American Hospital Association

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August 18, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS 1611-P, Medicare and Medicaid Programs; Home Health Prospective Payment System Rate Update; and Survey and Enforcement Requirements for Home Health Agencies; Proposed Rule; July 7, 2014.

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including more than 1,000 hospital-based home health (HH) agencies, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2015 proposed rule for the HH prospective payment system (PPS). Our comments focus on the proposed changes to the face-to-face encounter requirement, coverage for insulin injections, modification to the therapy reassessment schedule, and a new quality reporting demonstration.

FACE-TO-FACE ENCOUNTER REQUIREMENTS

CMS implemented a face-to-face encounter requirement for patients beginning HH services in January 2011, as required by the Affordable Care Act (ACA). The goal of this policy is to have a non-HH physician verify a beneficiary's eligibility for Medicare's HH benefit. This encounter must occur between 90 days prior to the initiation of services and 30 days after the start of services, and must include a narrative explanation of the patient's homebound status and need for either intermittent skilled-nursing or therapy services. The face-to-face encounter must be performed by the physician certifying a patient's eligibility for the Medicare HH benefit (or by a non-physician practitioner working with the physician). Alternatively, the face-to-face encounter may be provided by a physician (or non-physician practitioner) who cared for the patient in a general acute-care hospital or post-acute facility and who communicates the clinical findings of the encounter to the certifying physician.

The AHA supports CMS's proposal to eliminate the requirement that a face-to-face encounter include the narrative explanation, which will facilitate smoother transitions for hospitals discharging patients to home care and for hospital-based HH agencies initiating services. Both physicians and HH agencies have struggled to comply with the face-to-face encounter requirement, which was the catalyst for CMS's prior changes to streamline this requirement. Under this proposed rule, CMS would remove the requirement for a narrative explanation by the physician conducting the encounter, except for patients requiring skilled nursing care for management and evaluation services. Our members indicate that, under this exception, very few cases would require a narrative explanation. **To that end, we encourage CMS to state in the final rule its expectation that a face-to-face narrative should be included only in rare circumstances and to clarify how physicians and HH agencies should identify the cases that, under this exception, would require a narrative.**

The proposed rule clarifies that the ACA-mandated face-to-face encounter applies only for the initiation of HH services, not for re-certifications. Such initial episodes are the first in a series of episodes separated by no more than a 60-day gap. However, the rule also clarifies that patients discharged following the completion of their HH plan of care who are subsequently readmitted to the HH agency during the same 60-day period are required to be newly certified, not re-certified. They, therefore, must have a new face-to-face encounter. The AHA urges CMS to modify this clarification. Specifically, it would be excessively burdensome to require more than one face-to-face encounter during the same 60-day period. Doing so offsets the potential efficiency gains from the reduction of claims that would require a face-to-face narrative. **Therefore, we encourage CMS to consider requiring a new face-to-face encounter only when the patient returns to HH care during the same 60-day episode for treatment of a *new condition*.**

We also ask CMS to clarify the face-to-face and certification requirements for patients transferred from one HH agency to another midway through the completion of a plan of care. For this scenario, we recommend that the agency allow the initial face-to-face encounter to also serve the receiving agency if the patient is treated for the same primary condition at both the discharging and receiving agency.

AUDITING MEDICAL NECESSITY

The AHA opposes CMS's proposal to establish new audit procedures that would base audits of one provider on the medical record of another provider. While we understand the intent of the audit provisions in this proposed rule – to encourage physicians to engage in timely and well-documented assessments of HH eligibility – CMS's mix-and-match audit approach is inappropriate and would place HH providers at risk of a denial based on the documentation of individuals outside of their oversight and control. **Therefore, we strongly urge CMS to withdraw the following three audit-related proposals to avoid violating providers' accountability boundaries.**

HH Medical Necessity Audits. **The AHA does not support CMS's proposal to base Medicare HH medical necessity audits on "only the medical record for the patient from the certifying physician or the acute/post-acute facility."** Under this proposal, if the certifying physician's record lacks sufficient documentation of eligibility for Medicare HH services, payment would

not be rendered to the HH agency. **Rather, audits of HH medical necessity should be based on the documentation found in HH agencies' medical records.**

Physician Audits. Likewise, we oppose the agency's related proposal to base payment for physician claims for certifications (and re-certification) of HH eligibility on the status of a separate provider's claim – the HH claim. **Any audit of physician services should be based on the claims and medical records of that physician; therefore, we urge CMS to withdraw this proposal, as well.**

Proposed New Physician Condition of Payment. In a related provision, the proposed rule discusses a new Part B physician condition of payment, under which a physician's claim for certification/re-certification of eligibility for HH services would be linked to the payment status of the corresponding HH claim. If a HH claim is denied due to an incomplete certification or insufficient documentation to support eligibility for Medicare HH services, then the related physician claim also would be denied. The proposed rule does not explain when and how a HH denial would trigger a denial of and payment recoupment from the related physician. The regulation's preamble only briefly mentions CMS's plan to implement this new condition of payment through future sub-regulatory guidance – an inadequate method for proposing a new condition of payment. **The AHA urges CMS to withdraw this proposed condition of payment, due to both the noted policy and process concerns. If the agency elects to proceed with a regulatory proposal, it should do so through the *physician fee schedule* to ensure that all stakeholders, especially physicians, are aware of this proposed change and have the opportunity to submit public comments.**

We also are concerned that the proposed new audit relationship linking physician payment and audits to HH claims may discourage some physicians from assessing and certifying patients for HH eligibility to avoid vulnerability for audit denials. Should this occur, beneficiary access to HH services could be negatively impacted. In addition, any progress made since 2011 to increase physician compliance with this policy may be stalled or reversed.

Given CMS's intent to use this section of the proposed rule to encourage timelier and better documented assessments of patients transitioning to HH services, education is imperative for both providers and auditors – even if these proposals are withdrawn. **Specifically, education is needed on Medicare coverage and documentation requirements for face-to-face encounters and HH certifications.**

COVERAGE FOR INSULIN INJECTIONS

Medicare covers HH visits for the sole purpose of insulin injections only for patients who are physically or mentally unable to self-inject, and where no other person is available to assist. However, an August 2013 report by the Department of Health and Human Services (HHS) Office of Inspector General[1] (OIG), along with other analyses, found that some portion of these visits was unnecessary because the patient had the capacity to self-inject. CMS's analysis also

[1] Management Implication Report 12-0011, Unnecessary Home Health Care for Diabetic Patients.

found that these cases had disproportionately high concentrations in five states (Calif., Fla., N.Y., Okla., and Texas).

CMS does not propose any changes to insulin injection-related coverage of HH services. However, based on these and related analyses, it includes Table 28 in the proposed rule, ICD-9-CM Diagnosis Codes that "Indicate a Potential Inability to Self-Inject Insulin," which lists diagnosis codes for patients whom CMS has identified as being suitable for coverage for skilled-nursing visits for insulin injections. The rule also notes that CMS is considering a future proposal to limit coverage for skilled nursing visits for injection assistance only to patients with these conditions, which were identified by CMS and contractor clinicians.

The AHA agrees that daily nursing visits to administer insulin are expensive and an ineffective way to care for diabetic patients. We also agree that identifying selected diagnoses could provide additional information to help support the identification of patients with impairments in dexterity, cognition and vision that may cause them to be unable to self-inject insulin – and therefore be eligible for skilled nursing assistance with injections. **However, we would not support a future proposal to use a list of this nature as the sole means of establishing coverage eligibility for this service. Any future policy using a list such as that in Table 28 should allow providers to treat patients with conditions outside of the list, if medical necessity for this service is comprehensively documented in the medical record.**

As CMS considers a potential future policy change, we encourage the agency to revise Table 28 to include additional codes for conditions that are similar or related to those already on the list, which are detailed in a separate attachment. For example, ICD-9-CM code 362.01, Background diabetic retinopathy (mild damage to the retina due to diabetes), is on the list, but not other ICD-9-CM codes for diabetic retinopathy such as 362.06, Severe non-proliferative diabetic retinopathy (advanced stage of damage to the retina due to diabetes). Similarly, while some ICD-9-CM codes for cataracts, including the code for unspecified cataract, are on Table 28, related codes representing specific cataracts and legal blindness are not.

THERAPY REASSESSMENT SCHEDULE

The AHA supports the proposal to base the therapy reassessment schedule on calendar days rather than on the schedule of therapy visits – every 13th and 19th visit. Our members agree that converting this requirement to a calendar day-based interval will be far easier to track and manage. However, the proposed interval for therapy reassessments – every 14 days – may be too frequent. We also note that the 14-day interval is not linked to a clinical objective that benefits the patient. As a useful point of comparison, the HH plan of care elements directed by a registered nurse are required to be reassessed when a significant change in condition occurs, rather per a pre-set schedule. **Therefore, we recommend that CMS consider requiring therapy reassessments at a longer interval.** For example, a 30-day therapy reassessment interval would coincide with the 30-day requirement for physical therapy supervision of assistants. Aligning these two requirements could bring new efficiency to HH service delivery.

HH QUALITY REPORTING (HHQR) PROGRAM

The Deficit Reduction Act of 2005 required CMS to establish a program under which HH agencies must report data on the quality of care delivered in order to receive the full annual update to the HH PPS payment rate. Since CY 2007, HH agencies failing to report the data have incurred a reduction in their annual payment update factor of two percentage points.

Outcome and Assessment Information Set (OASIS) Data Completeness Standard. CMS indicates that, in order to calculate quality measures appropriately using OASIS data, it needs to match OASIS assessments completed at the start or resumption of HH agency care with OASIS assessments completed at the time of patient transfer or discharge. Taken together, these matched OASIS assessments create what the agency terms an OASIS "quality assessment." A 2012 report from the HHS OIG urged CMS to take steps to ensure that it collects complete "quality assessments" from HH agencies.

Thus, CMS proposes to establish a "minimum data submission threshold" – or data completeness threshold – that assesses whether HH agencies have submitted enough data to create an OASIS quality assessment. HH agencies that do not meet the data completeness standard would be subject to a 2 percentage point payment reduction. CMS has the authority to establish data submission requirements under the statute, which requires HH agencies to submit measure data "in a form and manner, and at a time, specified by the Secretary [of HHS]." For the CY 2017 payment determination, CMS proposes that HH agencies be required to submit complete OASIS quality assessments on a minimum of 70 percent of patients with episodes of care occurring during the applicable data reporting period. The minimum data threshold would increase to 80 percent for the CY 2018 payment determination, and 90 percent for the CY 2019 payment determinations and beyond.

The AHA supports CMS's proposed OASIS data completeness standards. HH quality data are publicly reported and, therefore, used by HH agencies and patients to gauge improvement. A data completeness standard would help to ensure HH quality measure data are accurate. However, the AHA also recommends that CMS provide HH agencies with a 30-day period in which to review CMS's assessment of their compliance and submit corrections if necessary. CMS uses a similar process for its other quality reporting programs. Given that 2 percent of payments are tied to compliance with this standard, we believe it is only fair that HH agencies have the opportunity to ensure CMS's findings are correct.

HH Value-Based Purchasing (VBP) Demonstration Project. CMS solicits comment on a HH VBP demonstration project it is considering for implementation in CY 2016. CMS states that its interest in a HH VBP demonstration program stems from a proposal in the president's fiscal year (FY) 2015 budget to extend VBP programs to HH agencies, and from the agency's HH pay-for-performance (PFP) demonstration project conducted from 2008 through 2010. The existing inpatient hospital VBP program includes a budget-neutral payment withhold of 1.5 percent for FY 2015, which will increase to 2 percent by FY 2017. However, CMS states its intent to test in the HH VBP demonstration project whether using larger incentive amounts – 5 to 8 percent – would lead to greater improvements in quality. The agency indicates that if it proceeds with a

HH VBP demonstration project, it would be conducted in five to eight states, and that all HH agencies in the state would be required to participate.

In general, the AHA believes that a mix of public quality reporting and PFP can align the health care delivery system – including HH providers – toward continuous quality improvement, and reward providers that improve. Therefore, we applaud the agency for seeking to test a HH VBP program in advance of a formal implementation. While testing the HH VBP program on a statewide basis has merit, CMS may obtain a more nationally representative demonstration by allowing individual agencies across the country to participate. We recommend that CMS consider testing such an approach.

Moreover, the implementation of future quality reporting and PFP efforts related to HH must recognize the resource constraints of the field. For this reason, we recommend that CMS reconsider the potential HH VBP incentive amount. Even though they are a small percentage of the field, hospital-based HH agencies often operate on very thin margins. According to the March 2014 Medicare Payment Advisory Commission report, the average Medicare margin for hospital-based HH agencies in 2012 was *negative* 15 percent. Placing up to 8 percent of a HH agency's Medicare reimbursement at risk, therefore, could unduly impinge upon the ability of agencies to provide needed services.

As HH agencies become an increasingly important component of integrated, coordinated care delivery models such as accountable care organizations (ACOs), they must be financially viable to meaningfully contribute to such model. CMS should, therefore, consider not only the financial risk of an HH VBP program, **but also how such a program would fit in the context of its care delivery innovation activities, such as the Medicare Shared Savings Program.** It is critical that the programs provide HH agencies with consistent measures and incentives to improve care.

As CMS considers the implementation of a HH VBP program, we offer the following additional principles to help inform the program's design. These principles are consistent with those outlined our June 2013 statement on federal quality measurement and pay-for-performance efforts in general, and our August 2013 letter on post-acute care reform.

- **In general, the AHA favors PFP programs that assess multiple aspects of care, and that recognize providers for both achievement versus national benchmarks and improvement versus baseline performance. We encourage CMS to adopt such an approach for any future HH VBP program.** The inclusion of multiple aspects of care within one PFP program provides a consistent evaluation mechanism and incentive structure, reducing confusion about how performance is evaluated. We believe this incentive structure provides greater inducement for providers to improve performance.

- **Measures in all federal quality reporting and PFP programs must be endorsed by the National Quality Forum (NQF) to ensure they are sufficiently rigorous to use in accountability programs. The Measure Applications Partnership (MAP) also should review the measures before being incorporated into programs to ensure they are aligned with national priorities.** Rigorous measures aligned with national quality priorities would ensure focused attention on the most critical areas of improvement and

promote an efficient use of limited quality improvement resources. It also would encourage coordination of efforts among all health care providers.

- **The AHA believes that measures should be added to PFP – including any HH VBP program – in a gradual, step-wise process. This will ensure that programs assess performance accurately, and address issues of high priority.** Our guidelines are as follows:

    - As previously stated, measures implemented in federal programs should be reviewed and endorsed by the NQF and supported by the MAP prior to inclusion in a federal program. These steps ensure that each measure focuses on a national priority, and is scientifically sound, useable and feasible to collect.

    - Before being used in a PFP program, each measure should be included in a national public reporting program for at least one year. **We recommend that CMS use the HHQR program as the mechanism of public reporting before adding measures into the HH VBP program.** In this manner, the results can be monitored to be sure that there is variation in performance; the causes for variation can be identified and, if related to patient characteristics (such as severity of illness), appropriate adjustments can be made to the measure; and potential unintended consequences of measurement and public reporting can be identified and addressed.

    - Monitoring of a measure's performance should continue throughout its use in a PFP program. When there is evidence of consistent and sustained excellent performance, the measure should be retired from performance-based incentive programs and public reporting programs. This will create room for identification of additional improvement opportunities and inclusion of new measures.

Thank you for the opportunity to comment on this proposed rule. If you have any questions, feel free to contact me or Rochelle Archuleta, senior associate director of policy, at (202) 626-2320 or rarchuleta@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

ATTACHMENT: Suggested Additions to Table 28		
Code	**Code Title**	**Rationale**
	Amputation	
V49.60	Upper limb amputation status, unspecified level	Traumatic amputation of arm, hand, unspecified level is included (887.4, 887.5). This code represents the same condition after the amputation has healed.
V49.62	Upper limb amputation status, other finger (s)	Amputation status thumb is on the list. Codes for traumatic amputation of other fingers are included (886.0 and 886.1). This code represents the same condition after the amputation has healed.
	Vision	
362.02	Proliferative diabetic retinopathy	Code 362.01, background diabetic retinopathy, is included on Table 28. It is unclear why other types of diabetic retinopathy would be omitted. Diabetic retinopathy is the most common diabetic eye disease and a leading cause of blindness in American adults.
362.03	Nonproliferative diabetic retinopathy NOS	
362.04	Mild nonproliferative diabetic retinopathy	
362.05	Moderate nonproliferative diabetic retinopathy	
362.06	Severe nonproliferative diabetic retinopathy	
362.07	Diabetic macular edema	
362.10	Background retinopathy, unspecified	Codes in ICD-9-CM subcategory 362.1 represent other background retinopathies and retinal vascular changes. These conditions result in diminished vision and even vision loss.
362.11	Hypertensive retinopathy	
362.12	Exudative retinopathy	
362.13	Changes in vascular appearance	
362.14	Retinal microaneurysms NOS	
362.15	Retinal telangiectasia	
362.16	Retinal neovascularization NOS	
362.17	Other intraretinal microvascular abnormalities	
362.18	Retinal vasculitis	
362.30	Retinal vascular occlusion, unspecified	The primary symptom of retinal vascular occlusion is a sudden change in vision. This could be blurriness, partial loss of vision, or complete loss of vision.
362.31	Central retinal artery occlusion	
362.32	Arterial branch occlusion	
362.33	Partial arterial occlusion	
362.35	Central retinal vein occlusion	

362.36	Venous tributary (branch) occlusion	
362.37	Venous engorgement	
366.30	Cataracta complicata, unspecified	There doesn't appear to be a rationale why these other types of cataracts would not be included on the list with the other cataract codes.
366.31	Glaucomatous flecks (subcapsular)	
366.32	Cataract in inflammatory disorders	
366.33	Cataract with neovascularization	
366.34	Cataract in degenerative disorders	
366.53	After-cataract, obscuring vision	This code specifies "obscuring vision" and should be included, especially when "after-cataract, unspecified" (366.50) is included.
369.02	Better eye: near-total impairment; lesser eye: not further specified	According to the ICD-9-CM "legal blindness" definition in the USA is when both eyes have severe visual impairment, profound visual impairment, near-total visual impairment or total visual impairment. The entire subcategory 369.0 is titled "Profound impairment, both eyes" and all codes in that subcategory should be included.
369.03	Better eye: near-total impairment; lesser eye: total impairment	
369.04	Better eye: near-total impairment; lesser eye: near-total impairment	
369.05	Better eye: profound impairment; lesser eye: not further specified	
369.06	Better eye: profound impairment; lesser eye: total impairment	
369.07	Better eye: profound impairment; lesser eye: near-total impairment	
369.08	Better eye: profound impairment; lesser eye: profound impairment	
369.12	Better eye: severe impairment; lesser eye: total impairment	
V49.85	Dual sensory impairment	This code includes "blindness and deafness" and "combined visual hearing impairment"
Cognitive/Behavioral		
046.11	Variant Creutzfeldt-Jakob disease	In the early stages of disease, people may have failing memory, behavioral changes, lack of coordination and visual disturbances. As the
046.19	Other and unspecified Creutzfeldt-Jakob disease	
290.10	Presenile dementia, uncomplicated	Presenile dementia is still a form of dementia. Dementia codes are included in Table 28.
290.11	Presenile dementia with delirium	
290.12	Presenile dementia with delusional features	

290.13	Presenile dementia with depressive features	
290.20	Senile dementia with delusional features	Senile dementia uncomplicated and senile dementia with delirium are included on the list, these two should also be included.
290.21	Senile dementia with depressive features	
290.8	Other specified senile psychotic conditions	
290.9	Unspecified senile psychotic condition	
291.2	Alcohol-induced persisting dementia	These codes also reflect dementia. Dementia codes are included on Table 28.
292.82	Drug-induced persisting dementia	
294.10	Dementia in conditions classified elsewhere without behavioral disturbance	ICD-9-CM codes 294.11, Dementia in conditions classified elsewhere with behavioral disturbance,and 294.21, Dementia, unspecified, with behavioral disturbance, are included in the list. Whether or not there is behavioral disturbance should not be a factor for inclusion or omission from Table 28, if other dementias are included.
294.20	Dementia, unspecified, without behavioral disturbance	
Arthritis		
714.1	Felty's syndrome	Codes for rheumatoid arthritis are included in Table 28. Code 714.1 should be included as Felty Syndrome is defined by the presence of rheumatoid arthritis, an enlarged spleen (splenomegaly) and a decreased white blood cell count (neutropenia), which causes repeated infection.
714.2	Other rheumatoid arthritis with visceral or systemic involvement	This is a combination code that includes rheumatoid arthritis along with involvement of other organs.
714.4	Chronic postrheumatic arthropathy	Codes for rheumatoid arthritis are included in Table 28. Code 714.4 represents a chronic version of rheumatoid arthritis.
Movement Disorders		
333.0	Other degenerative diseases of the basal ganglia	Parkinson's disease is included on Table 28. Code 333.0 includes Parkinsonian syndrome associated with idiopathic orthostatic hypotension and symptomatic orthostatic hypotension.
333.4	Huntington's chorea	Huntington's chorea is a disease characterized by jerky, involuntary movements and mental deterioration, both intellectual and emotional. This would make it difficult to self-inject. Also, Parkinsonism with Huntington's chorea is coded to 333.4.

333.5	Other choreas	Patients with this condition would have involuntary, unpredictable, jerky body movements which would affect the patient's ability to self-inject with insulin.
333.92	Neuroleptic malignant syndrome	Patients with this condition have muscle rigidity, muscle cramping, tremors, cognitive changes and delirium.
357.0	Acute infective polyneuritis	This code includes Guillain-Barre which can progress to muscle weakness and evolve into paralysis.
After Effects from Stroke/Other Disorders of Central Nervous System/Intellectual Disabilities		
335.20	Amyotrophic lateral sclerosis	Patients with this condition suffer muscle weakness of the hands, arms or legs with twitching and cramping of muscles, especially those in the hands and feet, causing impairment of the use of the arms and legs.
340	Multiple sclerosis	Among the various symptoms associated with this condition, patients can have blurred or double vision, clumsiness or a lack of coordination, and weakness in an arm or leg, any of which would affect the patient's ability to self-inject with insulin.
342.00	Flaccid hemiplegia, affecting unspecified side	Codes specifying whether affecting dominant and nondominant side 342.01 and 342.02 (flaccid hemiplegia) and 342.11 and 342.12 (spastic hemiplegia) are on the list. The code for unspecified side should also be included.
342.10	Spastic hemiplegia, affecting unspecified side	
343.1	Congenital hemiplegia	Codes for congenital diplegia and quadriplegia are on the list, as well as other types of hemiplegia.
344.09	Quadriplegia and quadriparesis, other	All the other codes in this subcategory representing quadriplegia and quadriparesis are included on Table 28. It is unclear why this code was omitted.
344.40	Monoplegia of upper limb, affecting unspecified side	Codes for monoplegia affecting dominant and nondominant side are on the list. This is the most commonly assigned code. While the documentation may reflect right or left side, it's not always clear which side is dominant.
348.1	Anoxic brain damage	Patients with this condition may be confused and have poor coordination.

437.0	Cerebral atherosclerosis	Symptoms of cerebral arteriosclerosis include headache, facial pain, and impaired vision. It is also related to vascular dementia.
438.0	Cognitive deficits	This code is for cognitive deficits after stroke.
438.20	Hemiplegia affecting unspecified side	Codes for hemiplegia affecting dominant and nondominant side are on the list. This is the most commonly assigned code. While the documentation may reflect right or left side, it's not always clear which side is dominant.
438.30	Monoplegia of upper limb affecting unspecified side	Codes for monoplegia affecting dominant and nondominant side are on the list. This is the most commonly assigned code. While the documentation may reflect right or left side, it's not always clear which side is dominant.