue. CMS rightfully acknowledges the absolute importance of carefully constructing quality measures that will be effective ways to measure quality for payment purposes and accurately measure quality across all settings, such as both short-term skilled nursing care and long-term nursing home care. The development of any quality measures should involve the input of all stakeholders, including consumers. CMS should also seek MedPAC's advice on this important issue.

Overall, the incentives of post-acute payment methods must safeguard access to necessary, high-quality covered services for all beneficiaries, without regard to the intensity or duration of care required.

We appreciate the opportunity to comment on these important issues to help ensure that beneficiaries have access to quality care. If you have any questions or need additional information, please contact Rhonda Richards of our Federal Affairs staff at (202) 434-3770

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", with a stylized flourish at the end.

David M. Certner
Director
Federal Affairs

Submitter : Mr. Scott Amrhein
Organization : Continuing Care Leadership Coalition (CCLC)
Category : Health Care Professional or Association

Date: 07/12/2005

Issue Areas/Comments

GENERAL

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Issue

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Proposed Revisions to the SNF PPS Labor Market Areas

See Attachment

Proposed Refinements to the Case-Mix Classification System

See Attachment

Case-Mix Adjustment and Other Clinical Issues

See Attachment

CMS-1282-P-106-Attach-1.DOC

CONTINUING CARE LEADERSHIP
COALITION



July 11, 2005

VIA E-MAIL

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Subject: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006; Proposed Rule, *Federal Register*, Vol. 70, No. 96, May 19, 2005, pp. 29070-29162. [CMS-1282-P]

Dear Dr. McClellan:

The Continuing Care Leadership Coalition (CCLC) represents over 100 not-for-profit and public long term care providers in the New York metropolitan area. The members of CCLC provide services across the continuum of long term care to older and disabled individuals. CCLC's members are leaders in the delivery of skilled nursing care, home care, adult day health care, respite and hospice care, rehabilitation and subacute care, senior housing and assisted living, and continuing care services to special populations. CCLC's members have also had a significant impact on the development of innovative solutions to long term care financing and service delivery in the U.S., with several of its members having played pioneering roles in the development of managed long term care programs in New York and Social HMO and PACE programs at the national level.

On behalf of the long term care providers in the CCLC membership, I appreciate this opportunity to comment upon the Center for Medicare and Medicaid Services' (CMS's) proposed rule (CMS-1282-P) regarding the Skilled Nursing Facility Prospective Payment System for FY 2006.

Key Changes to the SNF PPS

CMS has proposed the following four key changes to the SNF PPS rate:

- Implementation of new labor market definitions when determining the labor portion of the Medicare SNF rate for each RUG category.
- Elimination of the existing temporary add-ons to Medicare rates (20% for certain specified clinically complex RUGs and 6.7% for other rehabilitation RUGs).
- Expansion of the number of RUG categories from 44 to 53 by adding nine new "Rehabilitation plus Extensive" groups, and updating the case-mix weights for each RUG category.

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- Providing a full market basket increase of 3% inflation for FY 2006.

CCLC Comments

CCLC's comments below are offered in the context of significant concern over the declining financial situation facing SNFs in New York State and the potential harm that further funding reductions that would be triggered under the proposed rule would have upon these facilities and the Medicare (and Medicaid) beneficiaries that they serve.

Over the last ten years, the financial status of New York SNFs has been impacted not only by the implementation of the SNF PPS in 1998, but also by several successive rounds of Medicaid funding cuts that have, in the aggregate, reduced Medicaid payments to New York SNFs by close to \$2 billion. As a consequence, the majority of New York SNFs are facing significant financial challenges, with more than 55% of the State's facilities incurring losses at the operating level¹. In the last two years alone, more than a dozen New York SNF's have closed their doors, and the frequency of nursing facility closure activity in our State appears to be increasing.

CCLC has undertaken an analysis that examines the impact of each of the components of the proposed SNF PPS rule on nursing facilities in New York. Based on the results of this analysis, CCLC is deeply concerned that the proposed rule, if enacted in its current form, would further jeopardize the financial status of SNFs in our State. On a Statewide basis, our analysis indicates that facilities would lose \$26 million annually if this rule were adopted. In the New York metropolitan region alone, the losses would exceed \$15 million annually, with a substantial portion of these losses resulting from the proposal to fully base the New York City wage index in FY 2006 on a new Core Based Statistical Area, which expands the definition of the New York City Metropolitan Statistical Area (MSA). Losses of this magnitude would not only disadvantage already financially struggling facilities; they would substantially compromise the ability of New York SNFs to deliver the level of long-term care services that New York Medicare beneficiaries need and deserve.

Use of Core Based Statistical Areas in Determining Wage Indices for FY 2006

CMS has proposed to adopt revised labor market definitions and use these to set payment adjustments to reflect variation in costs across geographical areas. The revised definitions (Core Based Statistical Areas) would change the existing New York City (NYC) Metropolitan Statistical Area (MSA) in a way that would substantially reduce Medicare payments to New York metropolitan area SNFs. This is because the proposal would expand the MSA - which currently includes only New York City and the New York counties of Westchester, Rockland, and Putnam - to include the New Jersey counties of Bergen, Hudson and Passaic, which would reduce the wage index from 1.3465 to 1.3185, a 2.8% reduction. This directly translates to an annual loss of \$11.8 million to skilled nursing facilities (SNFs) in the NYC MSA.

The CBSAs were developed after the 2000 census and are based on general migration and commuting patterns, rather than wages in prevailing labor markets. The Office of Management & Budget (OMB) had even cautioned agencies not to use the CBSA for purposes unrelated to statistical reporting unless the new boundaries were studied and found to be appropriate. Nevertheless, CMS has proposed using the CBSAs in its SNF PPS rule for FY 2006, the impact of which will be sudden and disproportionate losses for facilities in the NYC MSA and in other MSAs across the State and Nation.

¹ Year 2003 New York State Residential Health Care Facility (RHCF-4) Cost Reports.

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CCLC therefore urges CMS to use the existing MSAs in the calculation of the SNF wage index until such a time that an updated wage index methodology that accurately reflects the wages in labor markets is developed. At a minimum, CMS should provide a transitional methodology for calculating the wage indices of SNFs that would be negatively impacted by the use of CBSAs, as was done for hospitals that would have been similarly disadvantaged in FY 2005. Under the hospital inpatient PPS rule for FY 2005, CMS agreed to compute area wage indices for disadvantaged hospitals based upon a 50/50 blend of the old and new labor market definitions.

CMS should at minimum provide the same blended approach for SNFs that that would be disadvantaged by the MSA definition change in FY 2006 that was provided to hospitals in FY 2005. Such an accommodation would provide a more appropriate transition and would at least partially alleviate the abrupt and substantial reduction in Medicare payments that would otherwise hit facilities located in the NYC MSA and other affected MSAs.

Elimination of Temporary Add-Ons, New RUG Categories, and Case Mix Weights

Section 101 (a) of the BBRA and section 314 of the BIPA provide a temporary increase in the per diem adjusted payment rates of 20% for certain specified clinically complex RUGs and 6.7% for rehabilitation RUGs respectively. Pursuant to the direction of Congress under BBRA and BIPA, the add-ons are to remain in effect until the implementation of case mix refinements in the SNF PPS. According to CMS, the add-ons would represent \$1.02 billion in annual payments to providers if retained in the SNF PPS rates for FY 2006.

CMS has proposed eliminating the add-ons effective January 1, 2006 and simultaneously creating 9 new RUG categories and updating the case-mix indices for all 53 RUGs. CCLC is greatly concerned about that fact that payments for the 53 new RUG groups would cover only 50% of the loss resulting from the elimination of the temporary add-ons. According to CCLC's analysis, the resulting shortfall would exceed \$46 million annually for SNFs Statewide in New York and \$20 million annually for facilities located in the New York metropolitan area.

It was the clear intent of Congress in establishing the current add-ons to compensate for what were widely agreed to be inadequacies in the capacity of the RUG-III case-mix system to appropriately reimburse providers for the costs of non-therapy ancillary services. In directing CMS to keep the add-ons in place until appropriate case-mix refinements were implemented, Congress clearly anticipated and expected that any refinements to the RUG-III case mix system be effective in remedying the underpayment of non-therapy ancillary services.

Unfortunately, as is acknowledged in the rule itself, the addition of nine new payment categories would only minimally increase the current payment system's low predictive ability. As a result, we anticipate that nursing facilities will continue to be underpaid for the provision of nontherapy ancillary services, while at the same time losing 50% of the benefit of the add-ons that were explicitly intended to offset the underpayment of these services.

In essence, CCLC does not believe that the modifications to the case mix system proposed in the rule constitute the level of refinement that would justify elimination of the current add-ons.

As a result, CCLC strongly recommends that CMS retain the existing add-ons while pursuing more appropriate and targeted refinements to the RUG-III case-mix system. This should be coupled with a full SNF market basket increase to cover the costs of inflation in FY 2006.

In the alternative, if CMS were to retain the proposed case mix changes in FY 2006, CCLC would strongly recommend that the RUG-III case-mix weights be further adjusted to ensure that

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aggregate payments under the new system fully match the level of aggregate payments that would have been provided had the current case mix system and add-ons been continued, and that a full market basket increase be provided to cover the cost of inflation in 2006.

Extension of AIDS Payment Add-on

CCLC's members have a long history of providing services to adults and children with chronic care needs related to HIV and AIDS. *CCLC therefore strongly endorses and supports the proposed extension of the 128 percent add-on payment for AIDS patients who are serviced in Medicare certified SNFs as a critical measure for promoting and ensuring access to care for this special population.*

Hospital Observation Days and the Three-day Inpatient Hospital Stay Requirement

In response to the question posed in the proposed rule regarding whether hospital observation days should be included in satisfying the three-day hospital stay requirement for a Medicare nursing home admission, *CCLC supports the position that observation days be included and encourages CMS to move forward with guidance clarifying that such days will count toward the fulfillment of the three-day hospital stay requirement.*

On behalf of CCLC and its members, I want to reiterate my appreciation for the opportunity to comment on this proposed rule. We encourage CMS in particular to work toward making needed modifications to address the impact of the CBSA change and to close payment gap that would result from the proposed elimination of BBRA and BIPA-mandated add-ons. We stand ready to work with you and your staff in addressing these issues, and we encourage you to contact Desmond D'sa, CCLC's Director of Finance and Reimbursement, at 212-258-5331 if you have any questions about these comments.

Sincerely,



Scott C. Amrhein
President

cc: The Honorable Hillary Rodham Clinton
The Honorable Charles E. Schumer

Submitter : Ms. Katherine Carver
Organization : National Association for the Support of Long Term
Category : Health Care Provider/Association

Date: 07/12/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1282-P-107-Attach-I.DOC



National Association for the
Support of Long Term Care

Insight • Advocacy • Action

Attachment #107

1321 Duke Street
Suite 304
Alexandria, Virginia
22314
703-549-8500

July 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independent Avenue, S.W.
Washington, D.C. 20201
Attention: CMS-1282-P

RE: *Comments on Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006, Proposed Rule, 70 Federal Register 29070, May 19, 2005, CMS-1282-P*

Dear Medicare & Medicaid Services:

The National Association for the Support of Long Term Care ("NASL") submits the following comments in response to the Proposed RUG Refinement Rule.

NASL is a trade association representing providers of both ancillary services and products to the long-term care industry. Our member companies provide speech-language pathology, physical, occupational and respiratory therapy; portable x-ray/EKG and ultrasound; pharmacy, long term care ("LTC") software systems and other ancillary services. NASL members also provide products such as complex medical equipment, parenteral and enteral supplies, equipment and nutrients, and additional specialized supplies for post-acute care settings nationally.

NASL wishes to comment on the four following areas under the Proposed RUG Refinement Rule ("proposed rule"): (1) proposed refinements to the case-mix classification system; (2) Minimum Data Set (MDS) issues; (3) CMS clarification of additional clinical issues; and (4) consolidated billing. These comments are described in detail below.

1) Proposed Refinements to the Case-Mix Classification System

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CMS requests comments on the proposed refinements to the case-mix classification system. CMS is proposing to refine the SNF PPS RUG-III case mix classification system and apply the refined system starting in January 1, 2006.¹ The case-mix indices for the proposed RUG-III system adopts the same method used for calculating the initial SNF PPS case-mix indexes. The nursing and therapy indexes would continue to be based on minutes of staff time for nursing and therapy services where appropriate by reclassifying patients into the proposed 53 RUG-III groups. The addition of the 9 new RUG-III categories would cause the nursing weights to change more than the therapy weights due to the redistribution of patients from existing groups to the newly created proposed groups. The therapy weights would be affected only slightly. With the reclassification, the nursing indexes in the new categories and in the existing rehabilitation would show less variability than those in the rehabilitation categories under the 44 RUG-III category system. CMS has calibrated the new payment model, such that aggregate payments under the new 53-group system are the same as those under the 44-group system, excluding the add-ons.

NASL analyzed the proposed refinements to the case-mix classification system. The nine new categories will have detrimental effects unless certain changes occur, which include: (I) The proposed change from RUG-44 to RUG-53 does not specifically address non-therapy ancillary and other services; (II) Each level of therapy care should be treated the same and have the same index; (III) There is an anomaly in the nursing case mix index for category RMX that must be corrected; (IV) Without addressing the payment for nontherapy ancillary services, the BIPA/BBRA add-ons should not be eliminated. (V) NASL questions whether the proposed RUG refinement rule is budget neutral because of the shift of payments to the new RUGs categories.

I. *The proposed change from RUG-44 to RUG-53 does not specifically address non-therapy ancillary and other services.*

The purpose of the case mix refinement is to more accurately estimate costs for non-therapy ancillary and other services. This proposed change from RUG-44 to RUG-53 does not specifically address non-therapy ancillary and other services. These changes expand the RUG categories to address the issue of residents who receive both extensive services and rehabilitation, but do not address specific payments for non-therapy ancillary and other services. While the proposed rule states that the Urban study "verified that non-therapy ancillary costs are higher for Medicare beneficiaries who are classified into the Extensive Services category than for those classified to other categories,"² the proposed rule did not respond to how the nursing and therapy case-mix indices affect those non-therapy ancillary costs. Further, the proposed rule stated that the R-square (explanation of variance) only increased to 8% in the 53 group model, "that added nine Rehabilitation plus Extensive groups."³ This proposed rule expands from a 44 group model to a 53 group model, which includes these nine Rehabilitation plus Extensive groups, but does not include the additional five non-therapy groups. Under this 53 group model, the most that the Urban study stated the R-square increased to was 10.3%. At

¹ Federal Register, Vol. 70, No. 96, at p. 29076.

² Federal Register, Vol. 70, No. 96, at p. 29076.

³ Federal Register, Vol. 70, No. 96, at p. 29076.

best this is a minor change and a very weak correlation. The proposed rule does not respond to patient needs for those non-therapy ancillary services and products received by beneficiaries who are not receiving therapy services

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Furthermore, the proposed rule states that "CMS has reviewed data that shows great variability in the ancillary services (such as pharmacy) utilized by different SNF residents classified into the same RUG-III group."⁴ Without a non-therapy ancillary component, either case-mix adjusted or as an outlier payment, as part of the PPS payment computation the variances for these services will not be appropriately covered. Adjusting the nursing or therapy case-mix does not address these non-therapy ancillary services and products.

II. *Each level of therapy care should be treated the same and should have the same index.*

According to the proposed rule, the "nursing weights changed more than the therapy weights, due to the redistribution of patients from existing groups to the newly created proposed groups."⁵ However, the proposed rule was modified to update the nursing and therapy case-mix indices for 2001 data, shows significantly different case mix indices for therapy with extensive services versus therapy without extensive services. NASL questions why there would be such a difference given the fact that the therapy minute minimums are the same for both the existing therapy groups and the newly created proposed groups.

The following examples illustrate these significant differences. The index for RUX/RUL is 2.46 versus 2.20 for RUC/RUB/RUA, a difference of 11.8% more for the category with extensive services. The index for RVX/RVL is 1.18 versus 1.33 for RVC/RVB/RVA, a difference of 12.7% less for the category with extensive services. The index for RHX/RHL is 1.04 versus 1.10 for RHC/RHB/RHA, a difference of 5.6% less for the category with extensive services.

These differences when reduced to a cost per minimum care minute of therapy delivered produce the following differences, which show very large and unexplained differences in the amounts being paid per minute of therapy delivered:

RUX	\$2.48	RUC	\$2.21
RVX	\$1.71	RVC	\$1.92

CMS needs to explain its rationale and account for these differences considering the same number of therapy minutes defines each category.

A review of the RV therapy category demonstrates that the index has decreased from 1.41 in FY 2005 to 1.18 for therapy with extensive services and 1.33 for therapy only in the proposed rules. While all other therapy indices showed extensive increases and with therapy tending to be the most costly service, NASL questions this decrease.

⁴ Federal Register, Vol. 70, No. 96, at p. 29076.

⁵ Federal Register, Vol. 70, No. 96, at p. 29077.

NASL recommends further clarification, disclosure, formulas, and calculations used to establish these significantly changed rates.

III. *There is an anomaly in the nursing case mix index for category RMX that must be corrected.*

The nursing case-mix index for RMX is 1.84, which is the highest nursing case-mix (even higher than RUX). The result of this high index is that the RMX rate becomes one of the highest paid. It is greater than either the RVX or the RHX category. This anomaly is similar to the one corrected by Section 314 of the BIPA were payment rates were higher than rates for categories with more intensive services. This anomaly needs to be corrected in the proposed rule.

IV. *Without addressing the payment for nontherapy ancillary services, the BIPA/BBRA add-ons should not be eliminated.*

The purpose of the BIPA/BBRA add-ons was to provide SNFs with increased payment to cover the costs of non-therapy ancillaries and was to continue until a revised RUGs system was implemented. This proposed rule increases the therapy RUGs categories to provide for the additional costs associated with extensive services. The elimination of the add-ons to the non-therapy RUGs categories, which may have great variability in non-therapy ancillaries, would create an under funding of those categories.

V. *NASL questions whether the proposed RUG refinement rule is budget neutral because of the shift of payments to the new RUGs categories.*

A review of the proposed rule indicates that budget neutrality seems to be a primary goal. With the large shift in nursing and therapy indices in favor of the proposed therapy plus extensive services it would appear that these proposed rates will under fund non-therapy RUGs categories. Further, the shift of payments to these new categories makes it difficult to determine whether the goal of budget neutrality will be reached. NASL recommends further clarification and disclosure and formulas and calculations used to establish these significantly changed rates.

VI. *Recommendations*

The proposed change from RUG-44 to RUG-53 does not specifically address non-therapy ancillary and other services. One recommendation is to create either a case-mix adjustment for non-therapy ancillaries or create an outlier payment system as part of the PPS payment computation. Merely adjusting the nursing or therapy case-mix does not address these non-therapy ancillary services and products.

Each level of therapy care should be treated the same and have the same index. NASL recommends further clarification, disclosure, formulas, and calculations used to establish these significantly changed rates.

There is an anomaly in the nursing case mix index for category RMX that must be correct. NASL recommends that CMS correct this case mix category immediately.

Without addressing the payment for non-therapy ancillary services, the BIPA/BBRA add-ons should not be eliminated. NASL recommends that the elimination of the add-ons to the non-therapy RUGs categories, which may have great variability in non-therapy ancillaries, would create an under funding of those categories.

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Finally, NASL questions whether the proposed RUG refinement rule is budget neutral because of the shift of payments to the new RUGs categories. The shift of payments to these new categories makes it difficult to determine whether the goal of budget neutrality will be reached. NASL recommends further clarification and disclosure and formulas and calculations used to establish these significantly changed rates.

2) Minimum Data Set (MDS) Issues

This section discusses the following issues: (1) look-back periods; (2) grace periods; and (3) anticipated therapy. CMS is appropriately seeking comment on other policy options to enhance the accuracy of the payment system and improve the quality of care provided to Medicare beneficiaries during a SNF stay. In particular, CMS raises MDS issues regarding potential elimination of the look-back period, the grace period, and the projection of anticipated therapy minutes and seeks comments on other alternatives.

A. Look-Back Periods

CMS asks for comments on removing the look-back into the hospital stay from the 5-day and 14-day PPS MDS assessment. CMS indicates that the creation of the proposed new Rehabilitation plus Extensive Services groups underscores the importance of ensuring the accuracy of patient classifications that encompass medically complex patients. CMS asks whether this could be accomplished by ensuring that the MDS data used in making such classifications reflect only those services that are actually furnished during the SNF stay itself rather than during the preadmission period (for example, during the prior qualifying hospital stay).⁶

NASL argues that eliminating the look-back period will have detrimental effects because (I) Eliminating the look-back period will severely limit the ability to treat beneficiaries' at the level of care that is clinically required; and (II) Eliminating the look-back period will likely result in significant and drastic cuts in SNF reimbursement.

I. *Eliminating the look-back period will severely limit the ability to treat beneficiaries' at the level of care that is clinically required.*

Eliminating the look back period decreases the ability to identify the complexity of care needed by a patient because the MDS assessment tool is not only used for reimbursement but a treatment-planning tool as well. According to the July 30, 1999, SNF PPS final rule in a response to a comment concerning the appropriateness of the use of look-back periods in a prospective payment system, CMS stated, "our expectation is that the occurrence of one of the specified events during the 'look-back' period, when taken in combination with the characteristic tendency for an SNF resident's condition to be at its most unstable and intensive state at the outset of the SNF stay, should make this a reliable indicator of the need for skilled care upon SNF admission in virtually all

⁶ Federal Register, Vol. 70, No. 96, at p. 29079.

instances.”⁷ For example, during a Part A stay, the “spell of illness” begins with the hospital stay and initiates the potential eligibility for the SNF benefit. By capturing the appropriate services provided in the hospital, the true acuity of the beneficiary’s condition is captured. Therefore, the look-back period provides invaluable information from the hospital to the SNF to help treat the patient at the level of care that is clinically required.

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Further, for the 5-day PPS MDS assessment, this look-back period into the hospital stay serves as a predicator for the medical and nursing services that a beneficiary may require during the first 14 days of care. The types of services targeted in such a look-back for the purpose of identifying the need for “extensive services” in the SNF include: a 7-day look-back at IV feeding; a 14 day look back at IV medications; a 14-day look-back at suctioning needs; a 14-day look-back at tracheostomy care; and a 14-day look-back at ventilator/respirator use.⁸ These services point to the significant medical complexities of the beneficiary’s care and consideration for the need to continue extensive interventions. Knowing what transpired during a patient’s hospitalization is clinically important in determining treatments, goal setting, frequency/intensity/duration of therapies, and expected outcomes. Items that would currently lead to a Resident Assessment Protocols (“RAP”) and treatment planning for special medically complex issues or risk factors, may not be triggered by the MDS. Also, items that would currently qualify a patient for a higher, more appropriate RUG level may not be triggered on the MDS. Therefore, providers may feel the need to push patients through initial clinical assessments more quickly and/or begin therapy sooner in an attempt to identify and be reimbursed for a more appropriate higher RUG. For instance, learning that a patient was ventilator dependent during the look-back period impacts treatment during a patient’s stay – a patient who was ventilator dependent will likely require a longer recovery period, more extensive services from nursing, and therapy to fully recover than a person who was not ventilator dependent. This is vital patient information that is learned through the look-back period that significantly impacts a patient’s medical treatment to receive the clinically appropriate level of care.

II. *Eliminating the look-back period will likely result in significant and drastic cuts in SNF reimbursement.*

Second, eliminating the look-back period would likely result in significant and drastic cuts in SNF reimbursement. Changing this policy without the benefit of research could rapidly force CMS and providers to re-implement temporary add-ons to SNF reimbursement in order to ensure continued quality of care.

Also, changing the 5-day assessment to include only services provided since admission to the SNF will not follow Omnibus Budget Reconciliation Act (“OBRA”) MDS guidelines for the look-back period. The intent of the MDS is two-fold, which includes care planning and reimbursement. In determining the clinically appropriate level of care in the SNF, the look-back period into the hospital demonstrates to the SNF the clinical needs of the patient. With the elimination of the look-back into the hospital,

⁷ Federal Register, Vol. 64, No. 146, at p. 41668-69.

⁸ RAI User’s Manual, Chapter 6, Section 1.7, May, 2005.

this will not take into account either the care planning component nor the reimbursement component of the MDS.

Finally, reimbursement will not reflect the care needs of high acuity patients that are admitted to the SNF and then re-admitted to the hospital shortly after admission to the SNF (less than 14 days) if the look-back period for extensive services does not include the hospital services.

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In summary, MDS data is used for development of a treatment plan, for determining the level of reimbursement, and for measuring the quality of care. Therefore, elimination of the look-back period could have significant negative impacts into all of these above stated areas.

B. Grace Periods

CMS asserts that it has received recommendations to decrease or eliminate the grace day period specifically for the 5-day PPS MDS assessment. It invites comments on this specific recommendation as well as decreasing or eliminating the grace periods associated with all PPS MDS assessments.⁹

NASL argues that eliminating or decreasing the grace period will have detrimental effects because (I) Grace days give SNFs the flexibility to delay care until patients are stable ready to receive therapy, while ensuring that payments reflect the treatment levels that are provided to the patient; (II) Eliminating the grace period will likely result in significant and drastic cuts in SNF reimbursement; and (III) Not only will there be a decrease in SNF reimbursement, but there also will be an increase in costs since there is already a shortage of therapists, which will require therapists to work more often and longer hours.

- I. *Grace days give SNFs the flexibility to delay care until patients are stable and ready to receive therapy, while ensuring that payments reflect the treatment levels that are provided to the patient.*

The grace days allow providers an opportunity to place patients into the most clinically appropriate care category. According to the August 2002 GAO *SNF Responses to Payment Systems Report*, it states, "grace days are intended to give SNFs the flexibility to delay care until patients are ready to receive therapy, while ensuring that payments reflect the treatment levels that are provided to the patient."¹⁰ For instance, this allows a nurse to perform a comprehensive assessment on day 1 and a therapist to complete a comprehensive evaluation on day 1 or day 2 to allow proper programming of the medically challenged patients. A typical provider stated that, over 60% of their patients are considered medically complex.¹¹ Medically complex means that a patient has two or more medical conditions (cardiac, pulmonary, multiple organ failure) which impacts the patient's rehabilitation. Also this provider stated that, in 2005, the average facility length of stay is only 19.43 days and acute care discharges are 26 percent; and over 69 percent

⁹ Federal Register, Vol. 70, No. 96, at p. 29080.

¹⁰ August 2002 GAO-02-841 SNF Responses to Payment Systems Report.

¹¹ Todd Bergstrom, President, HealthPRO Management Services, July 8, 2005.

of the therapy patients return home.¹² In contrast, in 1997 through 2000, over 30 percent of patients were discharged to acute care settings and the length of stay was 25 plus days.¹³ Therefore, this example suggests that the average number of grace days has decreased over time with the implementation of the grace days.

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Furthermore, according to the July 30, 1999, SNF PPS Final Rule, it states, "the grace days are also provided to offset any incentive that facilities may have to initiate therapy services before the beneficiary is able to tolerate that level of activity."¹⁴ Another reason for the provision of three grace days for the 5-day assessment was to make it possible for beneficiaries to classify into the two highest RUG-III rehabilitation categories."¹⁵ Moreover, according to the RAI User's Manual, Chapter 2, it states, "Grace days can be added to the Assessment Reference Date ("ARD") in situations such as an absence/illness of the RN assessor, reassignment of the assessor to other duties for a short period of time, or an unduly large number of assessments due at approximately the same time. Grace days may also be used to more fully capture therapy minutes or other treatments." Therefore, the grace days allow providers to place the patients into the most clinically appropriate care category.

Furthermore, in comparing an Inpatient Rehabilitation Facility ("IRF") to SNF PPS, it is apparent that there is a need to make allowances for the impact of comorbidities and medical complications. For IRF PPS, there are several criteria that the patient must meet in order to qualify for IRF placement; one of those criteria is Intense Rehab Services, which is defined as receiving three hours of therapy each day per week (5 days minimum and a maximum of 7). CMS regulations state that a patient may be admitted to an IRF even when the patient is unable to meet this criterion and comes in with a graduated therapy program. In a graduated therapy program, the patient progresses to three hours per day over a 10-day time frame. This is predicated on the recognition that the patient may have a secondary diagnosis or medical complication that prevents full participation. Yet, this patient is afforded "reasonable time" to achieve this level because this is the level of care that best meets the beneficiary's need. It is most appropriate that grace days exist at the SNF for the 5 day and for each PPS Assessment for entirely the same rationale. Since the SNF patient may have a secondary diagnosis or medical complication this would preclude full participation at admission. Therefore, flexibility is required to appropriately assess and meet the clinical needs of the beneficiary.

II. *Eliminating the grace period will likely result in significant and drastic cuts in SNF reimbursement.*

Second, eliminating the grace period will likely result in significant and drastic cuts in SNF reimbursement. Especially for the first 5-days when patients require a higher level of service, it is not uncommon to need the flexibility of grace days for situations such as the following:

¹² Todd Bergstrom, President, HealthPRO Management Services, July 8, 2005.

¹³ Todd Bergstrom, President, HealthPRO Management Services, July 8, 2005.

¹⁴ Federal Register, Vol. 64, No. 146.

¹⁵ Federal Register, Vol. 64, No. 146.

- Admissions are late in the day or weekend admissions, often necessitating that the start of therapy care be postponed to day-2 or later;
- A patient's medical condition is such that the act of transferring to another facility necessitates a day or two to stabilize medically and/or physically (i.e. fatigue-factor); and
- When a patient's therapy is placed on hold pending test results, e.g., Doppler studies for DVT, x-ray results, etc.

However, best-practice standards should not limit access to care. Elimination of grace days for the 5-day assessment, could force SNFs to accept lower payment while a higher level of service is being provided until and during the next look back period.

One of the intents behind the grace days is to allow placement into the two highest rehabilitation RUG-III groupings. An elimination of the grace days would potentially disallow reimbursement for needed higher services early in the beneficiary's SNF stay.

In light of the proposed new categories, a decrease in or elimination of grace days will not only make it more difficult for providers to appropriately place patients into the Extensive Care or Rehabilitation RUG categories, but will also make it difficult for providers to place clinically complex patients into the new combined RUG categories.

III. *Not only will there be a decrease in SNF reimbursement, but there also will be an increase in costs since there is already a shortage of therapists, which will require therapists to work more often and longer hours.*

There is a very prevalent therapist staffing shortage. To address these proposed changes, therapy services would need to increase weekend coverage and increase late-day staff coverage, which will increase the cost of therapy services dramatically due to the therapy shortage and the lack of registered staff willing to work these hours/days. Essentially, CMS is proposing the addition of the Rehabilitation-Extensive Service categories but giving providers no clinically responsible manner to qualify patients.

C. Anticipated Therapy

CMS also invites comment on whether to eliminate the projection of anticipated therapy services during the 5-day PPS assessment.¹⁶

NASL argues that eliminating the projection of anticipated therapy services during the 5-day PPS assessment will have detrimental effects because (1) Eliminating the projection of anticipated therapy services during the 5-day PPS assessment will limit professional caregivers' ability to use their predictive and evaluative skills to identify beneficiaries' needs, abilities, and potential for improvement at SNFs; and (2) Eliminating the projection of anticipated therapy services during the 5-day PPS assessment will likely result in significant and drastic cuts in SNF reimbursement.

¹⁶ Federal Register, Vol. 70, No. 96, at p. 29080.

- I. *Eliminating the projection of anticipated therapy services during the 5-day PPS assessment will limit professional caregivers' ability to use their predictive and evaluative skills to identify beneficiaries' needs, abilities, and potential for improvement at SNFs.*

The initial 14 days of a beneficiary's stay provide a time for professional caregivers at the SNF to routinely use their predictive and evaluative skills to identify the beneficiary's deficits, needs, abilities, and potential for improvement. According to the RAI User's Manual, the intent of the MDS Section T is stated as, "To recognize ordered and scheduled therapy services [PT, OT, and SLP] during the early days of the resident's stay. Often therapies are not initiated until after the end of the observation assessment period. For the Medicare 5-Day or Readmission/Return assessment, this section provides an overall picture of the amount of therapy that a resident will likely receive through the fifteenth day from admission."¹⁷ In addition, the recent RAI User's Manual revisions provide clarification on counting days for Section T projections. This clarification should correct any past inaccuracies in counting therapy days and minutes.

For instance, during the 5-day assessment, when a patient's condition and therapy evaluation results point to the need for more therapy than the patient is able to participate in during the first few days of service, it is not uncommon for projections to be used to place the patient in the most appropriate RUG category especially during the following situations:

- When a patient needs a day or two to adjust to SNF placement before being able to fully participate in therapy; and
- When the patient's medications (e.g., pain, cardiac, or respiratory) require adjustment in order for the patient to be able to fully participate in therapy.

- II. *Eliminating the projection of anticipated therapy services during the 5-day PPS assessment will likely result in significant and drastic cuts in SNF reimbursement.*

Second, eliminating the projection of anticipated therapy services during the 5-day PPS assessment will most likely result in significant and drastic cuts in SNF reimbursement. The initial 14 days of a beneficiary's stay provide a time for professional caregivers at the SNF to routinely use their predictive and evaluative skills to identify the beneficiary's deficits, needs, abilities, and potential for improvement. The projection of therapy needs during this time period is consistent with the meaning of a prospective payment system in that it allows for a forward-looking projection of the patient's service needs until the needs can be more clearly defined. Without the projection of services, providers will be paid for fewer services than those actually provided.

In conclusion, the look-back period, grace period, and anticipated therapy are all three areas are integrated in that the MDS data is used for development of a treatment plan for beneficiaries; determining the level of reimbursement; and for measuring the quality of care. Elimination of the look-back period, grace period or elimination of the projection of anticipated therapy services during the 5-day PPS assessment will have significant negative impact on these areas.

¹⁷ RAI User's Manual, Section T, May, 2005.

3) CMS Clarification of Additional Clinical Issues

This section analyzes the following issues: (1) assessment of timeframes; (2) SNF certifications and recertifications performed by nurse practitioners; and (3) clinical nurse specialists.

A. NASL agrees with the clarification of the assessment of timeframes.

NASL appreciates the clarification of existing requirements concerning completion of Other Medicare Required Assessments ("OMRAs") for beneficiaries reimbursed under the SNF PPS. It is consistent with the instructions given under the proposed rule, "an OMRAs is due 8 to 10 days after the cessation of all therapy (occupational and physical therapies and speech-language pathology services) in all situations where the beneficiary was assigned a rehabilitation RUG-III group on the previous assessment."¹⁸

B. The clarification of requirements for a physician signature on the certification and recertification of the need for SNF care affirm the value of nurse practitioners ("NPs") and clinical nurse specialists ("CNSs") services while clearly addressing situations that could give rise to a conflict of interest in regard to provider reimbursement. However, NASL believes that the impact on patient care needs to be studied further.

CMS has clarified the requirement and invites comment on its proposal for a physician signature on the certification and recertification of the need for SNF care as it relates to nurse practitioners ("NPs") and clinical nurse specialists ("CNSs"). CMS explains that Medicare law bars NPs and CNSs from having a direct or indirect employment relationship with a SNF in order to sign a certification or recertification of the need for care.¹⁹ By contrast, Medicare law addressing the delegation of physician tasks in Medicaid nursing facilities only bars NPs, CNSs, and physician assistants ("PAs") from performing delegated tasks if they are actually employed by the facility.²⁰ CMS has provided a new regulation clarifying the meaning of indirect employment and invites comment on the proposed regulation.

CMS proposes to revise the regulations at 20 CFR § 424.20(e)(2) to identify the existence of an indirect employment relationship in terms of the type of services that the practitioner performs in the SNF. According to the proposed rule, "We [CMS] believe that, even in the absence of a direct employment relationship, an SNF that has an NP or CNS perform these general nursing services is essentially utilizing the NP or CNS in the same manner as it would an employee, so that an indirect employment relationship can be considered to exist."²¹ According to the proposed rule, in situations where there is no direct employment relationship between the SNF and the NP or CNS, CMS proposes that an indirect employment relationship exists whenever the NP or CNS not only performs delegated physician tasks, but also provides nursing services under the regulations at 42

¹⁸ Federal Register, Vol. 70, No. 96, at p. 29082.

¹⁹ Omnibus Budget Reconciliation Act of 1989, § 1814(2)(2).

²⁰ Omnibus Budget Reconciliation Act of 1989, § 1919(b)(6)(A).

²¹ Federal Register, Vol. 70, No. 96, at p. 29082.

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CFR 409.21, which include such services within the scope of coverage under the Part A SNF benefit.²² The rule states that CMS believes that this criterion is appropriate, because there “would be a potential conflict of interest if an NP or CNS who is engaged in furnishing covered Part A nursing services to an SNF’s resident were also permitted to certify as to that resident’s need for Part A SNF care.”²³

Many physicians have come to rely on the time-efficient continuity of care the NPs and CNSs are able to provide in the SNF setting. NPs and CNSs who routinely work in SNFs, have the advantage of having a working knowledge of the beneficiaries and the SNF, that allows them to understand the beneficiaries’ needs and the types of services available in the SNF. This advantage also allows them to work in collaboration with the physician(s) to identify and address the needs of SNF beneficiaries in a time-and cost-effective manner.

The clarification provided in the proposed rule affirms the value of this working relationship between the non-physician practitioner (“NPP”) and physician, while ensuring that the working relationship of the NPP and the provider is not construed as being for the primary purpose of promoting Medicare Part A reimbursement. However, the administrative burden of obtaining the required timely signatures on certifications and re-certifications continues to be a significant issue for providers. In that NPPs are supervised and work in collaboration with physicians in a manner that positively impacts time-and cost-effective delivery of services, it is recommended that CMS further study the impact of delayed certifications by physicians on meeting beneficiary care needs and the actual risk of conflict of interest in regard to provider reimbursement created by the practice of NPs and CNSs providing a timely assessment for and signatures on certifications and recertifications.

C. Concurrent therapy is clinically justified, beneficial to the patient, and requires the skills of a qualified PT/OT/SLP, in many cases.

CMS invites comment on the most effective way to ensure that concurrent therapy is performed only in those instances where it is clinically justified. According to CMS, the practice of concurrent therapy “involves a single professional therapist treating more than one Medicare beneficiary at a time—in some cases, many more than one individual at a time.”²⁴ In contrast to group therapy, “in which all participants are working on some common skill development, each beneficiary who receives concurrent therapy likely is not receiving services that relate to those needed by any of the other participants.”²⁵ CMS’ concern is that although the care that each beneficiary receives may be individually prescribed, it may not conform to Medicare coverage guidelines; that is, the therapy is not being provided individually, and it is unlikely that the services being delivered are at the complex skill level required for coverage by Medicare.²⁶

²² Federal Register, Vol. 70, No. 96, at p. 29082.

²³ Federal Register, Vol. 70, No. 96, at p. 29082.

²⁴ Federal Register, Vol. 66 No. 147, at p. 23991.

²⁵ Federal Register, Vol. 66 No. 147, at p. 23991.

²⁶ Federal Register, Vol. 70, No. 96 at p. 29082.

There are several issues that NASL will address in this discussion of concurrent therapy: (I) There are many clinical situations where concurrent therapy is clinically justified, beneficial to the patient, and requires the skill of a qualified PT/OT/SLP or PT assistant/OT assistant under the direction of a PT/OT. (II) It is unreasonable for CMS to argue that facility management might inappropriately attempt to increase productivity by coercing a therapist against his or her own judgment to perform concurrent therapy because concurrent therapy has been a service delivery option used for many years by other health care providers, and state practice acts and the professional associations have adopted Standards of Practice and Codes of Ethics for professional therapist to follow; (III) There are effective methods to prevent coercion against a therapist's professional judgment, to perform concurrent therapy; and (IV) There are also substantial legal implications associated with the inclusion of the "concurrent therapy" language in the proposed rule.

I. *There are many clinical situations where concurrent therapy is clinically justified, beneficial to the patient, and requires the skill of a qualified PT/OT/SLP or PT assistant/OT assistant under the direction of a PT/OT.*

CMS states in the proposed rule that "although the care that each beneficiary receives may be prescribed in his or her individual plan of treatment, it may not conform to Medicare coverage guidelines; that is, the therapy is not being provided individually, and it is unlikely that the services being delivered are at the complex skill level required for coverage by Medicare."²⁷ There are many clinical situations where concurrent therapy is clinically justified, beneficial to the patient, and requires the skills of a qualified physical therapist/occupational therapist/speech language pathologist (or physical therapist assistant/occupational therapist assistant under the direction of a physical therapist/occupational therapist). These situations are explained in detail below. It is important to note that in the CMS provider article entitled, "Medicare Therapy Part B Billing,"²⁸ it states, "Note: Part A therapy is different from Part B: In order to be considered group therapy under Part A, the SNF residents perform similar activities whereas, under Part B, therapeutic interventions can be similar or different." Because the proposed rule addresses Medicare Part A services, these examples are intended to illustrate situations where the specific beneficiary activities differ despite the shared treatment environments. It is understood that under Part B coverage, similar situations would be defined as group therapy.

- A speech and language pathologist may be working with 2 patients on cognitive tasks, one focusing on reading and the other on writing in a workbook. The patients are working in their own individual workbook and the skills of the speech and language pathologist are required to supervise their work, provide verbal or visual cues to assist them in making choices individual to each workbook activity, provide tactile cues to assist them in completing in completing each individual's written task as appropriate. This is a complex treatment activity, but one in which the therapist is able to assist more than one patient.

²⁷ Federal Register, Vol. 70, No. 96, at p. 29082.

²⁸ <http://www.cms.hhs.gov/providers/therapy/billing.asp>

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- A speech and language pathologist may be working with 2 patients for dysphagia rehabilitation. Each patient may have different exercises to complete based upon their individual neurological deficits. A speech and language pathologist can start patient 1 on his/her exercises then go to patient 2 and begin working with him/her. Because both patients are in the speech and language pathologist's line of sight, he/she can supervise and analyze each patient's activities. The speech and language pathologist may need to provide verbal cues to patient 1 to correct his/her exercise techniques and provide tactile cues to patient 2 to facilitate the contraction of particular muscles. The speech and language pathologist may need to provide visual cues to patient 1 to enhance his/her posture while patient 2 needs tactile cues to achieve his/her safe posture. The skills of a therapist are needed for the safety of the patient in this instance. It requires the skills of a therapist to know what cues are needed to safely perform the activity and to progress to a higher level of independence. In this example the patient at a higher level of dependence (patient 2) is going to benefit from interacting with a patient at a lower level of dependence (patient 1) because he/she may be more motivated by working with another person who has improved from a similar state of dependence.
 - An occupational therapist may be working with 2-3 patients on activities of daily living (ADLs) in the kitchen in preparation for return home. The patients each have different diagnoses, but all three have the goal of returning home and being able to function at a higher level of independence in the kitchen. Patient 1 has a diagnosis of hip fracture and needs verbal cues to perform bending and reaching activities safely. Patient 2 has a diagnosis of a stroke and needs tactile cues and physical assistance to be able to stand and perform tasks at the sink. Patient 3 has Chronic Obstructive Pulmonary Disease ("COPD") and requires supervision and cuing to use energy conservation techniques and breathing strategies to prevent dyspnea while doing a food preparation activity. Because the patients are all working with occupational therapist in the kitchen, the occupational therapist can effectively supervise their activities and their individual plans of care. Each patient needs the skills of a therapist to either physically assist them and/or provide verbal or tactile cues. The skills of a therapist are needed to analyze the tasks, determine when and how to provide the cues necessary to advance them towards their rehabilitative goals. The therapeutic tasks are completed in the same context, but they are not the same since each is working on a different Activities of Daily Living ("ADL") task and with different supportive strategies. However, this does not preclude the therapist from being able to supervise each of them at once in a safe and effective manner. Once again, the patients benefit as well from watching others

overcome their deficits and learning from the visual demonstrations of techniques implemented.

- A physical therapist is working with 2 patients, each with a hip fracture. However, Patient 1 has an intertrochanteric fracture requiring a bipolar replacement of the hip while Patient 2 has a subtrochanteric fracture requiring open reduction-internal fixation with plates and screws for stabilization. Each patient has similar functional deficits, such as difficulty walking, decreased strength and range of motion, impaired balance, and physical dependence in bed mobility and transfers. However, each one requires a different approach to his/her plan of care and rehabilitation because of the difference in muscles affected by the fractures and subsequent surgery. Patient 1 may have no weight-bearing restrictions but does have positioning restrictions. Patient 2 may have weight-bearing restrictions but does not have positioning restrictions. The therapist can supervise each patient's exercise programs at the same time, even though each one is performing different exercises. The therapist has to be constantly present so that he/she (for example) can provide the verbal cues to patient 1 to perform the exercises within the safe range of motion, while having to provide tactile cues to patient 2 to facilitate a weakened muscle group. The skills of the therapist are required to know when to cue and when to hold a cue to see if the patient can learn to sequence the task him/herself.
- A physical therapist is working with 2 patients on different goals. Patient 1 is working on increasing strength and tolerance to extended activities so he/she can return to their community level activities. Patient 2 is working on improving his/her independence with bed mobility and transition movements with a new back brace prescribed by the physician following back surgery. Both patients require a therapist to supervise their treatment activities to enhance safety and efficiency of movement. Patient 1 is exercising on a restorator while patient 2 is laying on the mat exercise table preparing for practicing rolling, supine to sit, and sit to supine activities. The therapist is able to provide verbal and tactile cues to patient 1 to ensure he/she is using the correct biomechanical techniques to safely perform the activity. While patient 1 proceeds with the exercise and the therapist is supervising him/her, the therapist can physically assist patient 2 in proper rolling techniques with the back brace. At any point, the therapist can stop patient 1 in his/her activity and attend to his/her needs. At the same time, the therapist is attending to patient 2 and insuring his/her safety in sitting up on the side of the bed. Each patient is benefiting from the therapist's involvement.

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- An occupational therapist is working with two patients who are preparing to be discharged home in the next few days. The occupational therapist is working with each of them on their home exercise program – one for upper extremity range of motion following a total shoulder replacement and the other for upper extremity strengthening and muscle tone control following a stroke with right hemiparesis. The occupational therapist is able to provide skilled teaching, observation, correction of technique, and development of the most appropriate exercises to both. By providing this in the context of concurrent therapy, as opposed to separately, there is the potential that each will be discharged home sooner, resulting in decreased inpatient costs.

Therefore, as stated above, there are many clinical situations where concurrent therapy is clinically justified, beneficial to the patient, cost-effective, and requires the skills of a qualified PT/OT/SLP (or PT assistant/OT assistant under the direction of a PT/OT). Concurrent therapy does conform to Medicare coverage guidelines. In conclusion, CMS has not provided any additional information in this proposed rule that would contradict their conclusion reached by the CMS in the Final Rule in 2002 namely that “concurrent therapy can have a legitimate place in the spectrum of care options.”²⁹

- II. *It is unreasonable for CMS to argue that facility management might inappropriately attempt to increase productivity by coercing a therapist against his or her own judgment to perform concurrent therapy because concurrent therapy has been a service delivery option used for many years by other health care providers, and state practice acts and the professional associations have adopted Standards of Practice and Codes of Ethics for professional therapist to follow.*

State practice acts and the professional associations have adopted Standards of Practice and Codes of Ethics for the professional therapist to follow. The decision to choose concurrent treatment as a service delivery option is, and should continue to be, made by the therapist based on his/her clinical judgment because only the therapist knows the clinical indicators that makes the individual, concurrent, or group treatment the best option for treatment (or the appropriate combination thereof). Therefore, the choice of treatment delivery options should be left to the therapist’s judgment based on clinical factors rather than being dictated by regulation. If the therapist is having issues and is feeling pressured, it is his/her responsibility to address those concerns with his/her employer. There will always be practice issues and concerns that arise in the real world which all professionals (those outside the health care field) will have to address. It is unreasonable for CMS to issue rules that govern the professional responsibility of the therapists.

NASL sees no reason to modify the current CMS position: “we continue to believe, as do many of the commenters, that concurrent therapy has a legitimate place in

²⁹ Federal Register Vol. 66, No. 147 at p. 39568.

the spectrum of care options available to therapists treating Medicare beneficiaries. Our goals are to safeguard the health and safety of beneficiaries and assure that they are provided the most effective, skilled care available. We agree that, at times, such care can be provided concurrently with another patient, as long as the decision to do so is driven by valid clinical considerations.”³⁰

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III. *There are effective methods to prevent coercion against a therapist's professional judgment, to perform concurrent therapy.*

This section addresses effective methods to prevent abuse of concurrent therapy. It is inappropriate for a provider to force a professional therapist to perform an activity that is inappropriate based upon the professional therapist's clinical judgment, and what is truly in the best interests of the patient.

Program integrity and oversight systems within Medicare already address the reported instances of abuse by “facility management.” These methods include:

- SNF documentation requirements currently specify that therapists document the level of complexity and sophistication of services for reimbursement; and
- Focused medical reviews of Part A stays by FI's are intense. They entail reviews of the medical necessity of the therapy services, whether the services are provided at the level billed, and the clinical justification of said services.

In lieu of an attempt to stop rehabilitation professionals from providing clinically sound treatment that is in the beneficiary's best interest and using professionally accepted procedures confirmed instances of abuse should be handled directly with the Medicare approved facility. The integrity of the clinical discretion of the therapist in determining what is in the beneficiary's best interests must be preserved without rule of thumb determinations and unconfirmed reports of abuse.

IV. *There are substantial legal implications associated with the inclusion of the “concurrent therapy” language in the proposed rule.*

There are also substantial legal implications associated with the inclusion of the “concurrent therapy” language in the proposed rule. These implications are fully explained in the accompanying legal analysis prepared for NASL by the law firm Morgan Lewis & Bockius LLP. The full legal analysis, drafted by Donna Thiel, is attached to the comments as Appendix A and is incorporated herein by reference.

4) Consolidated Billing

CMS requests comments on further exclusions from PPS consolidated billing of services within four categories specified by section 103 of the BBRA – chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices).

³⁰ Federal Register, Vol. 66, No. 147, at p. 39568.

In Section IV of the proposed rule, CMS addresses the small number of services that the statute specifically identifies as being excluded from the consolidated billing provision.³¹ Specifically, CMS requests potential additions to the list of high-cost, low probability events that could have devastating financial impact on SNFs, because their costs far exceed the payment that SNFs receive under the prospective payment system. These items fall within four categories as identified in section 103 of the Balanced Budget Refinement Act ("BBRA"), that include chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices. These additional potential exclusions are sought due to changes of major significance that may have occurred over time due to the development of new medical technologies or other advances in the state of medical practice.

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NASL believes for the following reasons that (I) CMS should expand in the SNF setting items excluded from consolidated billing to include those categories provided in settings other than hospitals.

- I. *CMS should expand in the SNF setting items excluded from consolidated billing to include those categories provided in settings other than hospitals.*

As acknowledged in the proposed rule, the state of medical practice advances over time. While many of the items included in the list of exclusions may have been strictly within the purview of hospitals in 1998, many of the items are now performed routinely in settings that are alternatives to hospital outpatient departments. The small list of services that were excluded from consolidated billing prior to BBRA was because they were deemed to lie well beyond the scope of SNF care plans. Unlike the exclusions provided by BBRA section 103, these items are currently excluded from consolidated billing only when provided in a hospital outpatient setting. In the interim final rule there were five services specifically cited as examples. These services included cardiac catheterization, computerized axial tomography ("CT") scans, magnetic resonance imaging, ambulatory surgery involving the use of an operating room, and emergency services.³² Later, in the Program Memorandum (A-98-37) that provided Intermediaries' guidance on this matter, radiation therapy was added as well. In its reply to comments included in the final rule,³³ CMS stated that these exclusions were targeted specifically at those services that under commonly accepted standards of medical practice lie exclusively within the purview of hospitals. In fact, Medicare has deemed them to be covered outpatient services when provided in these alternate settings to the general Medicare population. Still, these services remain well beyond the scope of SNF care plans and are therefore appropriate for exclusion from consolidated billing.

³¹ Federal Register, Vol. 70, No. 96, at p. 29097.

³² Federal Register, Vol. 63, No. 69, at p. 26298-99.

³³ Federal Register, Vol. 65, No. 149, at p. 46791.

NASL is not requesting additions to the list of items excluded from consolidated billing. Rather, NASL requests that CMS consider an expansion of its exclusion to include settings other than hospitals. NASL requests that these settings be expanded to include all settings in which Medicare covers these services for beneficiaries that are not residents of SNFs. Ultimately, such an expansion would assure that SNF residents receive optimal care for their particular circumstances.

Conclusion

Thank you for your time in considering these comments and suggestions we submit. NASL appreciates CMS' efforts to expand access to the regulatory process to providers and suppliers for the improvement of delivery of quality healthcare to the beneficiaries of the Medicare Program. We welcome the opportunity to work with CMS in resolving the issues contained in this document. Please feel free to contact me directly at the following phone number (703) 549-8500 with any questions that you may have.

Sincerely

Peter C. Clendenin

Peter C. Clendenin
Executive Vice President

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APPENDIX A

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MEMORANDUM

FINAL DRAFT,

Deleted: JUNE 27

TO: Peter Clendenin
FROM: Donna K. Thiel
DATE: June 20, 2001
SUBJECT: HCFA's Preamble Discussion of Concurrent Therapy

The members of the National Association for the Support of Long Term Care ("NASL") have expressed concern regarding the comments of the Health Care Financing Administration ("HCFA")¹ in the May 10, 2001 Federal Register Notice regarding the expression "concurrent therapy." You have asked me to address some of the legal implications of HCFA's comments.

EXECUTIVE SUMMARY

NASL believes that HCFA's approach of 'regulation by preamble' is in conflict with the Social Security Act and with the obligations of notice and comment rulemaking. The Preamble, which lacks a clear legal basis, can only lead to further confusion and disarray in a service line that has experienced greater and more frequent changes in reimbursement and coverage than any other.

Second, NASL members are deeply concerned that the Preamble suggests a "rule of thumb" that regardless of the reasonableness or necessity of the therapy service, if the therapist is not treating one on one with a patient, the services are not covered. Neither the suggestion, nor the implementation of such a rule of thumb, is founded on any Medicare authority.

Third, NASL members perceive the Preamble discussion as a portent of yet another regulatory incursion into the clinical practice of therapy without justification or consultation with the profession. NASL views the suggested limitations on therapy practice as contrary to accepted standards of clinical therapy and as usurping state prerogatives on the scope of practice.

BACKGROUND

¹ Although HCFA has changed its name, I have used HCFA here to be consistent with the Preamble language and to avoid confusion.

For several years, HCFA has been engaged in efforts to control the delivery of therapy services, in particular, in the SNF setting. The implementation of limitations on levels of supervision, the use of students, and the limitations of group therapy have had a significant impact on the clinical aspects of therapy.

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The therapy community, including NASL, has often challenged the consistency of the HCFA policies with federal statutory and regulatory authority. The therapy community has been concerned that HCFA's efforts have proscribed the therapy benefit in ways that are not supported by the Social Security Act ("SSA" or the "Act"). Nonetheless, as will be discussed below, where HCFA promulgated regulations in accordance with the notice and comment provisions of the Administrative Procedure Act ("APA"), the therapy community has conformed its practices in accordance with those regulations.

Recently, however, there appeared in the HCFA Preamble to the Final SNF PPS regulations, May 10, 2001 (the "Preamble"), a discussion of uncertain legal impact, but with the potential for yet another serious impact on the provision of therapy services to Medicare beneficiaries. Cited in full below, the Preamble addressed anecdotal information that the therapy community was now engaged in promoting a practice called "concurrent therapy."

The Preamble initially notes a concern with rumors that some therapy vendors are "requiring" therapists to render concurrent therapy to patients in the Part A setting. The Preamble requests public input on the practice. It then goes on to suggest, more ominously, that concurrent therapy is not skilled therapy and will not be covered by Medicare.

THE MAY 10 PREAMBLE

In the May 10, 2001 Federal Register, in the final rule on Prospective Payment System ("PPS") for SNFs, HCFA made the following observation in the Preamble:

Further, in the context of our ongoing efforts to ensure accurate payment for appropriate care, we note a situation regarding rehabilitation therapy that is being provided in SNFs in a manner that conflicts with Medicare coverage guidelines. This issue involves providers that refuse to employ therapists who are unwilling to perform, on a routine basis, concurrent therapy. Concurrent therapy is the practice of one professional therapist treating more than one Medicare beneficiary at a time—in some cases, many more than one individual at a time.

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Concurrent therapy is distinguished from group therapy, because all participants in group therapy are working on some common skill development and the ratio of participants to therapist may be no higher than 4 to 1. In addition, in the July 30, 1999 SNF PPS final rule (64 FR 41662), we specified that the minutes of group therapy received by the beneficiary may account for no more than 25 percent of the therapy (per discipline) received in a 7 day period. By contrast, a beneficiary who is receiving concurrent therapy with one or more other beneficiaries likely is not [Page 23992] receiving services that relate to those needed by any of the other participants. Although each beneficiary may be receiving care that is prescribed in his individual plan of treatment, it is not being delivered according to Medicare coverage guidelines; that is, the therapy is not being provided individually, and it is unlikely that the services being delivered are at the complex skill level required for coverage by Medicare.

The Medicare SNF benefit provides coverage of therapy services only when the services are of such a level of complexity and sophistication (or the beneficiary's condition is such) that the services can be safely and effectively performed only by or under the supervision of a qualified professional therapist. Therapy services that are concurrently being delivered by one treating therapist to many beneficiaries would not appear to meet these criteria. If the therapist or therapy assistant can provide distinct services to several beneficiaries at once, then it is unlikely that the services are sufficiently complex and sophisticated to qualify for coverage under the Medicare guidelines.

We note that there have always been isolated instances in which a professional therapist has been allowed to have some overlap in the time of concluding treatment to one individual and the time of commencing the treatment of another, even to the point of briefly providing therapy concurrently in certain cases. However, the key principle here is that Medicare relies on the professional judgment of the therapist to determine when, based on the complexity of the services to be delivered and the condition of the beneficiary, it is appropriate to deliver care to more than one beneficiary at the same time. Our concern now is that in some areas of the country, concurrent therapy is becoming a standard practice rather than the exception, and is being dictated by facility management personnel rather than according to the professional judgment of the therapists involved.

We believe that it is important to heighten the SNF and therapy industries' awareness of the applicable Medicare policy in this regard. Medicare policy has not, until now, specifically addressed coverage of skilled rehabilitation therapy in situations in which a single professional therapist (or therapy assistant under the supervision of the professional therapist) simultaneously provides different treatments to multiple beneficiaries. As noted above, we have relied on the professional

therapist's judgment as to when it is appropriate for an individual therapist to provide services to more than one beneficiary. We now wish to advise the providers of care of our concern about the potentially adverse effect of this practice on the quality of the therapy provided to beneficiaries in Part A S NF's says, as well as our concern about the implications of making payments in such situations. We solicit public comments regarding the scope and magnitude.²

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DUE TO HCFA'S USE OF CONFUSING AND CONTRADICTIONARY LANGUAGE, PRACTITIONERS CANNOT DISCERN HCFA'S INTERPRETATION OF THE LAW.

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"CONCURRENT THERAPY" INCLUDES COVERED SERVICES.

As noted above, the first concern of the NASL members is that the term 'concurrent therapy' is not a term with a universally understood definition. The Preamble makes an informal attempt at a definition, suggesting that "concurrent therapy" refers to:

The practice of one professional therapist treating more than one Medicare beneficiary at a time—in some cases, many more than one individual at a time.³

The problem with this ambiguous language is that it covers both the "permitted" and the "prohibited."

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Practitioners and Providers can envision a scenario where professional supervision is so lax as to fail to meet regulatory minimums. However, under the Preamble's definition, there is *no* inherent inconsistency between what HCFA has termed "concurrent therapy" and skilled therapy. By HCFA's own reckoning, the expression "concurrent therapy" would include the "*overlap in the time of concluding treatment to one individual and the time of commencing the treatment of another, even to the point of briefly providing therapy concurrently in certain cases,*" a practice that the Preamble acknowledges is allowed.⁴ With the use of such contradictory language, HCFA could not reasonably expect providers and practitioners to understand what Medicare prohibits, and what it permits.

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HCFA must also recognize that within the scope of the language used in the Preamble, the anecdotal evidence of therapists being "required" to conduct "concurrent therapy" may be misunderstood or overstated. In seeking public input on the need for regulation on this topic, HCFA must first refine its terms or the feedback received will be muddled and unreliable.

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DUE TO HCFA'S USE OF CONFUSING AND CONTRADICTIONARY LANGUAGE, RULES AND REGULATIONS MAY BE TOO VAGUE TO BE ENFORCEABLE.

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There is legal significance to the Preamble's lack of clarity about what constitutes improper behavior. It is a basic principle of legal due process that a rule is void for vagueness if its prohibitions are not clearly defined. Grayned v. City of Rockford, 408 U.S. 104 (1972). Under Supreme Court precedents, the test of vagueness has two distinct

² Federal Register, Vol. 66, No. 91, at p. 23991-92.

³ Id.

⁴ Id.

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elements. First, a law must provide “fair notice.” That is, it must “give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly.”⁵ Because of the lack of clarity, in the language used, it is not clear what HCFA would permit or prohibit.

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The second element of the vagueness analysis is that rules must provide “explicit standards.”⁶ Unless a rule provides clear guidelines, the rule may permit “a standardless sweep [that] allows policemen, prosecutors, and juries to pursue their personal predilections.” Kolender v. Lawson, 461 U.S. 352, 358 (1983).⁷

It is the specter of the “standardless sweep” of the Preamble language that concerns NASL members. Under the Preamble’s broad definition, whether concurrent therapy is acceptable or unacceptable is a matter of facts and circumstances. The Preamble provides absolutely no standards—“minimal,” “explicit” or otherwise—by which a provider or intermediary can ascertain whether the services provided were, billed improperly. Even now, NASL members anticipate a round of intermediary disallowances and appeals based on the Preamble language alone. In the final rule, HCFA should be certain that intermediaries understand that the Preamble is not policy.

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DUE PROCESS IMPOSES LEGAL LIMITATIONS ON HCFA’S ABILITY TO PROSCRIBE THE THERAPY BENEFIT.

Beyond the concern with definitions, lies NASL members’ true concern with the Preamble: that HCFA will now seek to impose new restrictions on clinical therapy practice.

Deleted: The Preamble does not reveal how HCFA would propose to control concurrent therapy. Perhaps it will propose to limit the services which may be counted as minutes of total therapy as only one-on-one services, or perhaps it will limit concurrent therapy to no more than two patient “groups.” Drafting a rule on concurrent therapy will be quite challenging and would almost inevitably lead to the adoption of an arbitrary rule. NASL members’ view is that any arbitrary limit would substantially change therapy practice, would substantially increase the cost of rendering therapy and would not improve the quality of therapy care. ¶

⁵ Grayned at 108 & 109.

⁶ Grayned, 408 U.S. at 108-09.

⁷ Internal citation omitted. Laws imposing civil penalties violate the Due Process Clause if they are vague. See, e.g., Giaccio v. Pennsylvania, 382 U.S. 399, 402-03 (1966).

**HCFA CANNOT, WITHOUT FORMAL RULEMAKING, IMPOSE NEW OR
ADDITIONAL COVERAGE CRITERIA.**

The NASL members acknowledge that HCFA may, consistent with the Administrative Procedure Act ("APA"),⁸ regulate the practice of billing Medicare for therapy. However, if HCFA would promulgate new regulatory requirements, it must do so lawfully, explicitly and prospectively under the Notice and Comment provisions of the APA. From a legal perspective, HCFA must be mindful both of the role it serves in the legal process, as well as of the provisions of the Social Security Act it is interpreting.

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The Social Security Act provides a listing of the types of services covered under the Medicare program. There is no controversy that therapy services are covered under Medicare. The Social Security Act and its implementing regulations set forth specific coverage criteria for therapy services in the outpatient context,⁹ but are less specific on the inpatient context where the services are considered integral elements of the extended care benefit.¹⁰

As an example, the federal regulations include the following conditions of coverage for speech therapy services:

Medicare Part B pays for outpatient speech pathology services if they meet the following conditions:

- 1) They are furnished to a beneficiary while he or she is under the care of a physician...
- 2) *They are furnished under a written plan of treatment ...established by a physician...or a speech pathologist which will provide the services to the particular individual; [and]*
- 3) *They are furnished by a provider or by others under arrangements with, or under the supervision of, a provider.*¹¹

Similar regulations govern physical therapy,¹² and occupational therapy.¹³ Such regulations defining therapy coverage, are significant because they represent the only lawfully promulgated, regulatory limitations on the coverage of therapy services.

Having promulgated these regulations under the APA's notice and comment process, HCFA cannot embroider upon these requirements. That is, HCFA cannot, without formal rulemaking, impose new or additional coverage criteria. In particular, we know of no legal authority for HCFA to distinguish in coverage criteria for therapy based on the site of service. By statute and regulation, therapy outpatient services that are covered in the SNF are also covered in the clinic setting.

Based on existing regulations, HCFA is charged with the duty to determine whether therapy services meet the above coverage criteria. The only other legal basis for

⁸ 5 U.S.C. §533.
⁹ 42 USC § 1395x(l), 42 USC § 1395(a)(8).
¹⁰ 42 USC § 1395yy(e)(2)(A)(i), 42 USC § 1395x(i)(3).
¹¹ 42 CFR § 410.62.
¹² 42 USC § 1395x(g), 42 CFR § 410.60.
¹³ 42 USC § 1395x(p), 42 CFR § 410.59.

denying payment for therapy services is if the Medicare statute otherwise excludes the services under 42 U.S.C. §1395y(a). That is, the SSA excludes even covered services unless the services are:

Reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.¹⁴

The significance of the above discussion is to highlight the legal limitations on HCFA's ability to proscribe the therapy benefit. That is, HCFA may determine whether services meet the regulatory coverage criteria and then evaluate whether those services are "reasonable and necessary." HCFA cannot without formal rulemaking impose new or additional criteria for excluding therapy services from coverage.

HCFA CAN DEVELOP INTERPRETIVE CRITERIA TO BE USED TO EVALUATE 'REASONABLENESS' BUT CANNOT IMPOSE 'RULES OF THUMB'.

As significant as the terms are neither the statute, nor the Medicare regulations, on therapy set forth criteria to determine "reasonableness and necessary." This is in recognition of how fact-driven and individual to the patient, such determinations must be.

HCFA has published interpretive guidelines to be used to help evaluate reasonableness. These interpretive criteria do not have the effect of regulations, or of law.

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¹⁴ 42 U.S.C. §1395y(a)(1)(A).

The interpretive guidelines of Skilled Nursing Facility Manual §230.3 set forth only four criteria for judging whether a therapy claim is reasonable and necessary.

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Reasonable and Necessary. --To be considered reasonable and necessary the following conditions must be met:

The services must be considered under accepted standards of medical practice to be a specific and effective treatment for the patient's condition,

The services must be of such a level of complexity and sophistication or the condition of the patient must be such that the services required can be safely and effectively performed only by a qualified physical therapist or under his supervision....

There must be an expectation that the condition will improve significantly in a reasonable (and generally predictable) period of time based on the assessment made by the physician of the patient's restoration potential after any needed consultation with the qualified physical therapist or the services must be necessary to the establishment of a safe and effective maintenance program required in connection with a specific disease state, and

The amount, frequency, and duration of the services must be reasonable.

[Emphasis added.]¹⁵

Having operated under this guidance for many years, the therapy community understands, and has no quarrel with, HCFA's *published* guidelines. Now, however, the Preamble appears, at a minimum, to propose a change to these guidelines. The therapy community *does* have a quarrel with the anticipated change.

In the view of NASL members, the Preamble's interpretation does not appear to be directed at evaluating the reasonableness of the therapy. Instead it shifts the analysis away from the therapy and focuses instead on the therapist. To illustrate this point, we note that the May 10 Preamble uses (but does not cite) the language of the SNF Manual's reasonableness analysis when it says:

*The Medicare SNF benefit provides coverage of therapy services only when the services are of such a level of complexity and sophistication (or the beneficiary's condition is such) that the services can be safely and effectively performed only by or under the supervision of a qualified professional therapist.*¹⁶

The therapy community shares HCFA's concern that the services rendered to inpatients are of a level of complexity and sophistication that renders the services skilled. However, the Preamble fails to include the remaining discussion included in the SNF Manual. The SNF Manual goes on to provide that:

¹⁵ SNF Manual §230.3.

¹⁶ Federal Register, Vol. 66, No. 91, at p. 23991-92.

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When the intermediary determines the services furnished were of a type that could have been safely and effectively performed only by a qualified physical therapist or under his supervision, it will presume that such services were properly supervised. However, this assumption is refutable and if in the course of processing claims, the intermediary finds that physical therapy services are not being furnished under proper supervision, the intermediary will deny the claim.¹⁷

Under this SNF Manual provision, HCFA properly based its evaluation of reasonableness on the therapeutic benefit to the beneficiary. Where those services are of a complexity and sophistication indicative of reasonable and necessary, HCFA directed intermediaries to assume there is appropriate supervision, absent evidence to the contrary.

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In contrast, the May 10 Preamble moves the analysis—from the therapy—to the therapist— when it states:

If the therapist or therapy assistant can provide distinct services to several beneficiaries at once, then it is unlikely that the services are sufficiently complex and sophisticated to qualify for coverage under the Medicare guidelines.¹⁸

Apart from its questionable clinical foundation, this Preamble statement also concerns NASL members because it is a direct reversal of the analysis published in the SNF Manual. What rule shall therapists and intermediaries apply?

Most significantly, however, the above statement causes concern because it provides no instruction on how to evaluate the reasonableness of the therapy - or even the reasonableness of supervision. Instead, HCFA is creating a "rule of thumb" that distinct services rendered to several beneficiaries at once do not qualify for coverage. In effect, the Preamble says that regardless of the therapeutic benefit of the therapy services, if the therapist is not treating one on one with the patient, the services are not covered. Neither the suggestion, nor the implementation, of such a rule of thumb, is founded on any Medicare authority.

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From a legal perspective, absent a rulemaking procedure, HCFA is prohibited from imposing such rules of thumb that operate as independent means of denying coverage of services.¹⁹

HCFA's LANGUAGE IN THE PREAMBLE IS INCONSISTENT WITH ACCEPTED STANDARDS OF PRACTICE.

Deleted: CONCURRENT THERAPY

¹⁷ SNF Manual § 230.3.

¹⁸ Federal Register, Vol. 66, No. 91, at p. 23991-92.

¹⁹ SNF MANUAL, §214.7 states: Do not notify patients that services are not covered by Medicare because of "rules of thumb" such as lack of restoration potential, ability to walk a certain number of feet, degree of stability, or because of general inferences about patients with similar diagnosis or general data related to utilization. A decision as to whether care is covered by Medicare must be made based on thorough analysis of the patient's total condition and individual need for care.

The May 10 Preamble also conflicts with another published SNF Manual provision on evaluating the reasonableness of services. That is,

*To be considered reasonable and necessary...the services must be considered under a ccepted s tandards of p ractice t o b e a s pecific an d effective treatment for the patient's condition.*²⁰ [Emphasis added.]

What HCFA has termed as "concurrent therapy" is consistent with accepted standards of practice, as HCFA has recognized. The regulations expressly cover therapy performed by a qualified physical therapist *or under his supervision*.²¹ That professional supervision is not limited to supervision of other staff, but includes patients in the execution of their own exercises.

It bears noting that HCFA itself has acknowledged that it specifically contemplated coverage of concurrent skilled services supervised by licensed professionals. In the HCFA instructions on the Long Term Care Resident Assessment Instrument, Version 2.0, HCFA stated that the amounts of time reported in the MDS must be the resident's time in treatment, not the time and effort of the staff.²²

Q 108: When looking at time for PT, OT or Speech, do we consider direct resident contact time only? For example, if you set a resident up for a treatment, is the entire time of the treatment counted or only the start/stop time required by the professional?

A: The MDS 2.0 measures the resident's characteristics and services received. The amounts of time reported in Section P1b must be the "resident's time in treatment," not the time and effort of the staff to produce and document the treatment. The resident's treatment time starts when he begins the first treatment activity or task and ends when he finishes with the last apparatus and the treatment is ended. Set-up time is also included. In some cases, the resident will be able to perform part of the treatment tasks with supervision, once set up appropriately. Time supervising the resident is a part of total treatment time. For example, as the last treatment task of the day, a resident uses an exercise bicycle for 10 minutes. It may take the therapist 2 minutes to set the resident up on the apparatus. This therapist or assistant under the supervision of a PT may then leave the resident to help another resident in the same exercise room. However, the therapist still has eye contact with the resident and is providing supervision, verbal encouragement and direction to the resident on the bicycle. Therefore, if it took 2 minutes to set the resident up with the cycling apparatus, the resident was supervised during two 5-minute cycling periods; one 2-minute rest between the exercise periods; and took 1 minute to get out of the apparatus, the total cycling activity is 15 minutes. Include in this example that the resident did three additional

²⁰ SNF Manual § 230.3.

²¹ See Footnotes 11, 12, 13, above.

²² MDS 2.0 Technical Information Site; Health Care Financing Administration Long Term Care Resident Assessment Instrument Version 2.0 Question and Answers August 1996 <http://www.hcfa.gov/medicaid/mds20/qaguide.htm>

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*treatment activities totaling 45 minutes before beginning to cycle. The total time reported on the MDS is 60 minutes. The key is that the resident was receiving treatment the entire time and had the physical presence of a therapist in the room, supervising the entire treatment process.*²³

This passage belies the May 10 Preamble assertion that it is intending “to heighten the SNF and therapy industries’ awareness of the applicable Medicare policy.”²⁴

²⁴ The disdain for the provision of these services is new.

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Even the Preamble properly recalls that Medicare has for many years relied on the “professional judgment of the therapist to determine when, based on the complexity of the services to be delivered and the condition of the beneficiary, it is appropriate to deliver care to more than one beneficiary at the same time.”²⁵ NASL’s goal in commenting on the Preamble is to preserve that deference to professional, medical judgment. To alter that practice would muddle a situation that has been handled without difficulty by therapists for years. HCFA must carefully consider the impact of having therapy professionals in an already complicated regulatory environment having to rethink their clinical practice.

In light of HCFA’s prior deference to therapists’ judgment in the provision of therapy services, NASL members ask: why change policy now? As noted above, NASL members are concerned—in fact, skeptical, about the support the anecdotal evidence provided for further regulation of clinical practice. The therapy community will perhaps be excused for its cynicism in light of recent history. The first foray by HCFA into regulating therapy practice without clinical foundation came about when HCFA dictated that no more than 25 percent of the therapy minutes rendered to a Medicare beneficiary under a Part A skilled stay could be rendered in the “group” setting.²⁶ NASL members challenged and continue to challenge the appropriateness of that interpretation as confusing and lacking in clinical support.

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In proposing to make another incursion into clinical practice and to regulate concurrent billing again, HCFA must be mindful that it does not have the legal authority to arbitrarily regulate clinical practice without a reasonable medical basis for doing so.

CONCLUSION

²³ Id.

²⁵ Id.

²⁶ HCFA instructions for completion of the MDS clearly contemplated a setting where multiple patients received services together, but the full time of the therapy was counted, not the time of the therapist.

The Long Term Care Resident Assessment Instrument Questions and Answers Version 2.0, also clarifies how to account for therapy provided to an individual within a group setting. It states that if the group has four or fewer participants per supervising therapist (or therapy assistant) then it is appropriate to report the full time as therapy for each patient. The example used is that of a therapist working with three patients for 45 minutes on training to return to the community. Each patient’s MDS would reflect receipt of 45 minutes of therapy for this session.
PRM §2837. [Emphasis added.]

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In summary, NASL members object strenuously to the use of the Preamble as a substitute for due process. NASL is deeply concerned that the proposed policy undermines historic standards of coverage and deference to professional judgment, in favor of a "rule of thumb". HCFA's proposal shifts the focus from evaluating the therapeutic benefit to the beneficiary to the actions of the therapist. Neither the suggestion, nor the implementation of such a rule of thumb, is founded on any Medicare authority.

HCFA, in the final rule, must make clear that the language in the Preamble on this issue was raised for discussion purposes only, and did not in any way change existing policy.

Deleted: concurrent therapy language

Submitter : Mrs. Paula Miller
Organization : Tiffany Care Centers, Inc.
Category : Health Care Professional or Association

Date: 07/12/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1282-P-108-Attach-1.DOC

July 11, 2005
 Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 Attention: File Code CMS-1282-P
 P.O. Box 8016
 Baltimore, MD 21244-8016

We appreciate the opportunity to comment on the proposed rule to update the payment rates in the Medicare Skilled Nursing Facility (SNF) Prospective Payment System (PPS) for the 2006 fiscal year and implement refinements in the RUG-III case-mix classification system, published in the May 19, 2005 Federal Register.

Tiffany Care Centers, Inc. owns, leases or manages a total of eight skilled nursing facilities throughout rural Missouri. We often employ the services of BKD for various services related to the Medicare and Medicaid programs, and to further obtain reimbursement according the Medicare (and Medicaid) program rules and regulations. They are experienced working with SNFs (and many other health care providers) and drafted the following from their unique perspective on the practical impacts of the proposed changes. We are in complete agreement with their comments and have added personal comments where deemed appropriate and respectfully ask that you consider these comments as submitted on behalf of all seven of our Medicare certified homes and on behalf of the nursing home industry overall.

<u>Tiffany Care Center Homes</u>	<u>Provider Numbers</u>
Tiffany Heights	26-5746
King City Manor	26-5728
Pleasant View	26-5744
McLarney Manor	26-5644
Nodaway Nursing Home	26-5653
Oregon Care Center	26-5629
Sunset Home	26-5745

The following comments are relative to "Proposed Refinements to the Case-Mix Classification System". The comments herein are specific to the proposed possible modifications to the Resident Assessment Instrument (RAI) Manual. We have significant concerns about each of the potential modifications to the current system including the look-back period, the use of grace days and projecting therapy minutes. The elimination of the look-back period, grace days and estimated therapy minutes from the RAI Manual will negatively affect the quality of services to the most acutely ill of the nation's SNF patients – the post-acute-stay Medicare-covered patients. It appears the changes could be especially damaging to patients in rural America, where all Tiffany Care Center Homes are based, reducing access to quality SNF services. We believe the three day qualifying hospital stay requirement should be modified to include observation stay time.

Look-Back Period

Elimination of the “look-back” into the hospital stay will reduce access to Medicare benefits for many individuals and reduce payments to SNFs for the most critical portion of the patients’ SNF stay – the initial few days.

The look-back period as it is currently implemented allows the facility to “look back” into the hospital stay of any Medicare Part A eligible beneficiary to gather certain information pertinent to level of care necessary once the patient has been admitted to the skilled nursing facility. The accumulation of this data is necessary to adequately plan for the provision of the appropriate care (and determine the appropriate RUG group). As stated in the SNF PPS final rule, “the characteristic tendency for a SNF patient’s condition to be at its most unstable and intensive state is at the outset of the SNF stay.” This requires the SNF to commit its greatest amount of resources to the care of the postacute patient within the first few days after admission to the SNF. The look back allows the SNF to properly analyze the patient’s conditions and develop a plan of treatment that addresses the critical needs of the patient. This is crucial to the patient’s improvement.

As patients transition from IV feeding and IV medications provided in the hospital, the SNF’s nurses must be actively involved to allow the patient’s recovery to progress appropriately or to take action if the transition does not proceed as planned. When the PPS was created, the Medicare program recognized the difficulties involved in the transition and allowed the look-back to acknowledge the required SNF level of care. If the look-back is removed, the SNF will be required to give the same care to the Medicare Part A patient, but will be paid substantially less in many circumstances. This action will reduce the SNF provider’s resources and ability to provide the quality services to the patient expected by the patient and the Medicare program.

The RUG categories that will be affected to the greatest extent will be Extensive Services. It should be a matter of record that the most common defining service during the hospital stay that creates the SE category at the sub-acute level is IV medications. Most Medicare Part A eligible patients, who are admitted to a hospital (either through the ER or with a planned admission), have an IV started in the hospital. By not being able to utilize the look-back period, it appears that patients transferred to skilled nursing facilities will not be able to appropriately utilize one of the proposed new upper nine RUG-53 groups due to the lack of accessible data to properly code the patient into an extensive services level of care along with rehab therapy minutes and activities of daily living.

Many patients are admitted to the SNF mere hours after the IV has been discontinued at the hospital. If the IV was, for example, to deliver chemotherapy, antibiotic therapy, heparin therapy, or blood transfusions, the patient will require a significant level of skilled nursing care for monitoring and treatment of symptoms associated with the causative medical condition. As it currently stands, the sickest of elderly patients are those in the first week after admission following a hospitalization for infections, chronic disease exacerbations (Congestive Heart Failure (CHF), Chronic Obstructive Pulmonary Disease (COPD), cancer, etc.) and surgeries. These patients also debilitate quickly under those circumstances and may benefit from rehabilitation services, but often are not able to participate in any meaningful therapy program within the first week to 10 days at the SNF. If the hospital look-back for IV meds is not allowed, it is very possible the sickest patients will have no RUG pathway to care. Surely, the intention of any changes to the

current PPS system is not to deny needed Medicare Part A benefits to the sickest of the elderly Medicare beneficiaries.

If the look-back is limited to only include those services furnished by a SNF after a patient's admission or re-admission, and eliminates the potential to capture treatments performed by the hospital prior to the SNF admission, overall SNF Medicare expenditures will be reduced. However, we disagree that this reduction in payment would be better aligned with services actually provided.

As noted on page 29076 of the May 19, 2005 proposed rule (section II.B.2.a.), data analysis performed by the Urban Institute "...again verified that non-therapy ancillary costs are higher for Medicare beneficiaries who classify into the Extensive Services category than for those who classify to other categories." CMS's research appears to indicate that a reduction in payment is not warranted because of the correlation between Extensive Services and higher cost. If the look back is eliminated, you significantly reduce the number of patients qualifying for Extensive Services, but your research indicates these patients presently qualifying have higher non-therapy ancillary costs than other categories.

The analysis cited in the proposed rule contends that the addition of nine new categories that combine Rehabilitation and Extensive Services improves the predictive power of the RUG-III model. However, revising the RAI Manual to only include special treatments and procedures furnished by the SNF would significantly reduce the number of residents that would be classified into the Extensive Services category. Adding nine new RUG-III categories that combine Extensive Services with Rehabilitation, when patients would not be able to qualify for Extensive Services, would seem to defeat the purpose of the RUG refinements and undermine the predictive power of the new RUG-53 model because many patients presently qualifying as Extensive Services would not be classified into the new levels (nor the present Extensive Services categories).

Decrease or Elimination of the Grace Period

A reduction or elimination of the grace day period used to set the assessment reference date, specifically for the 5-day PPS MDS assessment, would have negative patient care implications.

Used appropriately, grace days allow a SNF to better serve the patient's needs, allowing therapy evaluation and services to be provided to generate the greatest health benefit to the patient and adequate, but not excessive reimbursement to the facility. Grace days allow the evaluation and services to occur according to the clinically best time-frame, rather than requiring an artificial regulation-imposed time-frame for the services.

In the July 30, 1999 final rule CMS stated that the use of grace days may be appropriate, especially in cases when, "the beneficiary is not physically able to begin therapy services until he or she has been in the facility for a few days." The final rule goes on to say that the use of grace days for the 5-day MDS "make it possible for beneficiaries to classify into the two highest RUG-III rehabilitation sub-categories. Classification into the Ultra High and Very High Rehabilitation sub-categories is not possible unless the beneficiary receives the sub-category's minimum level of services during the first seven days of the stay." Both of these arguments in favor of the use of grace days remain valid. The newly admitted resident often needs a day or two to regain their health from their recent hospital stay before beginning the often demanding therapy.

When PPS was initially developed, the use of grace days for rehabilitation patients on the 5-Day assessment was legitimately expected for a number of reasons associated with both the availability of the therapist and the patient. The reality of the 5-Day Assessment, without the use of grace days, is that patients must be evaluated by a licensed professional therapist on Day 1. In order to achieve any RUG group at a level higher than Rehab Medium, the patient will have to be treated on all of the first 5 days in the SNF, which includes weekends.

Discharges from the hospital setting are not under the control of the SNF. It is the experience of many SNFs, that many hospitals are prone to discharge patients on Fridays (typically in the afternoon). Regardless of the day of discharge, patients usually arrive at the SNF after 1:00 pm. It is inappropriate to expect the new Medicare Part A patient to be able to tolerate all the assessments required by the SNF nursing and rehabilitation therapy staff within the first few hours of admission to the SNF. The ambulance ride alone, often 30 minutes or more to the SNF (especially in a rural setting), can be a traumatic experience for the patient.

Most patients are not physically able to appropriately participate in an effective rehabilitation therapy evaluation on the afternoon of the admission to the SNF. In many facilities, rehabilitation therapy services are often not available seven days per week, thus patients cannot be evaluated for rehab therapy needs until the Monday following the "common Friday afternoon admission." Thus, if grace days are eliminated, the average days that can be included in the assessment reference window for rehab therapy will be two (2). This will inappropriately restrict the Medicare beneficiary's access to the Medicare Part A covered benefits (especially for rural Medicare Part A patients where therapist availability is even more limited).

The current availability of therapists in most markets will not allow for 7 day per week schedules or weekend coverage. Many SNFs do not have Medicare units of sufficient size to support a full time therapist, so they must "share" therapists with other providers. The coordination of available therapists with an unknown hospital discharge time-table will predictably result in poor coverage and personnel crises, particularly in rural areas. In the rural setting especially, the hospitals often discharge patients on Friday afternoon into our facilities. Our contracted rehab company generally does not provide therapy over the weekend unless specifically requested. We have one Licensed Therapist and one Therapist Assistant that work out of each location, and some of these cover more than one of our facilities. The company does not have a pool of part time therapists to cover the rural settings for weekends. They are not reimbursed enough to be able to pay the overtime that would be required to provide these services. Thus, another valid reason to allow the grace days.

Elimination of the latitude for a SNF to use grace days on the initial 5-day assessment could result in patients whose condition primarily warrants skilled rehabilitation, such as hip fracture or CVA, not even being classified into a rehabilitation category. In the July 1999 SNF PPS final rule, CMS commented their intent was "to minimize the incentive to facilities to provide too high a level of rehabilitation therapy to newly admitted beneficiaries. Having these extra few days allows time for those beneficiaries who need it, to stabilize from the acute care setting and be prepared for the beginning of rehabilitation in the SNF." Reduction or elimination of the grace days for the 5-day PPS

MDS assessment creates incentives to prematurely initiate therapy before a resident is physically able to tolerate and benefit from it. The result of accelerated initiation of therapy is reduced improvement in health of the patient, which is not the goal of the patient, CMS, or the SNF. Used appropriately, grace days help improve the quality of services.

Patients are now discharged from the acute level in fewer days, resulting in sicker, less hearty patients at the time of the SNF admission. Often, there is little value in a therapy evaluation taking place in the late afternoon or evening of the first day for a frail, elderly patient who has experienced upheaval, ambulance travel and who is emotionally and physically exhausted. It is not appropriate for a medical system policy to mandate that a patient be required to endure such adverse, and often inappropriate, program requirements. A good clinical model is one that allows patients a day or so to adjust to their new reality and surroundings without compromising their recovery. The use of grace days on the 5-Day MDS accomplishes this end. The use of grace days on any assessment should be for the provision of the appropriate clinical program for the patient that results in a fair reimbursement to the provider. The same reasons exist today which existed in 1997, when the Balanced Budget Act of 1997 created the SNF PPS.

Elimination of Projected Therapy Minutes

Elimination of the projection of anticipated therapy services during the 5-day PPS assessment could negatively affect the quality of services and the benefits derived by the patients. Elimination could result in inappropriate incentives to either provide too much therapy too soon or delay therapy beyond when it would be best initiated for the patient's health. Inappropriate therapy minutes projections should be addressed, but not by eliminating projection of therapy services.

Elimination of the projection of anticipated therapy services will restrict the SNF's ability to appropriately classify patients into rehabilitation RUG-III categories when their condition clearly warrants the need for therapy services. Often, therapy is not initiated until after the end of the initial assessment, but is provided prior to the 14-day assessment. By allowing a beneficiary to classify into an appropriate RUG-III rehabilitation group based on anticipated receipt of therapy, a SNF can be paid for the therapy services being provided during the first 14 days after admission.

There are legitimate reasons to project a therapy RUG on the 5-Day MDS. The ability to do so financially protects a Medicare Part A provider who, in good faith, has assessed the needs of a patient and developed a plan of rehabilitation that is interfered with in unforeseen ways, including *unplanned* discharges prior to the planned 5-Day assessment reference date.

Currently, if any unforeseen or uncontrollable issue arises in the first 5 days of a SNF rehab stay, the only options to maintain a reimbursement model are the use of grace days or projected minutes. If both of these options are eliminated, quality of care becomes an issue for the majority of the SNFs – especially those located in rural communities (due to therapist availability). Once again, the same circumstances exist now that existed when the SNF PPS payment system was initially created.

By eliminating the ability to capture ordered and scheduled therapy services, there may be a tendency for providers to hasten to provide therapy services prematurely or at a level

that is too rigorous for the individual's health status. On the other hand, if starting therapy early is not possible, there may be an incentive to forgo or at least postpone therapy services that could be very beneficial to improving a patient's function. In either case, there is an incentive to schedule the onset of therapy services based upon whether the provider will be paid at a rehabilitation level, rather than what is the most appropriate for the beneficiary's care.

We realize there have been situations where estimated therapy minutes have been overstated, resulting in higher than appropriate therapy minutes allocation and potentially higher rehabilitation RUG categories. However, these cases should be handled the same way all inappropriate coding errors are addressed.

Qualifying Three-Day Inpatient Hospital Stay Requirement

We believe observation days should be counted toward the technical 3-day acute care stay requirement for eligibility for skilled care.

As noted by CMS, the care furnished during a hospital observation period is frequently undistinguishable from the care provided after a Medicare patient has been admitted to an acute care bed.

In a case where a hospital admits a patient for observation and that patient is ultimately admitted to acute care but is discharged prior to the third "acute" day, the patient could be deprived of their SNF benefit merely because the hospital was judicious in observing a patient to ensure admission to acute care was warranted.

Allowing observation days to count toward the required 3-day hospital stay will require a change to the "Common Working File" (CWF), because even though hospitals are required to "bundle" observation services with inpatient services, the formal acute admission date (not the date the patient is admitted for observation) is the date reported on the hospital's claim, which is ultimately recorded in the CWF as the actual admission date. There would need to be some mechanism to distinguish acute hospital stays that are actually less than three days from those that would be (at least) three days by allowing observation days, in determining whether there has actually been a qualifying hospital stay.

Since the implementation of SNF PPS, there have been numerous situations when SNFs have inadvertently counted an observation stay period as a part of an acute care inpatient admission, resulting in a non-qualifying three midnight acute care period. Counting observation midnights will assist with assuring fair compensation for subsequent postacute care and will not compromise services for the beneficiary. We appreciate CMS's consideration for this proposed change.

We believe there is a clinical basis to totally remove the three-day hospital stay as a requirement for skilled nursing care eligibility. The SNF environment and the types of patients treated are totally different in 2005 from 1965 when this requirement was implemented. There have been phenomenal changes in the health care delivery system over the last 40 years since the Medicare legislation was enacted and Congress imposed this requirement. In section III.M. of the July 1999 final rule, CMS discusses "presumption of coverage" when a beneficiary scores in the top 26 RUG-III categories and they are deemed to qualify for skilled care. Often, residents are admitted to SNFs that meet these requirements without ever having been admitted to an acute care hospital.

We encourage CMS to consider the impact on the Medicare program of reducing or eliminating the 3-day qualifying stay. Such a change would save the Medicare program significant dollars for eliminated hospital stays and allow beneficiaries placement in a less intensive setting.

Summary

Generally, the SNF PPS program has allowed Medicare Part A patients to continue to receive quality care, while reducing costs and risk to the Medicare Trust Fund. We believe strongly that the proposed changes in the look-back period, use of grace days, and projecting therapy minutes would be very damaging to the SNF's ability to provide the quality post-acute care for Medicare Part A patients desired by all. Beneficiaries have earned the right to utilize the Medicare program through their payment of payroll taxes throughout their work lives. The proposed RAI Manual changes would be damaging to many Medicare Part A patients (especially those living in rural communities where all Tiffany homes are located) by limiting access to coverage and services. The proposed changes could result in increased costs through increased re-hospitalizations and less rehabilitated SNF population ultimately requiring more, not less, services.

We respectfully submit our comments and appreciate your consideration when deciding on the proposed changes. Should you have any questions or if we can be of further assistance, please feel free to contact Mrs. Paula Miller, CPA, Chief Financial Officer, Tiffany Care Centers, Inc. at (660) 442- 3128.

Tiffany Care Centers, Inc.

Transmitted via e-mail to: <http://www.cms.hhs.gov/regulations/ecomments>

Submitter : Mrs. Alverta Robinson
Organization : Sentara Life Care
Category : Long-term Care

Date: 07/12/2005

Issue Areas/Comments

Issue

Issue

Grace Days- I support the elimination for graced days used to maximize reimbursement due to scheduling. However there are times when the resident condition warrants placing the resident on a medical hold. If these factors are built in the new medical complex categories, then the elimination of grace days is a mute point, however if this category is still minute driven, then there needs to be some concession for residents with change in status. This concession may come in the for on using grace days on the 14th day assessment.

Case-Mix Adjustment and Other Clinical Issues

Elimination of the look back period. I can support the elimination of the look back period, however the clinical indicators in the extensive services category should be expanded. There are diagnosis and clinical conditions that resident's present with that prevent them from being ready for therapy and do not involve suctioning and intravenous medications. These include Cardiac and Respiratory conditions which involve monitoring and the administration of aerosol medications. These are conditions that have stabilized from the acute care setting, but are time intensive for nursing in the skilled facility. Other high cost ancillary services that should be included in this category include, TPN and Wound Vacs. Beneficiaries may be denied admission due to the cost of these services.

Submitter : Claudia Burnett
Organization : Sharon Care Center
Category : Long-term Care

Date: 07/12/2005

Issue Areas/Comments

GENERAL

GENERAL

Removal of grace days is absolutely not in the best interest of sick, old people. Often there are complications (nausea, vomiting, diarrhea, pneumonias, fever etc. that legitimately impair a residents ability to immediately participate effectively, in therapy.

Our own facility has experienced admission of residents who have spent three days (for observation) in hospital beds, in hospital rooms, eating hospital food and receiving care and services from hospital staff...so why can't these "observations count toward a qualifying stay?

No one wants the government running things. And we don't want to run them either. Surely there is a cooperative way to upgrade and improve information technology, which of course will be hugely expensive.

You anticipate that groups in new MDS coding would encompass care that is at least as intensive as that identified by any of the upper 26 RUG-III groups under the original, 44-group RUG II classification sytems. We believe this to be incorrect, especiall in relation to Medicaid case-mix states such as Washington.

The look back period is critical in a facility's assessment of each resident's needs. The look back period should not be eliminated.

Issue

Issue

Implementing this proposal will not account for medically complex patients. It appears the proposed rule could have a negative impact on our facility's financial stability AND resident care.

Problems associated with consolidated billing call into question accurarcy of claims in 1999 and so cannot be of use. We question whether there is sufficient accurate data to make an analysis that PPs rates have covered the costs of care, especially when adjustmens of past costs and payment are still being made.

Submitter : Mr. Todd Ketch
Organization : American Health Quality Association
Category : Health Care Professional or Association

Date: 07/12/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Issue

Proposed Refinements to the Case-Mix Classification System

See attachment

CMS-1282-P-111-Attach-1.DOC

Attachment #111

July 12, 2005

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201



THE AMERICAN
HEALTH QUALITY
ASSOCIATION

1155 21st Street, NW
Suite 200
Washington, DC 20036
Phone: 202.579.5790 • Fax: 202.579.9334
www.ahqa.org

File Code: CMS-1282-P

Dear Dr. McClellan:

The American Health Quality Association (AHQA), representing the national network of Medicare Quality Improvement Organizations (QIOs), is pleased to provide comments on the proposed rule for “Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006” published in the *Federal Register* of May 19, 2005.

“Proposed Refinements to the Case-Mix Classification System”

AHQA supports CMS efforts to implement pay for performance initiatives as a tool to improve the quality of health care delivered to Medicare beneficiaries in skilled nursing facilities, as well as other settings in which beneficiaries receive care.

As discussed in the proposed rule, the CMS Nursing Home Quality Initiative (NHQI), primarily through the public reporting of quality data and development of local quality improvement partnerships among providers, QIOs, resident advocates, and other stakeholders, has resulted in real improvements for residents. In particular, those 15% of nursing homes nationwide that volunteered to work intensively with QIOs have achieved greater performance improvements on several Minimum Data Set (MDS) measures than nursing homes nationally.

Recommendation #1: In developing pay for performance for skilled nursing facilities, CMS should closely involve stakeholders with quality measurement and quality improvement expertise, such as staff from QIOs, as essential partners to ensure that pay for performance provides incentives for and supports health care quality improvement while avoiding unintended and potentially harmful consequences.

Recommendation #2: CMS should explicitly include QIOs and their quality improvement technical assistance under a pay for performance initiative among skilled nursing facilities.

In developing a pay for performance plan to spur further quality improvement, CMS should draw important lessons from the NHQI. Most notably, this includes recognition that quality measurement alone, whether used internally for quality improvement or posted externally for consumer use in selecting providers, is not enough to produce the improvement necessary to close the quality gap in long-term care. Providers participating in the NHQI quickly recognized that technical assistance and support—i.e. data analysis, improved patient assessment tools, development and implementation of best practices, peer learning opportunities, etc.—are essential for improving

performance on clinical indicators.

Recommendation #3: Pay for performance will galvanize attention around selected quality measures, but to achieve the ultimate goal of vastly improved quality, CMS must ensure that providers, particularly those that cannot afford expensive consultants, can access technical assistance from QIOs in order to make real and lasting improvements.

In 2002, CMS appropriately aligned its quality measures for public reporting with QIO program goals in the 7th Statement of Work. This was essential in focusing provider attention and resources on core aspects of quality care and helped drive providers to seek assistance from QIOs related to these measures. Beginning in 2005, QIOs are committed to helping nursing homes achieve “transformational” change by expanding upon activities designed to improve nursing homes care processes and organizational culture. A pay for performance initiative that provides incentives for high performance in these same areas will catalyze a consistent, nationwide campaign to produce substantial improvements in quality of care and quality of life for residents.

Recommendation #4: As CMS expands from public reporting to pay for performance, the agency should similarly ensure that performance measures for payment incentives are closely aligned with and compliment the quality improvement goals being implemented by CMS through the QIOs in the 8th Statement of Work and beyond.

CMS also should utilize these additional recommendations in designing a skilled nursing facility pay for performance program:

5. CMS should reward providers for operating at the highest levels of quality performance, but should also provide higher payments for those providers demonstrating significant “relative improvement,” defined as the percent reduction in the quality gap between baseline performance and perfect performance.
6. Should CMS opt to penalize those providers not meeting quality thresholds with payment reductions, AHQA encourages CMS to explore a one-time exemption from cuts for providers that demonstrate active engagement with their QIO on quality improvement projects.
7. CMS should use evidence-based measures that are endorsed by consensus standards organizations, such as The National Quality Forum, specifically for use in pay for performance programs.
8. CMS should carefully examine potential pay for performance measures to ensure that very high performance on these measures will not result in negative, unintended consequences for nursing home residents, such as refusing to admit sicker patients for fear of a negative impact on quality measures tied to payments.
9. CMS should investigate using for pay for performance measures that assess effective care coordination across settings, with an approach that supports high quality post-acute care, regardless of setting. But CMS first must place greater investments towards aligning and

developing cross-setting measures, such as measuring pressure ulcer care in hospitals and nursing homes.

10. CMS should prioritize the use of process measures that are in the direct control of skilled nursing facilities for pay for performance initiatives. To the extent that outcome measures are used, they should be sufficiently risk adjusted for patient acuity. CMS also should explore incorporating valid and reliable measures of resident and staff satisfaction and other non-clinical/quality of life measures that accurately assess facility performance.
11. When possible, measures for pay for performance should utilize existing data collection systems or use new technologies that minimize burden on providers.
12. Skilled nursing facilities payments should provide incentives for the adoption and implementation of health care information technology including, but not limited to an electronic health record, as well as promote nursing home participation in regional health information exchanges. CMS should utilize the QIOs to provide assistance to help nursing homes select appropriate clinical IT systems and use them effectively.
13. CMS should identify and account for special circumstances involving low-volume skilled nursing facilities that allow those nursing homes to meaningfully participate in pay for performance efforts.

AHQA appreciates the opportunity to comment on this important matter.

Sincerely,



Todd D. Ketch
Vice President, Government Affairs

dictates, i.e., Rehab medium is not accordance with standards of practice for the new stroke or fractured hip repair resident. Grace days allow for the medical instabilities conflicting with the therapy plan of care. Even Medicare regulation allows for missing days and still meeting the daily requirement, i.e., ?This requirement should not be applied so strictly that it would not be met merely because there is an isolated break of a day or two during which no skilled rehabilitation services are furnished and discharge from the facility would not be practical.? SNF Manual, Publication 12. Without grace days therapist would be forced to work weekends to provide the minutes the residents condition requires.

RE: H. Examples of Computation of adjusted PPS Rates and SNF Payments ? it seems the RUG examples used were only those that reflected a positive change. How will the Extensive Services categories be impacted especially in consideration of the above frail demented resident?

Case-Mix Adjustment and Other Clinical Issues

Quotation marks printed as question marks; unable to change

Submitter : Ellen Meyers
Organization : Medicare Compliance Systems
Category : Nurse

Date: 07/13/2005

Issue Areas/Comments

GENERAL

GENERAL

RE: IV. Consolidated Billing

Please consider excluding Barium swallow/video fluoroscopies from the consolidation of the BBA. Swallowing deficits are life threatening and when a facility is faced with a \$700 bill for the swallow study, it imposes a fiscal burden that the RUG rate cannot absorb equitably.

RE: V. Qualifying Hospital Stay ? Observation time in the hospital is indicative of one thing; the resident was acutely ill irrespective of the billing methodology. This time therefore should be counted in the qualifying hospital stay.

I encourage you to please consider the Administrators and nurses leaving the industry, the national nursing shortage and the impending baby boom need for long term care. Compare please the moneys spent for ?policing? the industry as opposed to funding it. Changes to the SNF PPS that will not equitably pay facilities for the noble work they do can negatively impact the industry for decades to come.

Respectfully submitted,

Ellen Meyers, RN, BSN
 Medicare Compliance Systems
 30419 Lettingwell Circle
 Wesley Chapel, FL 33543

Issue

Issue

RE: Background, C- What was the ?science? that precipitated the BBRA increases and is it still valid? If so, it shouldn't go away with refinements.

Background, D, third bullet-Section 312 of the BIPA ? has the GAO staffing study been integrated into the PPS refinement equation? In addition research has supported that caring for the cognitively deficated resident takes more time (Geriatric Nursing July/August 1991, pgs 185-187). National Institute on Aging has research that supports that up to 85% of nursing home residents are cognitively deficated.

RE: Case mix Refinement Research, a. ? The Urban Institute used 1999 matched MDS and SNF claims and cost report data from 1998 and 1999. The accuracy of MDSs has improved dramatically since this time as evidenced by the DAVE and other similar projects. Were the MDSs used tested for accuracy?

RE: Case Mix Refinement Research, c. Development of the Case-Mix Indexes ? Decreasing ?proportionally? the weights of the existing RUGs by adding the new RUGs, will pay even less money for the very high acuity, cognitively deficated resident who does not need IVs perhaps due to end-of-life planning and has no potential to improve in therapy. Paying facilities less for this difficult resident will penalize those who adequately evaluate therapy potential for ?material? improvement and might force other providers to initiate therapy just to generate enough revenue to pay for nursing costs in this complex resident. Fiscal intermediary budgets shortfall review for overutilization of therapy.

Proposed Refinements to the Case-Mix Classification System

3. Proposed Refinements to the Case-Mix Classification System ? ?? could adversely affect provider incentives to provide therapy to beneficiaries requiring extensive services? Some residents returning from a short hospital stay are too ill to tolerate therapy. The nursing acuity upon admission is usually the highest in the entire stay. Incenting providers to provide therapy in residents who are so ill is cruel and possibly abusive to the resident, they do poorly in therapy, and the provider sometimes suffer FI denials due to the lack of measurable improvement. Monitoring the well-being of residents with dementia requires constant attention, skill and time to appropriately assess residents? behavior and conditions to determine if they are normal, out-of-stage, an indicator of distress related to a psychotic manifestation, a change in cognitive and/or functional ability, an untreated chronic condition, an acute illness, pain, inappropriate caregiver action and/or of a stressful environment. A systematic process needs to be implemented upon admission without therapy to assure adequate hydration and nutrition, resolution of the acute medical condition, strategies for dementia-accompanying conditions such as skin hypersensitivity, neuromotor changes resulting in decreased mobility and falls, resistance to care, ADL declines, depression, anxiety and agitation. Selecting and/or developing appropriate interventions requires patience, flexibility, trial and error, and is time and labor intensive. Reducing payment for the extensive services category penalizes providers who are appropriately prioritizing care upon admission.

Furthermore deleting the hospital look-back, most often IV meds, could cause the resident to RUG no higher than in the lower 18 categories for the services in the above paragraph. Payment in the lower categories would not cover the above outlined expenses of these most frail residents. No RUG category captures this highest acuity, no IVs, not a candidate for therapy resident who upon admission is the highest risk for weight loss within the first two weeks of the SNF stay, suffers transfer trauma, is adjusting to new meds ordered in the acute, is monitored for side effects to these new drugs, and stabilizing the conditioning causing the acute stay so as to prevent rehospitalization.

Eliminating the grace days for the 5-day MDS could adversely impact SNFs as this is when the resident needs the most flexibility. Furthermore it could pressure therapists to render the therapy irrespective of whether the services could adversely impact the resident in an attempt to provide the minutes the residents diagnosis