American Hospital Association

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June 26, 2014

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

Re: CMS 1608; Medicare Program; Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2015; May 7, 2014.

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including approximately 1,100 inpatient rehabilitation facilities (IRFs), the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2015 proposed rule for the IRF prospective payment systems (PPS). In addition to explaining our concerns related to the proposed narrowing of cases that qualify under the IRF "60% Rule" presumptive test, this letter discusses the proposed group therapy reporting requirements, and makes several recommendations regarding the agency's proposed changes to the IRF quality reporting program.

The AHA strongly opposes any further proposals to restrict the codes that qualify for the 60% Rule presumptive test, including those in the FY 2015 proposed rule. The additional proposed reduction of NUMBER codes from the presumptive test, coupled with the already finalized reduction of 259 ICD-9-CM codes that will begin Oct. 1, 2014, would inappropriately narrow the 60% Rule compliance criteria. This would have the immediate effect of decreasing the presumptive compliance rate for many facilities, which in turn would impact IRFs' ability to admit other diagnoses having a significant negative impact on access for rehabilitation patients.

Our detailed comments follow.

PROPOSED CHANGES TO THE '60% RULE' PRESUMPTIVE COMPLIANCE METHODOLOGY

The 60% Rule requires that 60 percent of an IRF's cases for a prior 12-month period fall within 13 qualifying conditions or have qualifying comorbidities. Compliance with the 60% Rule is assessed through a two-step process. The first step is the presumptive assessment – a software audit by a CMS contractor that analyzes ICD-9-CM diagnosis codes submitted for each patient. IRFs that fail to demonstrate 60% Rule compliance using this initial presumptive test may then elect a second step involving a comprehensive assessment in which a contractor audits a sample of the facility's medical records to assess compliance with this policy.

REDUCTION OF ICD-9-CM CODES FROM PRESUMPTIVE TEST

In the FY 2014 final rule, CMS finalized a policy to remove 259 ICD-9-CM codes from those that qualify under the 60% Rule presumptive test, beginning Oct. 1, 2014. CMS stated that this change was intended to account for changes and variation over time in hospital coding, clinical practice, condition frequencies and 60% Rule enforcement by CMS contractors. CMS finalized this policy despite the AHA's significant concerns that several of the coding changes were unwarranted and inappropriate. Specifically, we were, and continue to be, concerned that the coding changes do not reflect clinically relevant distinctions, are administratively unrealistic, and do not further CMS's ability to ensure that IRFs are treating medically appropriate patients. We also expressed concern that these changes would have the immediate effect of decreasing the compliance rate for many IRFs, reducing IRFs' ability to admit diagnoses outside of the 60% Rule qualifying conditions, and potentially decreasing access for patients that would benefit from specialized IRF services.

For FY 2015, CMS proposes to remove an additional 10 ICD-9-CM codes for amputation cases that qualify under the presumptive test beginning Oct. 1, 2014. CMS notes in the proposed rule that patients with a deleted code may still be counted toward a facility's 60% Rule compliance percentage based on an audit of the medical record by a Medicare contractor. However, doing so would generally require that an IRF go to 100 percent audit review, which would result in increased administrative burden for hospitals and CMS alike, potentially significantly overloading Medicare contractors who would not be able to keep up with the workload.

The 60% Rule is intended to ensure that IRFs concentrate on treating patient populations that are distinct from the populations treated in other post-acute settings. However, this goal has been met as a result of a variety of regulatory interventions by CMS. First, the long-standing requirement that IRF patients require and receive at least three hours of therapy a day results in an IRF patient mix that, as a whole, is unlike the mix treated in other settings. In addition, the agency's substantial redesign of the "75% Rule" (now the "60% Rule") in 2004 initiated a period of major volume reduction for the IRF field – a decrease of more than 123,000 cases from 2004 through 2011. Further, CMS implemented new regulatory requirements in January 2010 that required IRF physicians to apply even more stringent admission criteria when considering whether a patient was medically necessary for the IRF setting.

Collectively, these regulatory actions have resulted in a substantial reduction in IRF utilization and an IRF case-mix that is, on average, more acute than in prior years.[1] Thus, CMS's proposed changes are not only concerning because of the effect they would have on access, but are also unnecessary. The proposed additional narrowing of 60% Rule eligible codes as discussed below is inappropriate, and we are concerned they would further reduce access to IRF services for patients who would otherwise meet IRF admissions criteria.

PROPOSED REMOVAL OF AMPUTATION ICD-9-CM CODES FROM PRESUMPTIVE TEST

CMS proposes to remove an additional 10 ICD-9-CM codes for amputation cases from the codes that qualify under the presumptive test, beginning Oct. 1, 2014. CMS's rationale for this change is that these diagnosis codes (shown in Table 7 of the rule) cannot, on their own, indicate whether a patient with an amputation status or with prosthetic fitting and adjustment needs has a condition for which IRF treatment is medically necessary.

We acknowledge that an ICD-9-CM "status" code *alone*, such as V49.75, below knee amputation status, does not provide specific enough information to determine whether the patient has a condition for which he or she would qualify for treatment at an IRF. Specifically, the ICD-9-CM code alone does not specify how long ago the amputation occurred (immediately before the IRF admission or years before), the underlying condition which precipitated the amputation, or which side of the body was affected. However, the loss of a limb is a major medical event and, at a minimum, it is a complicating comorbidity. Rehabilitation care and treatment will be different for a patient who has sustained an amputation in the past compared to other patients. These patients will have impairments related to their ability to conduct activities of daily living, significantly different safety concerns and challenges related to their ability to balance themselves.

Therefore, we urge CMS to retain the amputation status codes as qualifying codes, but consider them in conjunction with other related information in the inpatient rehabilitation facility-patient assessment instrument (IRF-PAI), as well as the imminent implementation of the more granular ICD-10-CM diagnosis codes. Specifically, the status codes can be used in combination with the etiologic diagnosis (the primary reason that led to the condition for which the patient is receiving rehabilitation), which will reflect recent injuries, in the IRF-PAI, and other comorbidity diagnosis codes to provide a more complete clinical picture of the patient. For example, a patient who has suffered multiple major traumas affecting the right leg, but also had a left-sided, below-the-knee amputation in the distant past, will have additional challenges requiring intensive rehabilitation to regain strength and mobility of the right limb – the remaining leg. We acknowledge that the ICD-9-CM codes for traumatic injury do not specify which side of the body was affected, but the more granular ICD-10-CM diagnosis codes do specify whether the right or left side was injured, while the "status post amputation" codes specify whether it is the right, left or unspecified limb. The additional information provided by the ICD-10-CM diagnosis codes will help support amputation as a qualifying condition under the presumptive test.

[1] Medicare Payment Advisory Commission Report to Congress. March 2013. Pages 224-225.

PROPOSED REMOVAL OF IMPAIRMENT GROUP CODES (IGCs) FROM PRESUMPTIVE TEST

IGCs are a unique set of codes specifically developed for the IRF PPS that indicate the primary medical reason for admission to an IRF, and are separate from ICD-9-CM codes. CMS proposes to remove the following four IGCs, beginning Oct. 1, 2014, from those that qualify under the presumptive 60% Rule test:

IGC 0005.1 – Unilateral upper limb above the elbow;
IGC 0005.2 – Unilateral upper limb below the elbow;
IGC 0006.1 – Rheumatoid arthritis; and
IGC 0006.9 – Other arthritis.

We oppose the removal of IGC 0005.1, Unilateral upper limb above the elbow, and IGC 0005.2, Unilateral upper limb below the elbow. As noted earlier, a patient who has sustained an amputation in the past will who will need different rehabilitation care and treatment than other patients. Specifically, these patients will have impairments related to their ability to conduct activities of daily living, significantly different safety concerns, and challenges related to their ability to balance themselves. As such, these codes should be retained.

We also oppose the removal of IGC 0006.1, Rheumatoid arthritis, and IGC 0006.9, Other arthritis, at the same time that CMS is proposing to implement a new IRF-PAI item for arthritis diagnosis codes. While CMS has stated that additional information beyond these IGCs is necessary to determine whether the medical record would support counting these cases toward the 60% Rule, the proposed rule notes that the new IRF-PAI item for arthritis diagnosis could "indicate that the prior treatment and severity requirements had been met for patients with arthritis conditions." Therefore, we urge CMS to consider IGCs 0006.1 and 0006.9 *in conjunction with* the new IRF-PAI item to determine presumptive compliance. The new IRF-PAI item should not be limited to use *after* a provider has failed the presumptive compliance test and is undergoing medical record review.

PROPOSED EXCLUSION OF IGCS THAT ARE ETIOLOGIC DIAGNOSES

The proposed rule seeks to revise Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria by revising the diagnosis codes listed as exclusions on the table and by revising the title of the table. The proposed rule would exclude 24 IGCs from qualifying under the presumptive test because they correspond to etiologic diagnoses that already have been excluded from the presumptive test by CMS.

We request that CMS specifically confirm that the changes to the "Impairment Group Codes That Meet Presumptive Compliance Criteria" list are a consequence of the removal of the 259 ICD-9-CM codes from those that meet the presumptive test, as finalized in the FY 2014 final rule – IRF providers have found the revisions and title of the table confusing. **And we urge CMS, in its clarification of the scope and intent of Appendix B, to explain how the IGCs in the appendix would not remove any further cases from compliance with the presumptive**

test, beyond those that were removed under the ICD-9-CM restrictions in the 2014 final rule.

Non-specific ICD-9-CM Diagnosis Codes. The AHA agrees that, whenever possible, IRFs should use the most specific code possible to describe a medical disease, condition or injury on the IRF-PAI. **However, we continue to strongly object to CMS's indiscriminate proposed approach of uniformly removing non-specific codes whenever more specific codes are available.** We note that the ability of IRFs to obtain more specific codes from the referring hospital, instead of using non-specific codes, is often administratively unrealistic. IRFs have to rely on the documentation provided by the referring general acute care hospital when assigning certain codes to describe the patient's status. It can be very difficult to obtain detailed medical documentation from the transferring facility, especially when the transferring facility itself may not have the level of specificity required by the proposed changes. The difficulty is compounded when the IRF admission is not directly from a general acute care hospital, for example, when a patient is discharged from a general acute care hospital, then treated in a long-term care hospital, and then transferred to an IRF.

Therefore, we urge CMS not to exclude non-specific etiologic diagnosis codes from the IGCs. Also, we disagree with CMS's estimate that this change will not have any significant financial effects on IRFs, as "IRFs will be able to switch to using the more specific codes that are available for the Etiologic Diagnoses instead." As alluded to above, we do not believe that IRFs will be able to actually find and/or use more specific codes for etiologic diagnoses in every case. First, while many hospitals are working with their physicians to improve the quality and specificity of their medical documentation in preparation for ICD-10-CM and ICD-10-PCS implementation and to mitigate the risk of payment denials due to audits by Medicare contractors, improvements in the specificity of the documentation will take time. It is therefore, again, administratively and clinically unfeasible to require IRFs to obtain the more specific codes, as illustrated below with the hip fracture and joint replacement and TBI examples.

In addition, there is no clinical rationale for excluding these codes. Unspecified codes do not reflect either poor documentation or poor coding. **We urge the agency not to finalize any of its proposals to remove non-specific codes from the list of qualifying codes. The examples below illustrate that CMS's proposals do not further ensure that IRFs are concentrated on treating medically appropriate patients.**

IGCs 08.11, Unilateral Hip Fracture, and 08.12, Bilateral Hip Fracture. CMS proposes to eliminate ICD-9-CM codes 820.8 and 820.9 for hip fractures, which generally correspond to IGCs 08.11 and 08.12, from the list of 60% Rule Etiologic Diagnosis qualifying codes. However, these codes specify the fracture of the neck of the femur – they are not unspecified codes – and CMS does not set forth a clinical rationale for their elimination. Our member IRFs indicate that they use the combination of IGCs 08.11 or 08.12 and Etiologic Diagnosis ICD-9-CM codes 820.8 or 820.9 to code hip fractures. ICD-9-CM diagnosis codes 820.8 and 820.9 still represent a hip fracture that is listed as a qualifying condition in 42 CFR 412.29(b)(2) which only specifies "fracture of femur (hip fracture)" and not a specific segment of the femur. It is unlikely

that more information will be readily available or provide meaningful additional specificity. For example, it is unlikely that the physician documentation would reflect anything more specific without a copy of the X-ray report, yet the X-ray may have been taken in an emergency department at a general acute-care hospital, in a nursing home or some other location, and therefore not available as part of the IRF record. Further, any additional specificity indicating which portion of the neck of the femur is affected would not impact the type or intensity of rehabilitation services the patient requires and therefore would not further CMS's ability to ensure IRFs are treating medically appropriate patients.

Hip and Knee Replacement IGCs (08.51–08.72). CMS proposes to refine hip and knee replacement IGCs by excluding various ICD-9-CM diagnosis codes for osteoarthritis as etiologic diagnoses. This proposed refinement seems to exclude knee replacement, hip replacement or both during an acute hospitalization immediately preceding the IRF stay from the list of qualifying codes. However, it does not consider the three clinical criteria specifically identified as qualifying conditions in 42 CFR 412.29(b)(2):

- The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission;
- The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF; and
- The patient is age 85 or older at the time of admission to the IRF.

We believe that compliance with these three clinical criteria can be demonstrated with a combination of diagnosis codes (either ICD-9-CM or ICD-10-CM) and either adding new data items to the IRF-PAI or using existing data items in the IRF-PAI, as follows:

- *The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute care hospital admission immediately preceding the IRF admission* – This information would require a new IRF-PAI data item to identify this criterion has been met. While the addition of a new item, such as this one, creates additional administrative work, we believe that it would result in considerably less burden than requiring audit review.
- *The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF* – This information can be reported using existing ICD-9-CM codes (V85.43, V85.44 or V85.45), or ICD-10-CM codes (Z68.43, Z68.44 or Z68.45).
- *The patient is age 85 or older at the time of admission to the IRF* – Given that the patient's date of birth is an existing field in the IRF-PAI, this information can be easily calculated.

IGC 02.22, TBI, Closed Injury and IGC 02.21, TBI, Open Injury. CMS proposes to remove approximately 90 ICD-9-CM codes for traumatic brain injuries from the list of 60% Rule etiologic diagnosis qualifying codes, which generally correspond to IGCs 02.22 and 02.21, including codes for skull fractures, cerebral lacerations and concussions, seemingly because these codes do not identify the duration of the patient's loss of consciousness (LOC). **We oppose this proposal, as the elimination of these codes is administratively and clinically**

unrealistic. For example, when the LOC is of short duration, the LOC information may be typically recorded at the scene of the injury by the emergency medical technician or the ambulance driver, and often is not available to the receiving IRF. As another example, a patient may sustain a fall at home. The patient's family may notice that the patient does not appear "right" and mobility is declining, prompting a visit to the emergency department where a diagnosis of subdural hematoma is made. After treatment in a general acute-care hospital, the patient is then transferred to the IRF to address mobility issues associated with a traumatic brain injury. In this example, neither the family nor the discharging general acute-care hospital possess or relay this information to the receiving IRF regarding the original LOC that precipitated the initial trip to the emergency department. Yet, despite the absence of this information, at the point of discharge from the general acute-care hospital, the patient's medical necessity for IRF services can be assessed without this information.

It is also technically inconsistent to exclude ICD-9-CM diagnosis codes for head injuries that do not specify the duration of the patient's LOC when it appears that LOC is not required for IRF admission. Specifically, IGC 02.22 and 02.21 would qualify for the 60% Rule presumptive test in conjunction with these two correlated ICD-9-CM codes, which specify "no loss of consciousness": 850.0, concussion with no loss of consciousness; and 800.61, open fracture of vault of skull with cerebral laceration and contusion, with no loss of consciousness. Therefore, these two IGCs should not be exempted from the 60% Rule presumptive test.

PROPOSED GROUP THERAPY REPORTING

In the proposed rule, CMS expresses interest in learning more about how group therapy fits within the overall IRF scope of services. We support the agency's plan to collect more data on group therapy to facilitate study of the role that this therapy mode plays in treating IRF patients, but note with concern CMS's intent to use its findings as it weighs a future group therapy cap per patient. As the agency proceeds, we encourage CMS to recognize the clinical value and advantages group therapy provides over other therapy modes for certain patients.

Group therapy is the preferred treatment method for patients for whom medical improvement, restoration of functional independence and the achievement of patient education goals are advanced through the social interaction and motivation gained through the group dynamic. The following examples illustrate clinical scenarios for which group therapy is advantageous:

- Speech therapy for patients recovering from conditions such as strokes can be more efficacious in a group setting. Speech therapy in a group promotes advances in conversational abilities that are more difficult to attain in a non-social setting and, as an added benefit, enhances community reintegration – a core mission of IRFs.
- Feeding therapy provided by an occupational therapist to patients recovering from brain and spinal cord injuries and other conditions also can be more beneficial to the patient when delivered in a group setting, as patients gain the added benefit of observing and learning from therapy advances of other patients in the group.

While the proposed rule states that group therapy remains widely used, many AHA members report using group therapy in a limited fashion, often only after the patient has received three hours of individual therapy per day. **As such, to enable the agency to better understand the range of group therapy practices, we generally support CMS's plan to collect data on group therapy practices.** When using these new data, the agency should be able to acquire a clearer profile of group therapy practices, and we encourage the agency to share such findings with providers.

In addition, the agency proposes new definitions for individual, group and co-treatment therapies that would apply to the therapy data collection process, but fails to provide a clinical foundation for the specifics in the proposed definitions. **We are concerned that CMS has not shared the origin and clinical rationale of these definitions, and encourage CMS to share any data or other analyses that support the proposed therapy definitions prior to their finalization.**

Of particular concern are two issues pertaining to the proposed definition for group therapy. First, the proposed rule does not provide CMS's clinical bases for defining group therapy in IRFs as groups of two to six patients, when, as a point of comparison, group therapy in a SNF applies exclusively to groups with four patients. In addition, it is unclear why CMS has not also provided a distinct definition for concurrent therapy, when this common IRF modality is clinically and structurally distinct from group therapy. We discourage CMS from blending concurrent therapy (one therapist providing *different* therapy for two patients) into the group therapy (one therapist providing the *same* therapy to two or more patients) definition. **Instead, CMS should add a distinct definition for concurrent therapy.**

The proposed rule discusses a potential, future individual cap for group therapy of 25 percent of total therapy received during an IRF stay. **Given that CMS still lacks the insights that would be gained through the proposed new collection of group therapy information, it is premature for CMS to contemplate a specific group therapy cap per patient.** Rather, CMS should collect the new information on group therapy, assess and share the findings, and then, prospectively from that point, consider the need for any policy changes based on the new data.

Finally, while we support this proposed new data collection, we remain concerned about the overall burden IRFs would face under the new group therapy reporting requirements. We are particularly concerned with CMS's estimate that the collection of new group therapy data would require 4 additional minutes per assessment, given the regulation's lack of explanation of the methodology used to calculate this estimate. We believe that implementation of electronic medical records across the IRF field is highly varied, and as such, the experience of adding new data collection and reporting duties would substantially vary by IRF. Further, when combined with existing reporting, the work that would be required to retrain staff to adapt to new 60% Rule guidelines and the growing IRF quality reporting program (QRP), the new group therapy reporting activities would represent a material addition to the administrative and reporting burden facing IRFs. **We urge CMS to respond to these concerns by explaining their burden estimate methodology, including sharing distinct estimates for IRFs using electronic medical records versus providers without.**

PROPOSED CHANGES TO THE IRF QRP

FY 2017 MEASUREMENT PROPOSALS

CMS proposes to add two additional healthcare-associated infection (HAI) measures to the IRF QRP for FY 2017—*Methicillin-resistant Staphylococcus aureus* (MRSA) bacteremia and *Clostridium difficile (C. Difficile) infection.* CMS proposes to collect both measures using the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) submission tool. IRFs also are required to use NHSN to submit the healthcare personnel influenza vaccination and catheter-associated urinary tract infection (CAUTI) measures finalized for the IRF QRP in previous rulemaking. Both measures are endorsed by the National Quality Forum (NQF) and have been reviewed by the Measure Applications Partnership (MAP). However, the MAP only conditionally supported these measures, citing concerns that the measures may not be ready for implementation in IRFs.

The AHA agrees with the MAP's assessment and recommends that CMS not add the MRSA and *C. Difficile* measures to the program at this time. We agree with the MAP that the measures would benefit from additional testing in the IRF environment before being added to the IRF QRP. In order to accurately assess the occurrence of MRSA and *C. Difficile* in a specific IRF, and compare that facility's results to those of others, the measures' specifications must be shown to obtain accurate results in the IRF environment.

Moreover, while the AHA strongly agrees that reducing preventable HAIs is an important goal for the health care system in general, we are not confident that the addition of these particular HAI measures to the IRF QRP will meaningfully contribute to that goal. The decision to add a measure to a particular care setting should not be driven simply by the availability of a measure from another care setting. Rather, there should be compelling evidence that the measure would help address an issue of importance to the patient population being served. Without such evidence, the considerable resources required to collect and report data yield little benefit to patient care. It was appropriate for CMS to adopt NHSN's CAUTI measure for the IRF QRP because of the prevalence of urinary catheters in IRFs. However, the only data on the national prevalence of MRSA and *C. Difficile* in IRFs the agency is able to cite are based on an analysis of five-year-old Medicare claims. Further, because IRF claims lack a present on admission indicator, the agency cannot determine whether the MRSA and *C. Difficile* infections in those claims were acquired during the IRF stay or in the community.

We remind the agency that the purpose of the NHSN HAI measures is to assess facilities on whether they are doing everything they can to prevent infections during the course of patient care. The NHSN measures specifically exclude infections that are present on admission so that providers can assess whether their approaches to reducing HAIs are effective, and so that they can be held accountable for the results of their interventions. We certainly commend CMS for continuing to focus on reducing HAIs, and strongly agree that providers should take steps to prevent them. However, if the agency wishes to include additional HAI measures in the IRF QRP in future years, then it should analyze clinical data to determine the most prevalent and important HAIs to be reported by IRFs.

FUTURE MEASUREMENT TOPICS

CMS solicits comment on several specific quality measures and measurement topics it is considering for future use in the IRF QRP. Notably, the agency is considering the implementation of four functional status measures. In general, functional status measures assess the extent to which patients regain the ability to perform activities (or "functions") essential to daily living. As we understand them, the IRF functional status measures are intended to assess whether IRF patients show improvement in two functional areas – "self-care" (e.g., eating, bathing and oral hygiene) and mobility (e.g., ability to sit up, stand, walk, get into a car). IRFs would be expected to complete detailed assessments of each patient's self-care and mobility functions at the times of admission and discharge using the Continuity Assessment Record and Evaluation (CARE) tool, which was initially developed as part of the Post-Acute Care Reform Demonstration (PAC-PRD). The results of the admission and discharge assessments would be converted into functional status scores. IRFs would receive two scores – one that reflects the difference in self-care and mobility function scores between admission and discharge, and another showing functional status scores at the time of discharge.

The AHA agrees that functional status is a measure gap for IRFs, and we commend CMS for developing measures that would address this important area. However, the measures, as currently designed, will require significant changes before they are appropriate for the IRF QRP. Most notably, the AHA is concerned that the data collection mechanism for the measures – the CARE tool – is not aligned with the CMS-mandated patient assessment instrument used by IRFs, the IRF-PAI. In stating this concern, we recognize that the original intent of the CARE tool was to provide a common mechanism for collecting consistent data on the clinical status and health resources provided to patients in all post-acute settings. The AHA agrees that collecting common data across post-acute providers is a laudable goal that could enhance the coordination of post-acute care and promote comparability of quality data across care settings. Several patient post-acute patient assessment instruments in addition to the CARE tool have emerged in recent years, however, and we welcome the opportunity to work with CMS in the future on the development of an appropriately designed common assessment tool.

However, the IRF-specific measure titles, as well as the inclusion of the measures on the MAP's pre-rulemaking list for the IRF QRP, suggest that these measures are envisioned for near-term implementation in IRFs. For these reasons, we believe that the measures should be designed to allow IRFs to collect measure data using existing data collection mechanisms. This approach would allow for the measures to be implemented in the IRF QRP more quickly and would reduce the burden of data collection.

Therefore, we recommend that CMS consider re-specifying the IRF functional status measures so that measure data can be collected using the IRF-PAI. CMS already requires IRFs to use the IRF-PAI to collect and report quality measure data in the IRF QRP program. Moreover, the IRF-PAI already includes items that assess patient mobility and self-care functions, making measure data readily available. The use of the CARE tool to collect measure data would, therefore, be unnecessarily redundant.

Moreover, this redundancy in data collection could introduce not only confusion among IRFs in reporting measure data, but also an unintended misalignment between IRF quality improvement efforts and reimbursement. As currently designed, the CARE tool and IRF-PAI use different "rating scales" to assess patient function. That is, the CARE tool rates patient function using six levels, while the IRF-PAI uses seven levels. The IRF staff collecting assessment information may inadvertently conflate the two scales, leading to the reporting of inaccurate data into both assessment instruments.

Lastly, in re-specifying the measures, CMS should pay particular attention to the risk adjustment methodology. Indeed, improvements in functional status depend on a variety of factors such as age, medical diagnoses and severity of illness. Appropriate risk adjustment ensures that measure results reflect real differences in quality of care provided by IRFs, and not simply the differences in an IRF's mix of patients. The draft specifications provided for public comment list several proposed risk adjustment factors (e.g., age, diagnosis and prior mobility status), but do not provide an empirical analysis of how those factors were chosen and tested. Once the measure development process is complete, we strongly urge CMS to make all testing data publicly available – including data related to the risk-adjustment model – to allow all stakeholders to replicate and evaluate. These risk adjustment data also should be submitted as part of the NQF endorsement process, and the AHA strongly recommends that the measures receive NQF endorsement before they are implemented in programs.

DATA SUBMISSION REQUIREMENTS

For the FY 2016 IRF QRP program, CMS proposes to establish, for the first time, data completeness standards and a measure validation process for the IRF QRP. CMS proposes that IRFs that do not comply with all data submission requirements – including the completeness and validation requirements – will be subject to a 2 percent reduction to the annual payment update, as permitted by statute.

Data Completeness. IRFs currently submit measure data using two mechanisms. The measures collected using the IRF-PAI are submitted using CMS's Quality Improvement Evaluation System (QIES), while HAI measures are submitted using the CDC's NHSN. CMS proposes that IRFs must submit data via the QIES that is at least 80 percent complete, while data submitted using the NHSN must be 100 percent complete. CMS states that QIES data will have met its proposed completeness threshold if 95 percent of an IRF's submitted IRF-PAI assessments contain 100 percent of the required quality indicator data items. For the HAI measures submitted via NHSN, CMS proposes to require IRFs to complete all data fields required for measure numerator and denominator data. **The AHA believes that data completeness standards will facilitate more accurate public reporting in the future. Therefore, we support the agency's proposals.**

Measure Validation. Measure validation processes are used in other CMS quality reporting programs, such as the hospital IQR program, to ensure that measure data have been accurately collected, thereby enhancing the accuracy of measure results. For FY 2016, CMS proposes to validate only the pressure ulcer measure collected using the IRF-PAI. CMS proposes to perform

validation on a random sample of 260 IRFs, and would randomly select five IRF-PAI assessments from each IRF in the validation group. CMS contractors would then request medical record data from the IRFs, and compare the data elements in the patient chart to the quality measure data submitted by the IRFs to CMS, identifying any differences that would affect the measure rate. The contractor would then calculate a percentage of matching data elements, creating a validation score. CMS proposes that IRFs selected for validation must achieve at least a 75 percent validation score.

The AHA believes that data completeness standards will facilitate more accurate public reporting in the future, and we support CMS's proposed numerical standards for data completeness. However, we recommend the agency apply the standards no earlier than FY 2017 payment determination, instead of FY 2016. The FY 2016 data collection period for the pressure ulcer measure is Jan. 1 through Sep. 30, 2014, and Jan. 1 through Dec. 31, 2014 for the HAI measures. Thus, much of the data for FY 2016 data already have been submitted by IRFs. It would be inappropriate and unfair to apply to the data completeness standards to data submitted before the standards were even proposed and, therefore, known to IRFs. Indeed, in the hospital IQR program, changes to data submission standards are proposed in advance of—not during or after—the data collection period. However, it would be reasonable to implement the standards for FY 2017 payment determination, as the FY 2017 data collection periods are Oct. 1, 2014 through Sep. 30, 2015 for the pressure ulcer measure, and Jan. 1 – Dec. 31, 2015 for the HAI measures.

Reconsiderations and Appeals Process. In last year's IRF PPS final rule, CMS finalized a reconsideration and appeals process for IRFs beginning with FY 2015 payments that allows IRFs to appeal findings of non-compliance with the IRF QRP program. CMS proposes to continue this process for FY 2016, and indicates that the reconsideration process will take into account the proposed data completeness and validation requirements. **The AHA supports this proposal.**

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/

Linda E. Fishman
Senior Vice President
Public Policy Analysis & Development