

June 26, 2017



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

Dear Ms. Verma:

***RE: CMS-1671-P, Medicare Program; Inpatient Rehabilitation Facility
Prospective Payment System for Federal Fiscal Year 2018.***

Dear Ms. Verma:

On behalf of the Arizona Hospital and Healthcare Association (AzHHA) and our more than 80 hospital, healthcare and affiliated health system members, thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2018 proposed rule for the IRF prospective payment system (PPS). Our comments address concerns related to the coding guidelines for the IRF "60% Rule" presumptive compliance test and quality-reporting provisions in the proposed rule. **Specifically, we support several of the proposed coding changes, but have concerns about others, including a lack of sufficient information to support some of these changes. We also recommend CMS reconsider some changes made to the IRF quality reporting program (QRP), including delaying implementation of new standardized patient assessment data elements into the IRF Patient Assessment Instrument (PAI).**

THE 60% RULE PRESUMPTIVE COMPLIANCE TEST

Technical Corrections

CMS is proposing to make changes to the IRF 60% Rule's presumptive compliance framework by adding and removing multiple patient diagnosis codes from the presumptive compliance list, that is the list of codes that require no other information in order to "count" toward satisfying the 60% Rule. Certain codes for traumatic brain injury (TBI), hip fracture, and major multiple trauma diagnoses would be restored to the 60% Rule's list of presumptively compliant codes, in order to correct technical errors associated with the transition to ICD-10. These errors caused diagnoses that were previously included in the presumptive compliance framework as expressed in their ICD-9 code format to no longer "count" in their ICD-10 format. **AzHHA fully supports the restoration of the codes associated with TBI, hip fracture and**

multiple trauma diagnoses to the 60% Rule's list of presumptively compliant codes.

In addition, under TBI, 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 exclusion of these 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.-)."

ICD-10-CM Code G72.89, Other Specified Myopathies.

CMS proposes 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% Rule. CMS further says G72.89 should be utilized based upon the results of specific medical testing. However, medical testing results by themselves should not be determinative of whether a case is justified for IRF treatment. Physicians and medical practitioners in some cases can clinically diagnose the presence of "Other Specified Myopathies" without subjecting the patient to additional testing. While we generally agree that code G72.89 is not the correct code for generalized weakness or general debility, we are concerned that eliminating this code would inappropriately disqualify true myopathy case. **We recommend CMS provide education on the appropriate use of this code, monitor its usage, and then reevaluate the utilization of this code.**

Subregulatory Process

CMS proposes establishing a subregulatory process for non-substantive updates to the ICD-10-CM Presumptive Methodology Code List. Notice-and-comment rulemaking would be reserved for substantive changes. While CMS provides some guidance regarding the types of changes it proposes addressing through the subregulatory process, the terms "substantive" and "non-substantive" are not defined, and application of this process could become subjective. Rather than relying on a subregulatory process, we recommend **CMS use formal rulemaking to identify both the additions and deletions to the presumptive methodology diagnosis code lists. This would give providers the ability to review codes for accuracy. Furthermore, this approach tracks the process used by CMS in the hospital inpatient PPS where CMS publishes tables for proposed additions, deletions, and revisions to the diagnoses and complication/comorbidities lists.**

Implementation Timeline

CMS does not clearly state when it will implement the rule's proposed changes. **We recommend that changes related to correcting errors should be implemented as soon as possible. However, providers will need at least one year to implement the more challenging changes related to compliance with the 60%**

Rule (e.g., removing conditions from IGCs). In general, it is easier for providers to implement additions than deletions to the 60% Rule. Deletions require a significant amount of time and effort to educate and train staff and clinicians. These changes should become effective no sooner than for compliance and review periods beginning October 1, 2018.

Supportive Documentation

Some of the proposed changes to this set of codes are supported with only limited clinical and/or policy rationale. This lack of information makes it difficult for stakeholders to fully assess the rationale for the proposals and gives the appearance of a seemingly arbitrary proposal process. **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. In addition, we recommend that the agency 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. This would also track more closely the process used for the inpatient PPS coding changes, a format that lends it self to greater transparency and ease of use.

Future of the 60% Rule

The 60% Rule was implemented in the early 1980’s at a time when fee-for-service was the predominate source of healthcare providers’ Medicare reimbursement. Since then, the system has increasingly transitioned to alternative payment models and pay for performance programs that require healthcare providers to assume more risk associated with their patient discharge decisions, post-acute acute care utilization, and patients’ outcomes. These dynamics call into question the need for continued application of the restrictive effects of the 60% Rule.

Moreover, the list of conditions comprising the 60% Rule was initially established in the early 1980s. In 2004, CMS made technical modifications to the Rule’s original list of medical categories. However, despite the advancements in medical rehabilitation and therapy for more than 25 years—which have enabled broader patient populations to benefit from IRF care and services, no significant medical categories have been added to the Rule’s list of conditions. **To the extent CMS maintains the 60% Rule, it should be updated and expanded to include additional medical categories, including those associated with organ transplant, oncology/cancer, pulmonary, and cardiac conditions and diagnoses.**

IRF QUALITY REPORTING PROGRAM (IRF QRP)

CMS currently requires IRFs to report on 18 quality measures. The agency proposes the replacement of one measure and removal of another 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 AzHHA appreciates that the proposed measures are intended to address significant patient health outcomes, the replacement measure for pressure ulcer needs significant improvement before it would be suitable for use in the IRF QRP. Furthermore, CMS's proposal that IRFs 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.

Pressure Ulcer/Injury – Changes to Skin Integrity

The IRF QRP currently includes a measure examining the percentage of patients that have new or worsened pressure ulcers. The agency would replace this measure with one that asks IRFs to capture data on both stageable pressure ulcers (those that can be assigned a numerical score of 1 to 4), and unstageable pressure ulcers, including deep tissue injuries, assessing which ones at each stage are unhealed. 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 PAC settings because this same measure is proposed for other post-acute settings.

AzHHA is concerned that the definition of pressure ulcers included in the measure is too subjective to collect reliable and accurate data across IRFs and other PAC providers. As a result, the measure could provide misleading portrayals of IRF performance. We are also 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. CMS posits that one of the benefits of this revised measure is that it would increase variation in measure scores across providers. However, the purpose of respecifying a measure is not to create performance variation. Any measure change 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. It is especially troubling when one considers that this increased variation may not stem from differences in quality, but rather from differences in the interpretation of the definitions and differences in the rigor in counting. **AzHHA strongly urges CMS to 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.

All-cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs.

AzHHA supports CMS's 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 response to the IMPACT Act, which requires the collection of standardized patient assessment data to facilitate data sharing and comparisons across PAC settings, CMS proposes to introduce 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.

AzHHA 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.**

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. CMS's proposal would add 18 new data elements to the already lengthy IRF-PAI. **Because many of these elements have multiple parts (i.e., a principal element and two to seven sub-elements or questions), 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 an IRF provider's workflow considerably.

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. We also are deeply concerned about IRF providers' ability to reconfigure their databases and electronic health records by October 2018 to comply with these 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; AzHHA suggests continuing this approach for an additional year to allow for further consideration of the additional data elements.

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 (MSPB);
- Discharge to Community; and
- Potentially Preventable 30-Day Post-Discharge Readmissions.

AzHHA believes IRF performance on all three measures may be affected by sociodemographic factors, and 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. In fact, CMS has proposed to implement sociodemographic adjustment in the Hospital Readmission Reduction Program—an important first step to improving the fairness of the program.

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 hospitals and other providers treating large proportions of vulnerable patients. It also can mislead and confuse patients, payers and policy makers by shielding them from important community factors that contribute to worse outcomes. Thus, **we urge CMS to incorporate sociodemographic risk adjustment for these outcomes measures.**

We also urge CMS to carefully evaluate the MSPB measure's clinical risk adjustment approach. We encourage the agency to work with providers to explore the feasibility of incorporating an adjustment for patient functional status, as this is an important determinant of patient outcomes.

We further recommend CMS to carefully assess the reliability and validity of patient discharge codes used to calculate the discharge to community

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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 rehospitalizations 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 published studies, including MedPAC, 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.

We thank you for the opportunity to comment on this proposed rule. Please feel free to contact me if you have any questions.

Sincerely,



Debbie Johnston
Senior Vice President, Policy Development