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March 18, 2011

Donald M. Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicaid Program; Payment Adjustment for Provider-Preventable Conditions Including Health Care-Acquired Conditions, Proposed Rule, 76 Federal Register 9283, February 17, 2011

Dear Dr. Berwick:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the proposed rule, *Medicaid Program; Payment Adjustment for Provider-Preventable Conditions Including Health Care-Acquired Conditions, Proposed Rule, 76 Federal Register 9283, February 17, 2011*.

AHCA is the nation's leading long term care organization. AHCA and our membership of nearly 11,000 non-profit and proprietary facilities are dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly, and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

AHCA has grave concerns regarding the proposed rule. We do not believe that the Centers for Medicare & Medicaid Services (CMS) has the statutory authority to issue and implement regulations that disallow federal financial participation (FFP) for "other provider preventable conditions" (OPPCs).

As explained below, Section 2702 of the Patient Protection and Affordable Care Act (the Affordable Care or ACA) limits CMS' prohibition of Medicaid payments to "health care acquired conditions" as defined by Section 2702, which specifically applies to conditions applicable to inpatient hospitals and reimbursed by diagnosis-related groups (DRGs). There is no authority to extend this prohibition to nursing facilities (NFs). Therefore, AHCA urges the Secretary to delete all of the provisions of proposed 42 C.F.R. § 447.26(b) referencing "other provider-preventable conditions."

In addition to the lack of statutory authority, there are additional critical reasons for withdrawal of the OPPC part of the rule. Layering yet another punitive process upon the heavily regulated nursing facility sector creates a further stopgap to a fundamental flaw in both Medicare and Medicaid payment systems—they cannot adequately tie payment to quality and value. An invalid and ill conceived OPPC mandate will not at all address such a fundamental flaw.

In addition, CMS fails to acknowledge the broad spectrum of problems inherent in an OPPC approach and fails to lay out any meaningful process for states to even consider OPPCs. There are massive clinical problems that currently prevent the application of OPPCs to NFs. We discuss those in detail below. Further, there are NF Medicaid and Medicare payment system characteristics that preclude isolating OPPCs and negatively adjusting payment based on OPPCs. Again, we explain these payment system considerations below.

Finally, it is difficult to consider the logic behind implementing this type of punitive payment program in a setting where the success of past and continuing collaborative quality improvement efforts have been forged by CMS, states, and providers. The proposed payment program ignores NF efforts, most notably since 2002 and the onset of the Nursing Home Quality Initiative—where provider collaborations were formed to address pain management, pressure ulcer prevention and management, and culture change workforce.

Again, based on the above stated considerations, fully explained below, AHCA urges the Secretary to delete all of the provisions of proposed 42 C.F.R. § 447.26(b) referencing “other provider-preventable conditions.”

Discussion

I. CMS Lacks Authority To Issue And Implement Regulations That Disallow Federal Financial Participation (“FFP”) For “Other Provider-Preventable Conditions

AHCA has serious concerns as to whether the Secretary of the Department of Health and Human Services (HHS), or CMS has the statutory authority to issue and implement regulations that disallow FFP for “other provider-preventable conditions” (OPPCs). As explained below, Section 2702 of the Affordable Care Act limits CMS’ prohibition of Medicaid payments to “health care acquired conditions” as defined by Section 2702, which specifically applies to conditions applicable to inpatient hospitals and reimbursed by DRGs. There is no authority to extend this prohibition to long term care facilities. Therefore, AHCA submits that the portions of the proposed rule intended to apply to OPPCs must be withdrawn.

Generally, Section 2702 of the ACA requires that the Secretary of HHS implement Medicaid payment adjustments for health care-acquired conditions (HCACs), as defined by the statute, and develop a framework for application of Medicare prohibitions on payment for HCACs to the Medicaid program.¹ Specifically, Section 2702(a) of the ACA directs the Secretary to (1) identify current State practices that prohibit payment for HCACs, as defined by the Section, and (2) to incorporate the practices identified, or elements of such practices, as deemed appropriate by the Secretary, for application to the Medicaid program in regulations. Section 2702(a) then requires that, effective as of July 1, 2011, the Secretary prohibit federal Medicaid payments to States expended for providing medical assistance for HCACs, as specified in regulations. The ACA

¹ Patient Protection and Affordable Care Act, Pub. L. 111-148 (2010).

stipulates that the regulations must ensure that the prohibition on payment for HCACs will not result in a loss of access to care or services for Medicaid beneficiaries.

Section 2702(b) of the ACA defines the term “health care acquired condition” as “a medical condition for which an individual was diagnosed that could be identified by a secondary diagnostic code described in section 1886(d)(4)(D)(iv) of the Social Security Act.” Section 2702(c) of the ACA expressly requires that the Secretary, in carrying out section 2702 of the ACA, apply the regulations issued under section 1886(d)(4)(D) of the Social Security Act relating to the prohibition of payments based on the presence of a secondary diagnosis code specified by the Secretary in such regulations, as appropriate for the Medicaid program. Further, Section 2702(c) states that the Secretary may exclude certain conditions identified under Medicare for nonpayment under Medicaid when the Secretary finds the inclusion of such conditions to be inapplicable to Medicaid beneficiaries. Notably, section 1886(d)(4)(D)(iv) of the Social Security Act refers to payment for inpatient hospital discharges under DRGs; there is no reference to any other provider type.

In fact, in the preamble to the proposed rule CMS acknowledges the limitations on the Secretary’s authority to promulgate regulations under Section 2702 of the ACA. CMS concedes, “Section 2702 of the Affordable Care Act did not grant the Secretary new authorities, indicating that existing statutory authorities are sufficient to fulfill the obligation.”² This language clearly implies that Section 2702 of the ACA did not grant the Secretary new authority beyond the authority previously granted under the Social Security Act.

Moreover, there is no indication that Congress intended the Secretary to adopt rules on disallowing payments beyond the inpatient hospital setting. Contrary to the specific statutory language, CMS claims that the proposed rules’ expansion to OPPCs is consistent with “policy” on adopting state practices, despite acknowledging the limitations of the statute:

The inclusion of the new terms, PPCs and OPPCs, is consistent with the implementation of the broader application of this policy which allows us to appropriately incorporate existing State practices. The adoption of a new term is necessary because the term, ‘health care acquired condition,’ is very narrowly defined in the Statute and does not provide for the inclusion of conditions other than those identified as HACs for Medicare, even excluding the 3 Medicare MCDs. Additionally, the statutory definition of HCACs only applies to the inpatient hospital service setting.³

In short, in the preamble to the proposed rule, the Secretary acknowledges that section 1886(d)(4)(iv), which is explicitly referred to in Section 2702 of the ACA, “applies specifically to conditions applicable to inpatient hospitals as defined in that section and reimbursed by diagnosis related groups.”⁴ Nonetheless, the Secretary ignores that specific statutory limitation to significantly expand the scope of authority in an attempt to deny FFP to states for OPPCs in nonhospital settings.

² 76 Fed. Reg. 9283, 9286 (Feb. 17, 2011) (emphasis added).

³ 76 Fed. Reg. 9283, 9288 (Feb. 17, 2011).

⁴76 Fed. Reg. 9283, 9288 (Feb. 17, 2011).

CMS then claims that the creation of the terms PPCs and OPPCs, and adoption of the term “other providers” is needed to remain consistent with Medicare’s expansion of its policy under 3008(b) of the ACA. However, Section 2702 nowhere refers to Section 3008(b) of the ACA.

Moreover, Section 3008(b) only requires a study on the possible expansion of the policy to other health care facilities, such as skilled nursing facilities, i.e., Section 3008(b) explicitly requires the Secretary of HHS to conduct a study on expanding the HAC policy to other settings, including inpatient rehabilitation facilities, long-term care hospitals, hospital outpatient departments, and other hospitals excluded from the inpatient prospective payment system, skilled nursing facilities, ambulatory surgical centers, and health clinics. This study is required to include an analysis of how such policies could impact quality of patient care, patient safety, and Medicare spending, and is due to Congress by January 1, 2012. It is clear that there was no Congressional intent for CMS to suggest that states extend a federal policy, that is currently limited to the hospital inpatient setting, to other provider settings, especially before this study is completed.

In sum, the proposed rule contradicts itself when discussing the basis for the Secretary’s statutory authority to expand HCACs, as defined in the statute, to the broader definition of PPCs—which includes HCACs and OPPCs. The proposed rule simultaneously admits the limitations of the ACA’s Section 2702 and then ignores those limitations in expanding a statutorily specific term, HCAC, to mean PPCs, which, again, includes HCACs and OPPCs.

The statutory language of Section 2702 of the ACA expressly precludes the Secretary from adjusting payments for HCACs that extend beyond the very specific definition contained in the statute, *i.e.*, by the Secretary’s own admission, “conditions applicable to inpatient hospitals as defined in that section and reimbursed by diagnosis related groups.”⁵ In proposing to expand the definition of HCACs to mean PPCs, which includes both HCACs and OPPCs, the Secretary is ignoring the plain meaning of the statute and going beyond her statutory authority. Therefore, AHCA urges the Secretary to delete all of the provisions of proposed 42 C.F.R. § 447.26(b) referencing “other provider-preventable conditions.”

II. Current Regulatory Environment

AHCA does not believe that mandating the introduction of the OPPC concept to the Medicaid nursing home payment system at this time will serve a productive public purpose in terms of stimulating improved patient outcomes. The complex and comprehensive regulatory system under which nursing facilities presently operate is unparalleled in its nature, reach, and intensity. Resident care, regulatory compliance, and quality expectations are all rigidly scrutinized and strictly enforced under a duplicative state/federal survey system which is highly punitive.

A. Adequate Sanctions for Poor Quality Care Already Exist

The enforcement of nursing home standards draws upon an expansive and diverse arsenal of remunerative and punitive sanctions that may be imposed for a facilities’ failure to meet federal and or state expectations. The state’s current armory of compliance “incentives” can individually and collectively trigger severe financial penalties associated with federal civil monetary penalties up to \$10,000 per day; state forfeitures up to \$10,000 per day with potential for triple forfeitures in the event of repeated violations; directed plans of correction; denial of payment for new.

⁵ 76 Fed. Reg. 9283, 9288 (Feb. 17, 2011).

admissions; revocation of licensure and termination of Medicaid certification. Any and all of these financial sanctions are currently in place and in use. They may individually or collectively be imposed to address any survey finding of inappropriate, or even the potential for inappropriate, care and treatment.

Indeed, nursing facilities are currently subject to intense scrutiny and sanction under both state and federal law. A single incident of alleged non-compliance can and does trigger imposition of financial penalties under both. The unproductive and unjust practice and cost of “double jeopardy” that facilities currently face would evolve into an even more unconscionable “triple jeopardy” scenario as a result of the creation of OPPCs. The rule also does not take into account the survey certification process that is unique to NFs.

The proposed rule does not indicate who makes the determination that an event “could have reasonably been prevented through the application of evidenced based guidelines” for purposes of reporting the event to Medicaid. If it is based on the determination of state surveyors, facilities will likely receive a “double penalty” for the incident, as described above. If a provider reports an incident to Medicaid, it will also result in a compliance survey that will likely result in a “double penalty.”

However, if a NF provider does not report an incident (e.g., a fall with injury) because the NF believes it was not preventable, but the state survey agency disagrees, will the NF be at risk for submitting a false claim to Medicaid? On the other hand, if a provider is cited by the agency and the incident is reported to Medicaid resulting in a payment reduction, but the deficiency is ultimately deleted through the informal dispute resolution or formal appeal process, will the NF be reimbursed by Medicaid for care related to the particular condition?

The proposed introduction of the OPPC concept into the payment system applicable to Medicaid providers could possibly serve as a productive “incentive” if, and only if, the regulatory system under which the providers operate lacked oversight or remedial/punitive sanctions to address adverse events. However, under no stretch of the imagination could it be asserted that such a void exists with respect to nursing homes. Rather, there is an excess of oversight.

B. Imposing Yet Another Punitive Program Runs Counter to Successful Collective Government and NF Provider Efforts at Improving Quality

The OPPC and the HCAC programs are punitive, and it is difficult to consider the logic behind implementing this type of payment program in a setting where the success of past and continuing collaborative quality improvement efforts have been forged by CMS, states, and providers. The proposed payment program ignores NF efforts, most notably since 2002 and the onset of the Nursing Home Quality Initiative—where provider collaborations were formed to address pain management, pressure ulcer prevention and management, and culture change/ workforce.

A provider -led executive group set the stage for the development of the current “Advancing Excellence in America’s Nursing Homes” campaign, where providers across the country are now actively involved in improving clinical and operational outcomes. CMS, State Survey representatives, and the Quality Improvement Organizations are participants in this campaign. Many of our members have worked very hard to achieve quality excellence and have received the Baldrige National Quality Award Program recognition. Our quality improvement efforts have been noteworthy, and should not be dismissed by the desire to control healthcare expenses through a payment program designed for hospitals having different regulations, reimbursement, and measuring systems.

III. Clinical Issues Regarding OPPCs

A. CMS Should Streamline The Data Collection System Used To Identify OPPCs

Attention needs to be first given to streamlining the data collection system used to identify OPPCs. Under the proposed and currently used systems, knowledge of OPPCs may come from several sources, such as provider or surveyor reported events, care complaints/claims, or from the Minimum Data Set Quality Measures (MDS QMs). Nursing facilities must currently comply with rigorous reporting requirements imposed by CMS, state licensing agencies, and law enforcement. This is inclusive of some of the OPPCs. Additionally, nursing facility residents/patients have extensive residents' rights that the nursing facility must guarantee. These rights include the right to refuse medication and treatment. The specific situation for each resident must be considered when determining reduction of payment due to OPPCs.

Nursing facilities are also subject to a federal compliance survey annually—more frequently when complaints have been registered. When a facility is found by the state survey agency to be non-compliant with federal regulations, depending on the severity of the noncompliance, the facility may be fined. The fines imposed can range from \$100 to millions of dollars. It is critical to recognize that both a fine and a reduction in payment due to an OPPC constitutes a double penalty and will result in a significant, negative impact on the ability of the facility to provide high quality care for all residents.

In order to streamline the data collection system to identify OPPCs, we recommend that a single data collection and reporting tool, used across all settings impacted by the payment programs, be implemented to ensure standardization. Standardization is needed in the following areas:

- definitions for Medicare, Medicaid, and dual-eligible patients;
- condition definitions like what is a fall and trauma; and
- data collection timeframes like length of look-back periods or the number of times per specified period care was received or the condition occurred.

CMS has already designed and is testing the CARE tool mandated by the Deficit Reduction Act with a report to Congress due by January 2012. It is a tool designed to be used across the various provider settings and to allow quality and cost comparisons. This tool is in the final stages of testing. AHCA recommends that if found sound, the tool be implemented before the Medicare HCAC payment system is considered for other settings and before states develop OPPCs.

B. CMS Should Consider How Managed Care, Private Insurance And Private Pay Patients Will Be Addressed Under An OPPC Program

When considering the implementation of a Medicaid payment system in the long term care setting and the use of MDS QMs to identify OPPCs, thought needs to be given to how managed care, private insurance, and private pay patients will be handled in the proposed payment systems. Even though these patients are not part of the Medicare and Medicaid system, their presence in a nursing facility can impact MDS QM measurement used to determine an OPPC.

For example, when calculating the number of Stage III or IV pressure ulcers, the non-Medicare and non-Medicaid patient assessments are excluded from the measure calculation. As a result, the measure denominator size (populated only by Medicare and Medicaid patient assessments) is reduced and may cause the measure to not be reported since measure validity cannot be assured.

Since the assessment outcomes for Medicare and Medicaid patients will end up being excluded from the measure and thus from the payment program, a less than a fair and consistent approach will ultimately result.

C. Before Mandating An OPPC Program, CMS Should Conduct Research Consistent With The HHS Strategic Framework To Better Understand The Issues Pertaining To Individuals With Multiple Chronic Conditions (MCCs)

The majority of patients cared for in our nation's nursing care centers are individuals with multiple chronic condition (MCCs). According to HHS' "Multiple Chronic Conditions: A Strategic Framework,"⁶ more than one in four Americans have MCCs, which is a state of having two or more conditions that commonly include arthritis, asthma, diabetes, health disease, chronic respiratory conditions, hypertension and others. The prevalence of individuals with MCCs increases with age and is substantial among adults over the age of 65. In fact, the Institute of Medicine (IOM) noted in the Crossing the Quality Chasm report that twenty-three percent of Medicare beneficiaries have five or more chronic conditions.⁷

Since there is limited knowledge of MCCs, and individuals with multiple conditions are not addressed in evidence-based guidelines and quality measurement, concern arises about the application of the proposed rule to patients in long term care settings. More robust risk-adjustment is needed in measuring quality outcomes for the MCC patient.

Individuals with MCCs require ongoing medical attention, and most experience limitations in activities of daily living (ADLs). According to an article published in the *Journal of Internal Medicine*, little is known about how chronic conditions cluster.⁸ Further, clinical guidelines and disease management programs focus on single conditions and exclude individuals with MCCs.

A known clustering of chronic conditions include individuals with obesity, hypertriglyceridemia, low-serum high-density lipoprotein, hypertension, and glucose intolerance; all associated with the risk of heart disease and mortality and where underlying genetic predispositions may be involved in cluster conditions. Like the HHS Strategic Framework, these researchers identify limited information on MCCs and specific condition combinations and identify the need for research to fill the knowledge gaps.

Individuals with MCCs are more likely at risk of an avoidable inpatient admission or a preventable complication.⁹ Considering that the prevalence of individuals with MCCs is growing and that healthcare costs are higher for individuals having multiple conditions, the need for quality measurement is apparent. According to the National Quality Forum's (NQF's), Multiple Chronic Condition Measurement Framework project, started in June of 2010 and being funded by HHS, individuals with MCCs are largely not addressed by available quality measurement. The

⁶ Available at http://www.hhs.gov/ash/initiatives/mcc/mcc_framework.pdf.

⁷ Committee on Quality of Healthcare in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington D.C. National Academies Press; 2001.

⁸ Christine Vogeli et al., *Multiple Chronic Conditions: Prevalence, Health Consequences, and Implications for Quality*, 22 Care Management and Costs Supplement 3, 391-395 (Dec. 2007).

⁹ J. Wolff, B. Starfield, G. Anderson, *Prevalence, Expenditures, and Complications of Multiple Chronic Conditions in the Elderly*. 162 Archives of Internal Medicine, 2269-2276 (Nov. 2002).

Multiple Chronic Condition Measurement Framework project further finds that these individuals are not included in clinical trials which provide the direction for evidence-based guidelines.

As indicated above, since there is limited knowledge of MCCs and individuals with multiple conditions are not addressed in evidence-based guidelines and quality measurement, AHCA is concerned about the application of the proposed rule to patients in long term care settings. The proposed rule provides a current list of Medicare HCACs and some may be applicable to conditions found among nursing facility patients, such as diabetes and Stage III and Stage IV Pressure Ulcers. Unfortunately, the HCACs are condition-specific and do not take into account the cumulative and cluster effects that multiple conditions have on the development, treatment, and resolution of only one of the identified conditions.

One illustration of this problem is the designation of a Stage III or IV pressure ulcer as an OPPC. Numerous scholarly papers conclude that patients with MCCs are at higher risk for pressure ulcers. In one study conducted in the United Kingdom encompassing 75,168 older adults, researchers found that pressure ulcer development was significantly associated with many conditions like Alzheimer's Disease, congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), cerebral vascular accident (CVA), diabetes mellitus, deep vein thrombosis, hip fracture, hip surgery, malignancy, osteoporosis, urinary tract infection (UTI), and others.¹⁰

Yet, the HCAC for consideration in the proposed rule cites only the Stage III or IV pressure ulcer without considering the unique patient or the number of multiple conditions experienced by that patient. It is illogical to assume that pressure ulcer development in a patient without MCCs has the same risk potential as the patient with MCCs. Considering this, one cannot assume that the condition is avoidable by using the current OPPCs or related quality measures,.

In March 2010, the NPUAP held a consensus conference with twenty-four multidisciplinary experts on pressure ulcer prevention.¹¹ The panelists agreed that not all pressure ulcers are avoidable. They define unavoidable pressure ulcers as follows:

Unavoidable - means that the individual developed a pressure ulcer even though the provider had evaluated the individual's clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with individual needs goals and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

The panelists also concluded "that there are patient situations that create unavoidable pressure ulcers. A condition seen in patients in critical care, hemodynamic instability may preclude turning or repositioning and lead to unavoidable pressure ulcers. Patients who refuse to be repositioned may also develop unavoidable pressure ulcers. The panelists agreed that the condition of skin failure exists." Currently, there are no widely-accepted evidence-based guidelines to prevent pressure ulcer development under these circumstances.

¹⁰ D. Margolis, J. Knauss, & M. Baumgarten, *Medical conditions as risk factors for pressure ulcers in outpatient settings*, 32 *Oxford Journal of Medicine* 3, 259-264.

¹¹ See http://www.npuap.org/A_UA%20Press%20Release.pdf.

In sum, AHCA submits that there is ample evidence to suggest a valid concern about the use of a Pressure Ulcer OPPC. There is generally a lack of sufficient evidence to determine, without a doubt, that the pressure ulcer was avoidable in all cases. Obviously, more robust risk adjustment is needed in measuring quality outcomes for the MCC patient, which nullifies the use of this OPPC for payment purposes. Using evidence and in collaboration with nursing facility representatives, CMS should develop quality measures with more robust risk adjustment for individuals with MCCs and test, refine, and validate measures before they are used.

D. CMS Must Consider The Implications Of Substandard And Inconsistent Care Along The Continuum

In the proposed rule, CMS states that “. . . one cannot prevent what one cannot detect.” This clear, simple statement has enormous applicability to the long term care environment. Patients in long term care facilities are admitted having experienced care and treatment from a wide variety of care providers -- primary care physicians, hospitals, and others. Uncoordinated and inconsistent care along the continuum can contribute to the development of OPPCs in the receiving setting.

The NQF proposed Serious Reportable Event (SRE) 2011 measure for patient death/serious injury associated with medication error is one of the OPPCs that can be caused by, or contributed to the discharging facility. The proposed NQF SRE also includes drug-to-drug interactions. One example of how this SRE can erroneously cite and financially penalize the long term care provider with poor care is the case of the elderly, 85-year old patient admitted to the hospital for a total knee replacement, and who after routine pre-operative testing, is diagnosed as having a urinary tract infection (UTI).

- The patient has multiple chronic conditions including diabetes, hypertension, hypercholesterolemia, arthritis, coronary insufficiency, and hearing impairment. The urine specimen was obtained by requesting a midstream voided urine specimen. However, the elderly female patient was unable to provide a midstream specimen without specimen contamination.
- The patient had some cognitive impairment and also was unable to comply with midstream instructions. The lab results reported a high urine bacteria count. The patient was without fever or other symptoms indicating a UTI.¹² Because surgery was scheduled for the next day, the patient was started on a round of antibiotic therapy.
- Antibiotic therapy continued post surgery and anticoagulant therapy was started since it was called for in post surgical, knee replacement protocol. Both drugs were administered during the post-operative period. International Normalizing Ratio (INR), a measure of coagulation, was monitored with no major concerns. By day seven of the hospital stay, the patient had completed the antibiotic therapy and was discharged to the NF for rehabilitation and therapy was started.
- Anticoagulation therapy continued and INR levels indicated longer bleeding times. A hematoma noted on admission at the incision site became more prominent and started to bleed. Anticoagulation therapy discontinued and later therapy was halted. The patient's

¹² AMDA, Clinical Practice Guideline: Common Infections in the Long Term Care Setting, 3-4.

post-operative pain became more severe and within the first week of the nursing facility stay, the patient was sent back to the hospital where it was determined that surgery with skin grafting was needed at the incision site.

So what went wrong? What caused the hematoma at the surgical site? Was the re-hospitalization due to poor follow-up and/or care at the rehabilitation center?

The above example is based on a true event and is one that is not uncommon in nursing facilities. The causes of the re-hospitalization started with a drug-to-drug interaction between the prescribed antibiotic and the anticoagulant administered in the hospital. Medication commonly given for UTIs, like Ciprofloxacin (Cipro), is known to be substantially excreted by the kidneys and the risk of drug toxic reactions may be greater in patients with impaired renal function. According to an HHS letter to Bayer Pharmaceuticals,¹³ the toxicity of drug and coadministration may dangerously increase Coumadin (warfarin) activity and INR should be monitored closely.

The aforementioned letter further states that "coadministration of ciprofloxacin with other drugs primarily metabolized by CYP1A2 results in increased plasma concentrations of these drugs and could lead to clinically significant adverse events of the coadministered drug."¹⁴ Aging that affects the kidneys also need to be considered when determining potential drug-to-drug interactions in elderly patients. According to a Merck publication, *Drug Therapy in the Elderly*, aging affects renal drug excretion, which decreases at age 80 and clearance is typically reduced to ½ of what it was at age 30.¹⁵

When considering scenarios, like the above drug-to-drug interaction that may result in a serious outcome, such as re-hospitalization, surgery and skin grafting, it becomes clear why determining who is at fault for the SRE cannot always be attributed to the setting of care in which the event appeared to have occurred.

When considering negative outcomes for MCC patients, measuring poor care outcomes, even death, cannot be easily determined. For example, after administering Cardio Pulmonary Resuscitation (CPR), the patient may still die --particularly if the patient is nearing or at end of life. The goal of care for this patient nearing end of life is to provide the best possible quality of life and the best chance for a good outcome.

The need for more research and care direction regarding the care and treatment of MCC patients is clear. Many complex factors need to be considered and the current OPPCs and quality measures, most common to the elderly patient, lack the needed specificity to properly evaluate care and outcomes for the MCC patient population and to validly determine whether payment should be withheld.

¹³ Available at

http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/019537s60,019847s36,019857s41,020780s20,021473s13ltr.pdf.

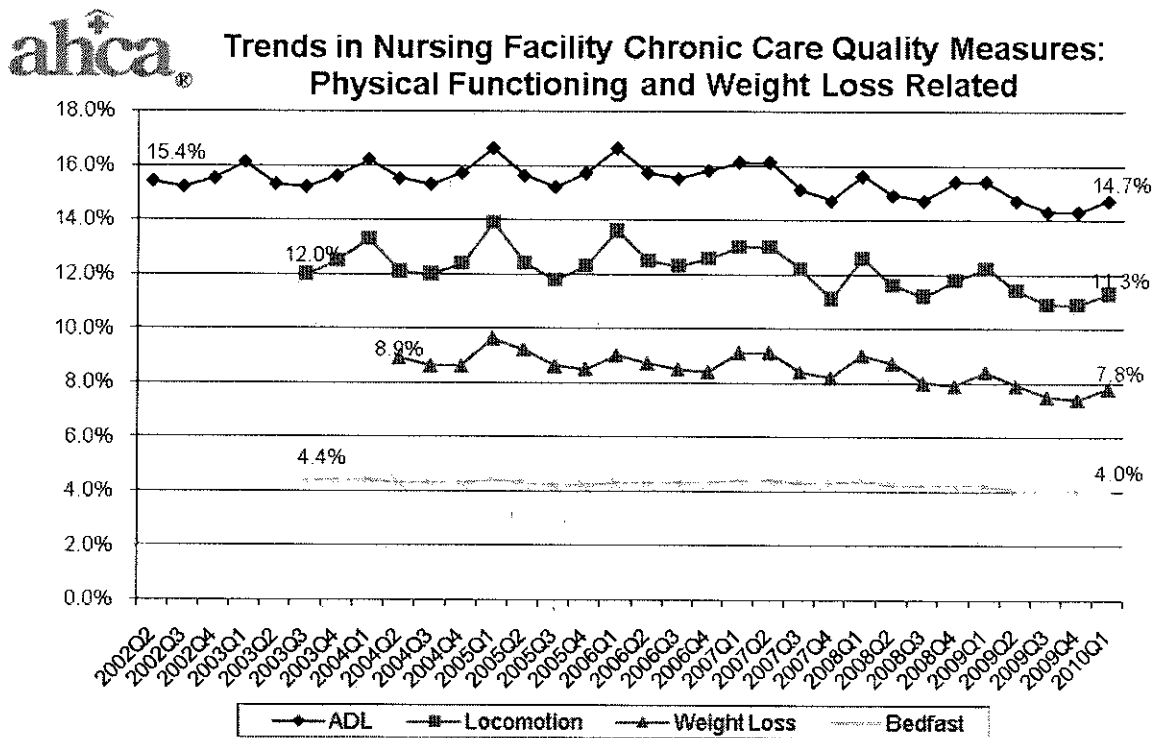
¹⁴ Ibid.

¹⁵ Available at <http://www.merck.com/mmpe/sec20/ch306/ch306a.html>.

E. CMS Should Not Use MDS Quality Measures To Determine OPPCs

AHCA objects to the proposed use of MDS quality measures as means to determine OPPCs. MDS measures were not designed or tested for use in payment systems. The NQF, through the consensus development process, identified measures for quality measurement and public reporting. Measure outcomes only reflect patient assessment data during a short period of time (look-back period) and cannot be considered a reliable source measuring patient change from one assessment to another. Many intervening conditions, treatments, abating symptoms, and flare-ups can arise between assessments. This important fact is being lost as the MDS and measures are updated. Measure developers and policymakers need to understand the limitations of the data, be responsible users of the data, and convey data limitations to consumers and other users of MDS data.

MDS measures are reported to be affected by seasonal variations. Since the onset of utilizing MDS data to report QMs, CMS has reported the QM average on a quarterly basis. As shown in the chart below, the quarterly QMs have a very prominent seasonal component with a clear pattern from year to year. This pattern exists for both chronic and post-acute care. AHCA, along with other organizations, raised this issue to CMS, and since January 2010, CMS has begun to calculate the QM average score using the most recent three quarters of QM data available.



Source: Computed by AHCA R&R Department using CMS Nursing Home Compare. Various years and quarters. American Health Care Association - Reimbursement and Research Department

AHCA does not recommend using MDS QMs to determine OPPCs. As previously mentioned, not all patient assessments are submitted to the federal government and as a result, not all patient data is calculated in the publicly reported quality measures. Patient information is withheld from federal and State agencies when the payer of the nursing facility services is neither Medicare or Medicaid. The purpose of the restriction relates to the need to protect patient information as

required by the Health Insurance Portability and Accountability Act (HIPAA). As a result, managed care, private insurance and self-pay patient data is excluded from the reported measures. MDS 3.0 coding addresses the information exclusions in Section A, 0410, Submission Requirement. This section lists the following instructions:

Code 1, neither Federal nor State required submission: if the MDS record is for a resident on a unit that is neither Medicare nor Medicaid certified, and the State does not have authority to collect MDS information for residents on this unit. If the record is submitted, it will be rejected and all information from that record will be purged.

Code 2, State but not Federal required submission: if the MDS record is for a resident on a unit that is neither Medicare nor Medicaid certified, but the State has authority, under State licensure or other requirements, to collect MDS information for these residents.

Code 3, Federal required submission: if the MDS record is for a resident on a Medicare and/or Medicaid certified unit. There is CMS authority to collect MDS information for residents on this unit.¹⁶

An outcome resulting from the MDS Submission Requirements is the reduction in the number of assessment files used in the calculation of the facility's quality measures. This means the measure denominator size is reduced and may render the measure invalid and not appropriate for public reporting. Obviously, the MDS quality measures are not appropriate for use in a payment system since the payment program cannot be universally and fairly applied to all nursing care facilities.

The MDS quality measures also cannot be used to identify OPPCs at the patient level since many records are never submitted to CMS or the State, and thus, not all patient's will have outcome information for regulatory consideration. This situation will leave the determination of an OPPC to approved record reviews that are time-consuming to complete, costly and inconsistent due to reviewer bias.

F. CMS Should Consider Possible Unintended Consequences of Implementing HCACs and OPPCs

Before implementing the HCAC and OPPC payment programs in the long term care setting, CMS must anticipate and evaluate the unintended consequences of such a payment adjustment. As previously discussed in the example of the patient with the drug-to-drug interaction, a mechanism is needed to determine to which setting the problem should be attributed, i.e., which settings of care and how much did each setting contribute to the HCAC or OPPC.

Unfortunately, other consequences can occur that result in harming the patient and increasing the cost of care. For example, under the Medicaid OPPC program, the nursing facility who admits a high-risk patient with a Stage II, deep tissue injury (DTI), or unstageable pressure ulcer and within a short period finds the ulcer to be at a Stage III or IV, is at risk for being identified as causing an OPPC. There is no incentive for the nursing facility to admit the high-risk patient, and if admitted and the OPPC occurs, there is no incentive to keep the patient. Transferring the

¹⁶ MDS 3.0 RAI Manual, December 2010. MDS 3.0 Chapter 3 Section A, *available at* http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage.

patient to another facility, whose can identify the ulcer on admission and get reimbursed is a reality.

Under the current Medicare HCAC program, there are strong disincentives to providing care or treatment that could result in a HCAC. For example, an elderly 80-year-old cardiac patient could be essentially confined to bed or chair, and not allowed to move in or out of bed and ambulate, even when no physical contraindications exists, because of the fear that unassisted movement will result in a fall and trauma. Patient assisted ambulation could be limited.

After a few days of inactivity and restriction, the elderly patient quickly could loose mobility and the ability to balance. The patient could then be recommended for nursing facility rehabilitation and/or home health care to help restore function. Obviously, in this example the hospital would try to keep the patient safe and prevent a fall and possible injury. The unintentional consequence of the hospital's concern over a HCAC could result in the patient's loss of strength, movement, and balance, and health care costs increase due to the need for post-acute care rehabilitation.

III. Payment System Issues Regarding OPPCs

Medicaid NF payment systems do not lend themselves to the financial negative adjustment envisioned by an OPPC system. It would be very difficult, if not impossible, for a NF to satisfy the reduction in provider payment provisions under §447.26(c).

The proposed rule states that the state must be able to “reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to, the provider-preventable condition.” This type of payment isolation is predicated on a payment coding system used in the inpatient hospital prospective payment system (IPPS). In the IPPS, when a HAC is identified, the care of that HAC is identified by code, and Medicare does not allow the hospital to be paid for that HAC.¹⁷ There is nothing remotely similar in Medicaid payment systems. NF reimbursement methodology varies from state to state; however, a majority utilize an acuity adjusted “case mix” per diem system that reimburses NFs based on a completed MDS assessment.

NF providers are required by law to accurately complete the MDS assessment, which includes information related to the presence of conditions such as pressure sores and falls. Although the MDS may identify a “facility acquired stage IV pressure ulcer,” the development of the ulcer may have been clinically unavoidable due to the individual's comorbid conditions, which will not be captured on the MDS and which would not make the condition a PPC.

As already indicated , the MDS assessment includes information related to the presence of conditions such as pressure sores and falls. First, although the MDS may identify a “facility acquired stage IV pressure ulcer,” the development of the ulcer, as explained above, may have been clinically unavoidable due to the individual's comorbid conditions, which will not be captured on the MDS and which would not make the condition an OPPC.

¹⁷ “HAC” refers to a hospital-acquired condition under Medicare. The Hospital-Acquired Conditions payment provision applies only to IPPS hospitals. For discharges occurring on or after October 1, 2008, Inpatient Prospective Payment System (IPPS) hospitals do not receive the higher payment for cases when one of the selected conditions is acquired during hospitalization (i.e., was not present on admission). The case is paid as though the secondary diagnosis is not present.

Second, even if the condition did constitute an OPPC, in many cases it would not result in an increased payment in the NF setting due to the presence of other significant comorbid conditions. For example, it is difficult to disaggregate the portion of the cost of care attributed solely to the treatment of a UTI and what additional care may be associated with the individual's comorbid conditions and overall decline in status.

Moreover, as described above, the NF is not permitted to exclude a pressure ulcer or fall with injury from the MDS assessment form even if the facility believes it was preventable. Therefore, as a practical matter, it is not clear how an OPPC could be separated out for purposes of a reduction in payment. The law and regulations were clearly designed for the hospital setting where an average length of stay can be measured for a particular condition, and if a patient exceeds that length of stay and incurs more costs due the development of a HAC, those costs to Medicare are also relatively easy to measure.

In addition, most aged residents in NFs experience a gradual decline in health until death. Consequently, it will be very difficult to determine when the effect of an OPPC ceases (ending the payment reduction related to a particular condition), and when the continuing need for additional care may be related to a separate comorbid condition and the resident's overall decline.

Moreover, even if an OPPC can be attributed to the NF, in the most severe cases that will result in an increase in the cost of care (e.g., a fall with a hip fracture that requires surgery), but the resident will not necessarily be receiving any additional care at the NF. Rather, the resident will be transferred to a hospital for surgery and post-surgical care.

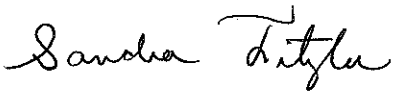
Lastly, it is an unfortunate possibility that any effort to impose OPPC programs on NFs may serve as an effective financial disincentive for facilities to admit individuals whose medical history is indicative of susceptibility to falls, pressure ulcers, or urinary tract infections. This can obviously cause access problems for those individuals who are in need the care facilities can provide but are unwilling to offer because of their inordinate exposure to punitive financial penalties lacking an adequate and coherent clinical basis. Indeed, it may also trigger increased Medicaid program expenditures and adverse outcomes for the individuals by virtue of their being cared for in more costly and less appropriate settings.

Conclusion

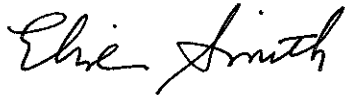
For the reasons discussed above, AHCA asks the Secretary to delete all of the provisions of proposed 42 C.F.R. § 447.26(b) referencing "other provider-preventable conditions. Due to clinical and payment considerations, imposition of an OPPC program is currently impossible and unwarranted. CMS should instead look to the success of past and continuing collaborative quality improvement efforts that have been forged by CMS, states, and providers and help NFs to continue and enhance their quality improvement efforts. In addition, CMS should conduct the study due to Congress by January 1, 2012 on the expansion of the HAC policy to other settings including the analysis of how such policies could impact quality of patient care, patient safety, and Medicare spending,

We would gladly meet with you to discuss any of these issues. If you have any questions, please contact Sandra Fitzler at sfitzler@ahca.org or Elise Smith at esmith@ahca.org.

Sincerely,



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cc: Jonathan Blum
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