June 26, 2017

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

RE: CMS-1671-P "Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2018, Proposed Rule" 82 Fed. Reg. 20690 (May 3, 2017)

Dear Administrator Verma,

On behalf of our more than 400 member hospitals and health systems, including all of New Jersey's inpatient rehabilitation facilities and units, the New Jersey Hospital Association (NJHA) appreciates the opportunity to comment on the IRF fiscal year (FY) 2018 proposed prospective payment system rule. This letter addresses our concerns regarding the 60 percent rule and the IRF Quality Reporting Program (QRP).

REFINEMENT OF CODES FROM THE 60% RULE PRESUMPTIVE TEST

The CMS 13 that comprise the 60 percent rule which was implemented in 2004 no longer aligns with patient-centered care or current medical practice. Overall, NJHA believes that the 60 percent rule should be eliminated because it is inconsistent with Medicare intent and direction of the Medicare program overall and because of the consequences it has on access to intensive rehabilitation services. Another option, if CMS chooses to retain the 60 percent rule, would be to expand the CMS 13 to include cardiac, pulmonary, cancer and organ transplant diagnoses and to lower the threshold to 50 percent. Since 2004, an increased need for intensive rehabilitation services has been identified for these categories of patients because of advances in medicine and changes in expected outcomes.

NJHA recommends the continued inclusion of the other IRF classification criteria that relate to the services and program structure provided, including multi-disciplinary medical teams, pre-admission screening requirements, intensive rehabilitation programs, and intensity of medical supervision. This would ensure that a physician's judgment on the need for admission based on the services provided at an IRF does not continue to be usurped by the 60 percent rule.

Since FY 2016, health care facilities have migrated from ICD-9-CM to ICD-10-CM diagnosis codes in compliance with the HIPAA code set standards. We support CMS efforts to correct errors that occurred in the application of the presumptive test related to the conversion to ICD-10. These errors resulted in certain diagnosis codes inadvertently omitted from counting towards

the 60 percent rule or changes in codes because of the conversion to ICD-10-CM. However, there are additional areas for improvement as noted below.

Transparency. Some of the proposed changes to this set of codes, as well as changes in prior years, have been supported with only a limited clinical and/or policy rationale. The absence of a detailed policy rationale results in a seemingly arbitrary proposal. As a result, it is difficult to determine whether the changes are based on purely the annual ICD-10-CM code changes, clinical reasons, policy changes or a combination of different reasons. In addition, it is nearly impossible to analyze and plan for the potential impact to provider's operations. **With regard to the current proposed coding changes, and those in future rules, we urge CMS to provide greater transparency by sharing a comprehensive policy rationale, with supporting data, for each proposed coding change.**

Furthermore, many of the proposed changes to the conditions that count presumptively toward the 60 percent rule are difficult to identify because of the format in which they are presented in the proposed rule. Specifically, the proposed rule points to the CMS website for the list of current ICD-10-CM codes used to perform the presumptive methodology and then a separate list for those codes used in the future. This format requires commenters to review thousands of diagnosis codes to compare the current list against the future list to identify the differences between the two. CMS does not identify specific proposed changes with specific rationales.

In the future, NJHA respectfully suggests that CMS provide separate tables in proposed and final rules for "additions" and "deletions" of ICD-10-CM codes, as well as a discussion of the rationale for the changes. Displaying separate tables will allow IRF providers to clearly identify the changes, analyze them and use the explanation to help educate patients and staff.

Traumatic Brain Injury. We applaud CMS' proposal to restore many of the ICD-10-CM codes for traumatic brain injury with either unspecified or no loss of consciousness (LOC). The lack of specificity regarding the length of LOC does not automatically equate to poor documentation. There are many instances where the information is administratively and/or clinically unavailable. IRFs should not be penalized for patients who have suffered traumatic brain injuries where it is not possible to determine if the patient lost consciousness or not, or if the patient did lose consciousness, for how long.

We urge CMS to reconsider clinically similar codes for fracture of the base of the skull with cerebral laceration or contusion. These codes were inexplicably excluded from Impairment Group Code (IGC) Brain Dysfunction - 0002.22, Traumatic, Closed Injury. The excluded etiology and IGC pairing list completely excludes the case from qualifying. In addition, it is the first step used to determine if a case is compliant and whether it excludes ICD-10-CM codes for fractures of the base of skull codes (choice A) ***if*** paired with a code from (choice B). The specific code pairs are shown in the table below.

ICD-10 Code	Choice	Code Title
S02.101A	A	Fracture of base of skull, right side, initial encounter for closed fracture
S02.102A	A	Fracture of base of skull, left side, initial encounter for closed fracture
S06.330A	B	Contusion and laceration of cerebrum, unspecified, without loss of consciousness, initial encounter
S02.101A	A	Fracture of base of skull, right side, initial encounter for closed fracture
S02.102A	A	Fracture of base of skull, left side, initial encounter for closed fracture
S06.360A	B	Traumatic hemorrhage of cerebrum, unspecified, without loss of consciousness, initial encounter
S02.101A	A	Fracture of base of skull, right side, initial encounter for closed fracture
S02.102A	A	Fracture of base of skull, left side, initial encounter for closed fracture
S06.9X9A	B	Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter
S02.91XA	A	Unspecified fracture of skull, initial encounter for closed fracture
S06.330A	B	Contusion and laceration of cerebrum, unspecified, without loss of consciousness, initial encounter
S02.91XA	A	Unspecified fracture of skull, initial encounter for closed fracture
S06.360A	B	Traumatic hemorrhage of cerebrum, unspecified, without loss of consciousness, initial encounter
S02.91XA	A	Unspecified fracture of skull, initial encounter for closed fracture
S06.9X9A	B	Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter

The exclusion of the above code pairs does not make sense either clinically or from a coding perspective. ICD-10-CM category, "S02, Fracture of skull and facial bones," has an instructional note to "Code also any associated intracranial injury (S06.-)."

Hip Fractures. NJHA also supports CMS' proposal to allow ICD-10-CM codes for fractures of "unspecified part of the neck of the femur" which counted towards 60 percent rule compliance under ICD-9-CM. The rehabilitation treatment plan for femoral neck fracture is the same whether specified to a specific part of the femur or not. Attempts to obtain more specificity from radiologists have not been successful as radiologists have been either unable or unwilling to be more specific in the X-ray impression for "femoral neck."

Multiple Trauma. The General Equivalence Mappings (GEMs) incorrectly mapped ICD-9-CM diagnosis code 828.0, Multiple *fractures* involving both lower limbs, lower with upper limb, and

lower limb (s) with rib (s) and sternum, to ICD-10-CM code T07, Unspecified multiple injuries. **We agree with CMS's proposal to correct this error by counting IRF-PAIs that contain two or more of the ICD-10-CM codes from three major multiple trauma lists in specified combinations.**

Traumatic Injuries. Most ICD-10-CM code categories for chapter 19 (Injury, poisoning, and certain other consequences of external causes) require a 7th character for initial encounter (A), subsequent encounter (D) and sequela (S). Categories for traumatic fractures have additional 7th character values. However, only the 7th characters for "initial encounter" and "sequela" have been included in the Presumptive Compliance List 2. The *Coding Clinic for ICD-10-CM and ICD-10-PCS* Editorial Advisory Board (which has representation from CMS and the Centers for Disease Control and Prevention as the ICD-10 code set maintainers) has provided several examples of the correct application of the 7th character. These examples demonstrate that "subsequent encounter" is the correct option for rehabilitation services, and **we urge CMS to include the applicable 7th character for "subsequent encounter" in the Presumptive Compliance List 2. IRF providers should follow all official ICD-10-CM coding rules regardless of the payer. This approach eliminates the need to keep up with different sets of coding rules.**

ICD-10-CM Code G72.89, Other Specified Myopathies. CMS is proposing to remove code G72.89 citing inconsistent use of this code among IRFs, including representing patients with generalized weakness who do not meet the requirements of the 60 percent rule. We agree that code G72.89 is not the correct code for generalized weakness or general debility. **However, we recommend CMS provide education on the appropriate use of this code, monitor its usage, and then reevaluate the utilization of this code. We are concerned that eliminating the code would inappropriately disqualify true myopathy cases.**

Sub-regulatory Process for Updates to Presumptive Methodology Diagnosis Code Lists. CMS is proposing a sub-regulatory process for non-substantive updates to the ICD-10-CM Presumptive Methodology Code List. Notice-and-comment rulemaking would be reserved for substantive changes. CMS appears to consider annual changes to the medical code sets made by the ICD-10 Coordination and Maintenance Committee the type of changes to be addressed through a sub-regulatory process. CMS would apply all relevant changes to the list of codes used in the presumptive compliance methodology so that the codes on that list would be consistent with the most recent ICD-10 medical code set. CMS says that it would apply the changes without regard to any policy judgments about use of the codes for the presumptive compliance methodology. Substantive changes, such as removal of codes from the list, would occur through the notice-and-comment rulemaking process. Under the proposal, each year's updated lists of ICD-10-CM codes for the presumptive compliance methodology would be available on the IRF PPS website prior to the effective date of the changes in the ICD-10 medical code data set.

We recommend that rather than relying on a sub-regulatory process, CMS use formal rulemaking to identify both the additions and deletions to the presumptive methodology diagnosis code lists and allow providers the opportunity to review the accuracy of the codes. This process is similar to the process followed by CMS in the hospital inpatient PPS

where CMS publishes tables for proposed additions, deletions, revisions to the principal diagnosis, secondary diagnosis and complication/comorbidities/major complication comorbidities lists.

Implementation Timeline. CMS does not clearly state when it will implement the rule's proposed changes. **We recommend implementing changes related to correcting errors (e.g., multiple fractures and traumatic brain injuries) as soon as possible. However, providers will need at least one year to implement the more challenging changes related to compliance with the 60 percent rule (e.g., removing conditions from IGCs). In general, it is easier for providers to implement additions than deletions to the 60 percent rule. Deletions require a significant amount of time and effort to educate and train staff and clinicians.**

IRF QUALITY REPORTING PROGRAM (IRF QRP)

CMS proposes two new measures and the replacement of one measure for the FY 2020 IRF QRP. In addition, CMS would require IRFs to collect certain standardized patient assessment data beginning with IRF admissions on or after Oct. 1, 2018 to meet additional requirements mandated by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014.

While NJHA understands that the proposed measures are intended to address significant patient health outcomes, we believe the measures require additional improvement. We also believe that CMS's proposal to report standardized patient assessment data is too much, too soon, and we believe the data elements require further testing prior to implementation. Therefore, we urge CMS to delay its proposal to report standardized patient assessment data for at least one year.

FY2020 MEASUREMENT PROPOSALS

Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. **NJHA is concerned about the adoption of this measure for the IRF QRP because of the inclusion of unstageable pressure ulcers and deep tissue injuries (DTIs) in the measure calculation.** CMS suggests this change is appropriate because it would capture a fuller range of skin integrity issues. CMS further posits that this measure would help the agency meet its IMPACT Act mandate to implement "interoperable measures" across post-acute care (PAC) settings because this same measure is proposed for other post-acute settings.

However, NJHA is aware of the considerable debate surrounding pressure ulcer terminology and how pressure ulcers are defined. If the definition of pressure ulcers included in the measure is too subjective, it will be challenging to collect reliable, accurate measure data across IRFs and other PAC providers. As a result, the measure could provide misleading portrayals of IRF performance. As CMS admits in the proposed rule, there are few studies that provide information regarding the incidence of unstageable ulcers in PAC settings. In addition, there is no universally accepted definition for DTIs; in fact, studies have shown that a significant proportion of DTIs are initially misdiagnosed as stage 1 ulcers or other dermatological diagnoses with similar symptoms that are not intended to be captured by this measure. As a result, the measure may be subject to surveillance bias in which providers have higher rates of DTIs because their surveillance systems are more sensitive to capturing them.

In addition, we are concerned that the measure change would result in artificial distinctions between IRFs that are attributed solely to the way injuries are counted, not in the quality of care provided. Notwithstanding the lack of standardized definitions of and approaches to assessing DTIs and unstageable pressure ulcers, CMS believes one of the benefits of implementing this revised measure is that it would increase the variation in measure scores across providers, "thereby improving the ability to discriminate among poor- and high-

performing IRFs." **However, the purpose of changing a measure is not to create performance variation. Rather, any measure changes should be rooted in evidence that specifications are inconsistent with current science, or that specifications need further clarity to ensure consistent data collection across providers.**

Therefore, NJHA respectfully recommends that CMS undertake additional testing of the measure to ensure it consistently collects accurate data. We believe this testing should assess whether the measure is subject to surveillance bias and other unintended consequences that could affect how IRF performance is reported.

Providers will need CMS to provide clear and multiple opportunities for additional training, as well as updated educational materials. CMS is proposing significant changes to the measure data collection approach. Rather than assessing the number of new or worsened pressure ulcers at each stage (as in the current measure), CMS would ask IRFs to count the number of unhealed pressure ulcers at each stage and subtract the number present upon admission. We believe excluding those pressure ulcers that are present on admission is an appropriate improvement to the measure, but it adds complexity in coding that will be essential to explain to IRFs. Furthermore, IRF performance on the revised measure will likely look quite different from the current measure. Thus, CMS should prepare consumer-facing educational materials explaining why IRF performance is different.

<u>All-cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs.</u> **NJHA supports is pleased with CMS' proposal to remove this duplicative and confusing measure from the IRF QRP and supports its removal.** We continue to urge CMS to review the remaining readmission measures used across its post-acute quality programs to ensure that they create consistent improvement incentives across the system.

STANDARDIZED PATIENT ASSESSMENT DATA REPORTING

In addition to requiring standardization and alignment of quality measures, the IMPACT Act also requires the collection of standardized patient assessment data. The reporting of these data is a requirement of the PAC quality reporting programs; as a result, failure to comply with the requirements would result in a 2.0 percentage payment reduction. In an attempt to facilitate data sharing and comparisons across PAC settings, CMS proposes to introduce the required reporting of standardized data elements into each setting's respective assessment tools. For the IRF setting, this would entail the addition of several new data elements to the IRF-PAI. Specifically, the agency would require IRFs to collect data on functional status, cognitive function, medical conditions, impairments, and several types of special treatments and services. While PAC providers would fulfill the FY 2019 requirement by reporting data elements already implemented in the various quality reporting programs (namely, those used to calculate the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened, Short Stay), IRFs would be required to report data based on several new elements beginning Oct. 1, 2018.

NJHA believes the implementation of these data elements is too much, too soon. We urge CMS to delay the reporting of the data elements by at least one year. This approach would allow the reporting of elements associated with the Pressure Ulcer measure to fulfill the FY 2019 and 2020 requirements. **We also urge the agency to carefully assess whether all of these data elements are necessary to meet the IMPACT Act mandate.**

Validity and Reliability of Elements. Of the proposed 23 data elements, only five are currently reported in the IRF-PAI. The other 18 are used in other post-acute setting tools, mainly the Minimum Data Set (MDS) 3.0 used in skilled nursing facilities (SNFs). CMS purports that the use of these elements in the MDS and the testing in the Post-Acute Care Payment Reform Demonstration (PAC PRD) are sufficient to show that collection of these elements in the IRF setting is feasible and that the elements will result in valid and reliable data. Unfortunately, the PAC PRD results were significantly affected by small sample sizes, and the reliability of many data elements was poor. Thus, it is unwise to depend on the PAC PRD results to judge the integrity of the proposed IRF-PAI data elements. In addition, for several of the elements, the precise items CMS proposes to add have not been tested in the PAC PRD or another PAC setting; rather a similar or related item was deemed close enough and thus appropriate for implementation.

Considering that providers are asked to report on these 23 data elements for admissions and discharges beginning in little over a year and that failure to report would result in a significant decrease in their market basket update, **we believe that CMS lacks sufficient evidence that these data elements are ready for inclusion in the IRF QRP.**

Burden on Providers. As mentioned previously, CMS's proposal would add 18 new data elements to the already lengthy IRF-PAI. **Because many of these elements have multiple parts, this could result in 50 additional tasks for a provider.** While any one task may not take a long time to complete, the addition of all of these elements at once would change a IRF provider's workflow considerably.

In fact, CMS is currently engaged in multiple contracts to develop several additional standardized patient assessment data elements for future years in PAC QRPs. Unless CMS plans to significantly reduce the current reporting burdens on PAC providers, it is unrealistic to mandate that providers comply with an exponentially growing list of reporting requirements. Therefore, we strongly urge CMS to delay implementation of these new data elements. Because the IMPACT Act requires the collection of standardized patient assessment data for FY 2019 and each subsequent year, CMS could consider data already reported in a standardized manner across the various PAC settings to be sufficient for FY 2019 and FY 2020. CMS proposes that reporting of the elements used to calculate the Pressure Ulcer measure, which is implemented in all four PAC settings, would satisfy the statutory requirement.

IRF QRP PUBLIC REPORTING FOR CY 2018

CMS proposes to publicly report data in calendar year (CY) 2018 for three assessment-based measures and three claims-based measures. The claims-based measures were those adopted in the FY 2017 inpatient PPS and IRF final rules, and include:

- Medicare Spending Per Beneficiary;
- Discharge to Community; and
- Potentially Preventable 30-Day Post-Discharge Readmissions.

Sociodemographic Adjustment. NJHA believes IRF performance on all three measures may be impacted by sociodemographic factors. We urge CMS to assess each measure for the impact of such factors, and incorporate sociodemographic adjustment where necessary.

The evidence continues to mount that sociodemographic factors beyond providers' control – such as the availability of primary care, physical therapy, easy access to medications and appropriate food, and other supportive services – influence performance on outcome measures. Most recently, this connection was clearly shown in a report to Congress from the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and in the National Academy of Medicine's series of reports on accounting for social risk factors in Medicare programs. These reports provide evidence-based confirmation of what hospitals and other providers have long known: patients' sociodemographic and other social risk factors matter greatly when trying to assess the quality of health care providers.

Yet, to date, CMS has resisted calls to incorporate sociodemographic adjustment into the quality measurement programs for IRFs and other PAC providers. Failing to adjust measures for sociodemographic factors when necessary and appropriate can adversely affect patients and worsen health care disparities because the penalties divert resources away from providers treating large proportions of vulnerable patients. It also can mislead and confuse patients, payers and policymakers by shielding them from important community factors that contribute to worse outcomes. Thus, **we urge CMS to incorporate sociodemographic risk adjustment for these outcome measures.**

Medicare Spending per Beneficiary for IRFs (MSPB-IRF). NJHA respectfully recommends that CMS work with providers to explore the feasibility of incorporating an adjustment for patient functional status to this measure. We believe patient functional status is an important determinant of patient outcomes. CMS could examine whether reliable information on functional status could be collected from claims data. In addition, given that IRFs and other post-acute care providers are required by CMS to collect information on functional status as part of patient assessments, CMS should explore whether it is feasible and not overly burdensome to providers to incorporate information from these assessments into the risk model.

Discharge to Community. NJHA is very concerned about the reliability and validity of patient discharge codes used to calculate the discharge to community measure. The measure assesses the percentage of Medicare fee-for-service (FFS) patients discharged from IRFs to home or home

health care (i.e., “community discharges”) with no unplanned re-hospitalizations or deaths within 31 days of discharge. CMS would identify community discharges using patient discharge status codes recorded on Medicare FFS claims. However, as noted by MedPAC and in other published studies, patient status discharge codes often lack reliability. Given that they are so integral to the calculation of the discharge to community measure, CMS should test the measure to ensure it provides an accurate portrayal of performance.

Potentially Preventable Readmissions (PPRs). NJHA applauds CMS for proposing to remove the duplicative all-cause unplanned readmissions measure from the IRF QRP. However, we urge continued evaluation of the PPR measure. In particular, the categories and lists of “potentially preventable readmissions” should be based on careful evaluation by clinical experts and detailed testing. We appreciate that a technical expert panel was consulted on the list of categories and codes of readmissions considered “potentially preventable.” However, we strongly encourage CMS to undertake additional empirical testing to ensure there is evidence that the codes actually are associated with the identified categories.

FUTURE CONSIDERATIONS FOR THE IRF QRP

We appreciate the opportunity to provide input on the longer term proposals related to the IRF QRP.

Development of Experience of Care Survey-based Measures. **NJHA appreciates the value that patient experience surveys offer to help providers improve the engagement and satisfaction of patients and their families. However, most IRFs already are engaged in this process through validated tools such as Press Ganey and others at substantial cost.** It is critical that surveys include a manageable set of questions so that valuable patient time and finite provider resources are used efficiently and effectively, and SNFs actually obtain a valid response rate.

We urge that any patient experience of care survey for IRFs be carefully aligned with other surveys to reduce duplicative collection activities. A patient's course of care often crosses multiple care settings and providers within a given time period, and the Consumer Assessment of Providers and Systems (CAHPS) program has surveys for nearly every setting. Typically, surveys are not distributed until days or weeks after a patient has received their care. This may create confusion about which provider or facility is actually being assessed. A patient may inadvertently attribute a positive or negative experience to the wrong provider.

NJHA recommends that CMS include questions on an IRF experience of care survey that better address therapy services. In addition, we strongly recommend that CMS make a draft survey/questions and survey implementation processes publicly available and allow an opportunity for stakeholder input well in advance of implementing it in the IRF QRP.

Modification of Discharge to Community Measure. **NJHA supports the modification to this measure, which would exclude baseline nursing facility residents from the calculation.** As CMS notes, these residents did not live in the community prior to their IRF stay and thus would not necessarily be expected to return "successfully" to the community following discharge as specified in the measure. This modification would more accurately portray the quality of care provided by IRFs while controlling for factors outside of the IRF's control.

IMPACT Act Measures on Transfer of Information. **NJHA respectfully suggests that CMS be cautious in its development of these Transfer of Information measures, and only adopt the measures once they have received National Quality Forum (NQF) endorsement.** The measures under development include "Transfer of Information at Post-Acute Care Admission, Start or Resumption of Care from Other Providers/Settings" and "Transfer of Information at Post-Acute Care Discharge to Other Providers/Settings and End of Care." We agree that the transfer of information between and among PAC settings is vital to ensuring safe and high-quality patient care; however, these measures are still in the early stages of development.

The Measure Applications Partnership voiced concerns that the measures did not ensure that the information being transferred was standardized or provided in a sufficient manner to benefit the patient's care, and many participants of the MAP worried that this process measure would not yield any useful information that would result in improvements in care or patient outcomes.

As noted in the proposed rule, CMS intends to specify these measures no later than Oct. 1, 2018 and begin data collection on or about April 1, 2019. If these measures cannot pass the NQF endorsement process prior to those dates, **we urge CMS to delay implementation of these measures until they receive endorsement.**

Request for Information on CMS Flexibilities and Efficiencies

As stated earlier, NJHA believes CMS should consider revising the **IRF Classification Criteria by reducing the threshold of the 60 percent rule to a maximum of 50 percent. In addition, the list of 13 qualifying conditions that satisfy the compliance threshold should be expanded to include patients with cardiac conditions, COPD, organ transplant, cancer and femur fracture.**

In addition, NJHA recommends that CMS should clarify the coverage criteria as follows:

- **Simplify the Intensity of Therapy Requirement and Ensure that Contractors Apply It Correctly and Consistently**: CMS should simplify the intensity of therapy requirement to require that the aggregate amount of therapy over the course of the IRF stay aggregates to at least 15 hours per week, as is currently permitted under the benefit manual when certain circumstances allow.

- **Clarify Policies Regarding Delivery of Non-Individual Therapy**: CMS should clarify in sub-regulatory guidance documents that group and concurrent therapy count toward the intensity of therapy requirement (*i.e.*,3-Hour Rule) when determined to be medically appropriate by the rehabilitation physician and therapy teams and documented accordingly.

NJHA sincerely appreciates the opportunity to submit comments on the IRF PPS proposed rule and to support many of the comments submitted by AHA and AMRPA. If you have questions concerning our comments, please feel free to contact me at 609-275-4102 or via email at tedelstein@njha.com

Sincerely,

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