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June 22, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1671-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted via regulations.gov

Re: 42 CFR Part 412 (CMS-1671-P) Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2018; Proposed Rule

Dear Administrator Verma,

On behalf of Uniform Data System for Medical Rehabilitation (UDSMR) and the more than nine hundred inpatient rehabilitation facilities we provide services to, we are pleased to present our comments on 42 CFR Part 412 Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2018; Proposed Rule, which was published on May 3, 2017, in the *Federal Register*.

Before proceeding with our comments, we present the following executive summary, which highlights our concerns and recommendations.

Executive Summary:

We are very concerned that the 60% rule and the methods used to review and enforce this regulation deny access to the necessary and beneficial care Medicare beneficiaries deserve, continue to produce unnecessary administrative burden, and prohibit IRFs from participating in ongoing payment model pilot programs such as BPCI and CJR.

We also continue to be very concerned that CMS, in implementing the IMPACT Act across postacute care (PAC) venues, continues to deploy assessment items and quality measures that shift a huge regulatory and financial burden onto facilities without any evidence that these measures increase the quality of care or control costs.

Concerns:

1. The FY 2018 update to the SPCF does not include an increase for the time and resources necessary for IRFs to collect and report the additional information added to the IRF-PAI in the past two final rules and in this proposed rule. The proposed increase does not cover the costs of changes to medical records and documentation, training, and data collection related to quality reporting items.

Concerns (continued):

2. The proposed modifications to the 60% rule
 - a. do not have a clearly stated effective date in the proposed rule,
 - b. do not provide reconciliation for IRFs who have previously been found noncompliant due to inaccuracies in the process and methodologies, and
 - c. put additional facilities at risk for meeting compliance standards and place additional burdens and costs on IRFs and CMS contractors to perform medical record reviews.
3. The proposed changes to the pressure ulcer quality measure
 - a. represent the fourth change to the measurement and assessment of pressure ulcers and skin integrity in the last five years;
 - b. produce a quality measure that is not endorsed;
 - c. are based on data from SNFs, which use pressure ulcer data for payment purposes;
 - d. may not identify a true change in skin integrity; and
 - e. create a “topped-out” measure that does not provide significant differentiation of quality between IRFs.
4. CMS does not provide access to claims-based quality measure data, such as readmission measure data, that allows IRFs to examine their performance and identify opportunities for improvement.
5. The proposed standardized patient assessment data
 - a. will produce additional administrative burden to train staff and implement these items in documentation,
 - b. does not provide evidence of predicting costs or improving quality of care in IRFs, and
 - c. does not consider the expertise of physicians and other clinicians in regard to screening and identifying patients.
6. The proposed changes to existing standardized patient assessment data
 - a. are not documented in the proposed rule and require careful review of CMS’s website to locate and identify,
 - b. should require quality measures that utilize these items to be reviewed for continued endorsement and for the reliability and validity of the items, and
 - c. will require IRFs to spend time, money, and resources retraining staff and incorporating these items into existing documentation.

Concerns (continued):

7. The IRF QRP data completion requirements related to the reporting of standardized patient assessment data
 - a. use thresholds that differ across the PAC sites, with IRFs having the highest threshold for complete standardized patient assessment data, and
 - b. use only three months of initial data collection for newly implemented standardized patient assessment data, potentially penalizing IRFs that are still adapting to the new requirements.
8. Public reporting of IRF QRP data on IRF COMPARE
 - a. does not provide a complete picture of IRF services and the quality of care being provided,
 - b. uses measures that continue to change, and
 - c. displays information for time frames that differ between measures.
9. The training, data-collection specifications, and support that CMS and its contractors have provided for the implementation of quality measures and standardized patient assessment data have been inconsistent and have not provided the necessary responses to questions from IRFs. As a result, we continue to be concerned that quality data is inaccurate and unreliable and that it lacks the reliability and validity needed to provide clinical standards for quality measurement.

Recommendations:

1. If CMS continues implementing quality measures and standardized patient assessment data elements that add considerable burden and cost to IRFs, it should increase the SPCF to accommodate the additional data-collection requirements and to offset the costs incurred by IRFs to train their staff and modify their documentation practices.
2. CMS should remove the 60% rule from the criteria used to classify facilities for payment under the IRF PPS.
3. The Secretary should suspend—or CMS should defer implementation of—all quality measures and standardized patient assessment data elements specified for meeting the IMPACT Act's requirements, including those previously finalized, until all of the following occur:
 - a. Quality measures are standardized and interoperable for all PAC sites.
 - b. Quality measures receive endorsement for the specified PAC site prior to use or implementation.
 - c. Standardized patient assessment data not only illustrates that it can be feasibly collected, but also provides evidence that it predicts cost and/or improves quality.
 - d. CMS's staff and contractors provide full support for the measures by providing training materials, data-collection specifications, and clear and accurate responses to questions from the industry.

Recommendations (continued):

4. CMS should modify its data completion requirements for submitting standardized patient assessment data by
 - a. allowing IRFs a three-month grace period for initial implementation issues related to new standardized patient assessment data,
 - b. requiring that payment penalties be based on at least twelve months of data, and
 - c. using a data-completion threshold for assessment data that is consistent across PAC venues.
5. CMS should suspend or delay the public display of IRF QRP data on IRF COMPARE until
 - a. all IMPACT Act domains are implemented to provide a comprehensive comparison of IRF performance, and
 - b. quality measures are provided on consistent time periods to account for potential differences in the case mix and severity of patient populations over time.

The remainder of this letter addresses our concerns and recommendations in detail.

1. The FY 2018 update to the SPCF does not include an increase for the time and resources necessary for IRFs to collect and report the additional information added to the IRF-PAI in the past two final rules and in this proposed rule. The proposed increase does not cover the costs of changes to medical records and documentation, training, and data collection related to quality reporting items.

As stated in section V of CMS-1671-P.

Beginning on October 1, 2016, IRFs were required to collect data for quality reporting purposes that caused the IRF-PAI to expand from ten to eighteen pages. In the FY 2016 final rule (CMS-1624-F), CMS estimated that the additional elements for the newly finalized quality measures would take 41.5 minutes to complete (25.5 minutes for admission data and 16.0 minutes for discharge data), resulting in a total of 96 minutes to collect and record the information for the IRF-PAI. This additional time nearly doubled OMB's previous estimate of the average time needed to administer this assessment. CMS further stated, "[T]he additional IRF-PAI items we are proposing will be completed by Registered Nurses (RN), Occupational Therapists (OT), Speech Language Pathologists (SLP) and/or Physical Therapists (PT), depending on the item." If the time estimate is accurate, the additional time critical IRF staff spend collecting this information has severely decreased their ability to perform the patient care activities necessary for quality improvement. Facilities with multiple daily admissions and discharges will need to increase staffing levels to accommodate the additional administrative workload on top of their existing patient care needs. Additionally, the need to train staff and update documentation to collect these items will add up to a financial burden that goes well beyond CMS's previous estimate of \$21,239.33 per IRF per year.

In this proposed rule, CMS is proposing to add standardized patient assessment data that will increase the IRF-PAI by another six pages. According to CMS, and after accounting for removal of some items that will no longer be utilized, the proposed estimate is that this will add roughly 9 more minutes and will cost IRFs an additional \$2,989.47 per year. As stated previously, this estimate does not account for additional costs for providers to train their staff and update their documentation practices to accommodate the new items.

The proposed SPCF change for FY 2018, after adjusting for all factors detailed in table 4 of section V, is an increase of only 0.8%, or \$127 per Medicare patient. CMS's estimated increase in IRF costs for implementing the measures in the FY 2016 final rule was roughly \$24 million, or approximately \$64 per Medicare patient; its estimated increase in IRF costs for implementing the measures in the FY 2018 final rule is roughly \$3.5 million, or around \$10 per Medicare patient.* The burden of data collection finalized in the FY 2016 final rule and this proposed rule consumes nearly 60% of the FY 2018 SPCF increase, leaving an increase of only \$53 per Medicare patient to account for changes to the market basket and budget neutrality factors.

UDSMR recommends that CMS add the estimated costs for implementing data collection for quality reporting purposes to the SPCF updates for FY 2018 and continue to add them on an ongoing basis. We further recommend that CMS conduct an ongoing market review of the costs IRFs will incur to implement these items, including the costs of training staff and revising documentation, both paper and electronic. This review will help CMS provide IRFs with adequate resources for providing quality data.

* This per patient estimate is based on roughly 375,000 Medicare cases, as detailed in MedPAC's March 2016 report to Congress.

2. The proposed modifications to the 60% rule

- a. do not have a clearly stated effective date in the proposed rule,**
- b. do not provide reconciliation for IRFs who have previously been found noncompliant due to inaccuracies in the process and methodologies, and**
- c. put additional facilities at risk for meeting compliance standards and place additional burdens and costs on IRFs and CMS contractors to perform medical record reviews.**

As stated in sections IX, X, and XI of CMS-1671-P.

Before addressing each of the concerns noted above, UDSMR recommends that CMS remove the 60% rule from the criteria used to classify facilities for payment under the IRF PPS. As noted in this letter's executive summary, the 60% rule and the methods used to review and enforce it continue to deny access to the necessary and beneficial care Medicare beneficiaries deserve, produce unnecessary administrative burden, and prohibit IRFs from participating in ongoing payment model pilot programs such as BPCI and CJR.

In terms of administrative burden, IRFs spend considerable time and resources managing their compliance. From screening patients at preadmission, to determining whether the patient has a compliant diagnosis, to monitoring compliance on a daily, weekly, and monthly basis, IRFs are required to evaluate the impact of new admissions on their ability to meet compliance requirements.

Depending on an IRF's ability to manage its compliance status and the patient's medical condition, Medicare beneficiaries may be denied admission to an IRF solely due to the 60% rule. In other words, a Medicare beneficiary may meet every requirement for IRF admission but be denied admission to an IRF because of a diagnosis that is not compliant with the 60% rule—a diagnosis that would place the IRF at risk for not meeting CMS's requirement. This system routinely denies patients access to necessary and beneficial care solely because of their diagnosis and then places them in a venue that increases their risk of readmission to acute care.

The 60% rule also affects IRFs' ability to participate in ongoing payment model pilot programs such as BPCI and CJR. Depending on the population of cases included in these payment models, the ability to admit cases for these programs is limited by the diagnoses defined by the 60% rule. For example, the CJR program is for joint replacement cases. Unless a patient has a bilateral joint replacement, has a BMI over 50, or is at least eighty-five years old, the patient would not count toward meeting the 60% rule. Even if an IRF wanted to participate in CJR by admitting patients with joint replacements, it would place itself at risk for falling out of compliance and for no longer being paid under the IRF PPS.

Due to the issues noted above, UDSMR recommends that CMS remove the 60% rule from the criteria used to classify facilities for payment under the IRF PPS. We believe that the other criteria currently used for this classification incorporate characteristics that clearly differentiate IRFs from other PAC venues. We also believe that the removal of the 60% rule will end the practice of prohibiting access to care based solely on a patient's diagnosis.

In addition, we have the following concerns about the proposed refinements to the presumptive compliance methodology if the 60% rule is not removed.

- a. **The proposed rule does not clearly identify an effective date for the proposed refinements to the presumptive compliance methodology.** The impact of these changes will differ significantly, depending on whether they are applied to all cases discharged on or after October 1, 2017, or are applied to each IRF's next compliance review period beginning on or after October 1, 2017. Historically, changes to presumptive compliance have been implemented and applied to an IRF's next compliance review period. This was done to allow IRFs to adjust to changes prior to their next review period and to avoid affecting IRFs differently depending on their compliance review period. If the refinements are not applied in this historical manner and instead are applied for all patients discharged on or after October 1, 2017, then the effects on each IRF may differ depending on how far the IRF is into its compliance review period. For example, the refinements may have a smaller effect on IRFs that are more than halfway through their current compliance review period because those IRFs have already determined their compliance for at least half of their cases and may be able to continue their current practices or make small adjustments to accommodate changes. By contrast, the refinements may have a larger effect on IRFs that are less than halfway through their current compliance review period because their compliance will depend more on the methodology with refinements than on current compliance methodology.

Additionally, if the refinements are applied to all cases discharged on or after October 1, 2017, CMS will need to utilize a blended presumptive methodology approach. CMS's contractors currently use a software report to calculate presumptive compliance. This report applies a methodology across an IRF's twelve-month compliance review period. If CMS implements refinements to create a new methodology, it would need to provide its contractors not only with a way to run the current methodology for a portion of an IRF's compliance review period, but also with a way to run the new methodology for the remaining portion of the IRF's compliance review period. The results would then need to be proportionally considered to determine the resulting compliance percentage.

If CMS is to continue the 60% rule, the refinements should be applied to the next compliance review period. This change will not only allow IRFs to adapt to these changes, but also allow the changes to be applied uniformly across all IRFs.

- b. **CMS does not provide reconciliation for IRFs who have previously been found noncompliant due to inaccuracies in the process and methodologies.** UDSMR is aware that a number of IRFs that utilize our services have recently been found noncompliant with the 60% threshold, as determined by the presumptive compliance methodology. As a result, a number of these IRFs have had to spend resources pulling medical records for the medical record review process, and they are awaiting feedback from their CMS contractor related to their results. However, reviews of the data for these IRFs typically show that if the proposed refinements were applied to their data for the period under review, they would have met or exceeded the 60% threshold and therefore would not have had to invest time and resources in the medical record review process.

Additionally, for IRFs currently undergoing a medical record review to determine their compliance, some may be found noncompliant because of the random sample of cases selected by the CMS contractor. If such a determination is made, the current process

indicates that the IRF would not be classified as an IRF for its next cost reporting period—and therefore would be ineligible for payment under the IRF PPS—even though the refinements would have allowed the IRF to be considered presumptively compliant.

UDSMR recommends that CMS consider some kind of reconciliation or reconsideration process related to these refinements to the 60% rule. Given that a number of these refinements are based on inadvertent issues caused by the transition from ICD-9 to ICD-10, IRFs should not bear the burden of inaccuracies resulting from the use of the General Equivalence Mappings (GEMs) tool, which produced unintended exclusions.

- c. **These changes put additional facilities at risk for meeting compliance standards and will place additional burdens and costs on IRFs and CMS contractors to perform medical record reviews.** Based on a review of the UDSMR[®] IRF database, which includes over 80% of all IRFs, we project that the resulting refinements will place 120 IRFs (over 13% of the IRFs in the UDSMR[®] database) at risk for requiring a medical record review to determine their ability to meet the 60% rule. Of these, 68 IRFs (about 7.5% of the IRFs in the UDSMR[®] database) are presumptively compliant, as determined by today's methodology. Additionally, nearly 60 others (about 6.7% of the IRFs in the UDSMR[®] database) appear to have a Medicare population that is less than 50%, which would cause them to be ineligible for presumptive compliance and would force them to undergo a medical record review to determine their ability to meet the 60% rule. Based on these estimates, approximately 20% of all IRFs—over 200 IRFs—might require a medical record review.

The medical record review process requires an IRF to provide medical records to a CMS contractor for either its entire twelve-month compliance review period (for IRFs with less than a hundred cases) or for a random sample of cases (for IRFs with more than a hundred cases). The process of collecting medical records and sending them to a CMS contractor can consume a great deal of administrative time and resources, depending on the extent of the information requested and the IRF's ability to create, copy, and scan these documents for the CMS contractor. The CMS contractor, in turn, needs additional time and resources to conduct the review, which will be based on the documentation provided by the IRF.

Given that the proposed changes will cause over 200 IRFs to require this medical record review process, we believe that CMS is placing additional administrative burden and cost on IRFs and CMS contractors to perform medical record reviews. This burden reduces the time spent providing patient care and increases the cost to the Medicare program.

UDSMR recommends that CMS reevaluate the changes it is making to the 60% rule and determine the impact of these changes on the Medicare program.

3. **The proposed changes to the pressure ulcer quality measure**
 - a. **represent the fourth change to the measurement and assessment of pressure ulcers and skin integrity in the last five years;**
 - b. **produce a quality measure that is not endorsed;**
 - c. **are based on data from SNFs, which use pressure ulcer data for payment purposes;**
 - d. **may not identify a true change in skin integrity; and**
 - e. **create a “topped-out” measure that does not provide significant differentiation of quality between IRFs.**

As stated in section XII.G.1 of CMS-1671-P.

- a. Our first concern is that the proposed changes to the pressure ulcer quality measure will be the fourth such change in five years involving measuring and assessing pressure ulcers and skin integrity. For FY 2014, the three-page IRF-PAI used thirteen items (48A–50D) to collect pressure ulcer data. In FY 2015, the IRF-PAI expanded to eight pages, solely due to an expansion to forty-one items related to pressure ulcers (M0210–M0900D and I0900A–I2900D). For FY 2017, the IRF-PAI expanded to eighteen pages, which included revisions to pressure ulcer items. This last change modified the M0300 series of items used for the pressure ulcer quality measure and added items M0800A–M0800F for collecting data about new or worsened pressure ulcers for use in the quality measure. Now, in the FY 2018 proposed rule, CMS is proposing that the quality measure for FY 2020 will go back to utilizing the M0300 items for the quality measure and will remove the data collection for items M0800A–M0800F and M0900A–M0900D.

Although IRFs believe that wound care and skin integrity are important, CMS's annual changes to the associated assessment items and quality measures have made it increasingly difficult for providers to manage the assessment and measurement of pressure ulcers. Each time IRFs have trained their staffs to understand the assessment items in order to ensure the reliability and validity of the collected data, CMS has implemented changes that require retraining and relearning.

The effects of these annual changes are not limited to the training of staff members. Pressure ulcers are currently reported on IRF COMPARE, CMS's public reporting website. IRFs are trying to manage their performance on this quality measure, but the constant changes to the associated items and the quality measure calculations make it increasingly difficult for IRFs to review their performance and improve it as needed. In some instances, an IRF's poor performance is due to a misunderstanding about the items and how to accurately document and assess them.

We recommend that CMS suspend or delay implementing this change to the pressure ulcer quality measure until (1) the assessment items have been collected in a standardized manner for at least twelve to twenty-four months and (2) a quality measure can provide reliable and valid results.

- b. Our second concern is that the proposed changes to the pressure ulcer quality measure will produce a quality measure that is not endorsed. Although we recognize that the IMPACT Act allows for the implementation of quality measures that are not endorsed, the changes will move the measurement of pressure ulcer data from a state of being endorsed and reviewed by

stakeholders for reliability and validity to a state of being not endorsed and not considered for the reliability and validity of the measure. This will continue CMS's practice of implementing quality measures to meet IMPACT Act deadlines instead of ensuring that what is being collected and reported on is reliable and valid.

Because of the lack of review for reliability and validity, we recommend that CMS suspend or delay implementing this change and the pressure ulcer quality measure until the quality measure is evaluated by an endorsement body and is endorsed by that body.

- c. Third, we are concerned that these proposed changes to the pressure ulcer quality measure are based on data from SNFs, which use pressure ulcer data for payment purposes. These changes were presented at the National Quality Forum (NQF) Measure Applications Partnership (MAP) committee meetings. When asked why these changes were needed, CMS and the measure developers replied that the M0300 series of items was potentially identifying more pressure ulcers than the M0800 series of items was. CMS and the measure developers further stated that this increase was primarily noted in SNF data. Following this meeting, UDSMR evaluated this statement and found that SNF payment under the SNF PPS increases when a patient is identified as having pressure ulcers that are being treated during the course of care. As a result, we question whether the increased numbers produced by the proposed items are indicative of true pressure ulcer status, or whether they represent an opportunity for increased payment instead.

We recommend that CMS and their measure developers conduct an independent medical record review before implementing these changes to determine whether the pressure ulcer status is supported in detail and whether a true difference is present in the payment items versus the current quality items. We further recommend that until such a review is completed, CMS suspend or delay implementing both this change and the pressure ulcer quality measure.

- d. Our fourth concern is that the proposed measure may not identify a true change in skin integrity. Whether because of a misinterpretation of how to code the assessment items or because of an issue with documenting a pressure ulcer present on admission, this quality measure may be reporting more about operational or documentation issues than about actual patient skin integrity issues. For example, if a patient is admitted on a Friday, an IRF has a three-day admission period in which to identify pressure ulcers present on admission. Whether a pressure ulcer is documented as present on admission for such a patient may depend on the weekend availability of a wound care specialist or another staff member trained in identifying and staging pressure ulcers. Also in this example, if a pressure ulcer is identified on Monday that was not previously documented over the weekend, this creates a situation where it cannot be identified as present on admission and is therefore excluded from being identified in the changes in skin integrity quality measure. In these circumstances, is the provider's performance truly based on patients who have changes in skin integrity, or is it instead more a measure of operational or documentation issues?

We recommend that CMS and its measure developers take a closer look at the proposed quality measure and determine whether it captures or measures what it truly intends to measure—namely, potential changes in patient skin integrity. We also recommend that CMS suspend or delay implementing both this change and the pressure ulcer quality measure until this review is completed.

- e. Our fifth and final concern is that the proposed changes to the pressure ulcer quality measure continue to create a “topped-out” measure that does not significantly differentiate quality between IRFs. Although the proposed changes will more than double the current IRF average reported for this measure, projecting an IRF performance average of only 1.5% of patients leaves little to no room for improvement and limits the amount of differential performance between IRFs. Additionally, we note that the quarterly updates on the IRF COMPARE website indicate that IRFs’ performance on this measure has continued to improve, with the national comparison value decreasing by a tenth of a percentage in the last three updates. With a quality measure that starts by identifying only 1.5% of Medicare patients and the potential for IRFs to resolve any operational or documentation issues that may affect their initial performance, we anticipate that this measure will ultimately see a decrease toward 1%, if not lower, within the first few quarters. As the measure continues to decrease, opportunities to improve the quality of care will diminish, leaving little opportunity for improvement and a situation where the measure is “topped out.”

Additionally, because of the low average rate, comparisons to the national average value often differ by only a tenth of a percentage point. What this essentially means is that the differentiation between IRF performance values often comes down to one or two patients. This offers IRFs little to no room for improvement, and patients who may present a potential risk for pressure ulcers may be treated differently due to their potential impact on the IRF’s publicly reported performance value.

We recommend that CMS suspend or delay implementing this change and the pressure ulcer quality measure until it can develop a measure that is not “topped out” and that provides opportunities for improving the quality of care.

4. CMS does not provide access to claims-based quality measure data, such as readmission measure data, that allows IRFs to examine their performance and identify opportunities for improvement.

In reference to sections XII.H and XII.O of CMS-1671-P.

UDSMR is concerned that CMS does not have a mechanism in place for each of the claims-based quality measures that will allow IRFs to access patient-level data in order to review and potentially correct errors with their data and to identify opportunities for improving their performance in regard to these quality measures. Because most claims-based quality measures use information from thirty to sixty days after a patient is discharged from an IRF, tracking performance on this measure is nearly impossible. For example, the readmission measures force an IRF to know every instance of one of their patients being readmitted to acute care. Patients could be readmitted to the hospital they were previously admitted to; in some instances, they could be readmitted to a completely different hospital, with some perhaps in another city, county, or state. Additionally, with the transition to potentially preventable readmissions, even an IRF that can track whether a patient was readmitted to acute care would need to know the readmission diagnosis in order to determine whether the readmission would be considered potentially preventable.

Without access to patient-level data for these claims-based quality measures, IRFs have little to no control over their own performance and little to no ability to analyze the data to determine

potential risk factors for patients being readmitted, which may help them improve the quality of care they deliver.

We recommend that CMS suspend or delay the use of claims-based quality measures until CMS can provide IRFs with patient-level data for each measure in order to facilitate a review of provider performance and the identification of opportunities for improvement.

5. The proposed standardized patient assessment data

- a. will produce additional administrative burden to train staff and implement these items in documentation,**
- b. does not provide evidence of predicting costs or improving quality of care in IRFs, and**
- c. does not consider the expertise of physicians and other clinicians in regard to screening and identifying patients.**

As stated in sections XII.J.2.a.2 and XII.J.2.a.3 of CMS-1671-P.

- a. Our first concern with the proposed standardized patient assessment data, as we have noted previously in discussing our SPCF concerns, is that it will produce additional administrative burden to train staff and incorporate these items into documentation. CMS estimates that the additional data elements will add roughly fourteen minutes, but this estimate does not include the time and costs involved in training staff and updating documentation to support the new data elements. IRFs will need to attend, either in person or via webinar, CMS's training related to the new data elements and then will need to provide this training back to their staff. These additional minutes and hours are not included in CMS's estimate, yet IRFs will need to account for them prior to implementation.

Additionally, these new data elements add another six pages to the IRF-PAI. IRFs will need to ensure that their documentation systems, whether paper or electronic, are capable of appropriately supporting these new data elements. CMS has not accounted for the time and costs attributable to these changes, yet they will add considerable costs to the Medicare program.

We recommend that CMS revise its estimates to include the training and implementation costs and that it add these costs to the SPCF, as previously noted, in order to ensure that IRFs have the financial ability to appropriately address these new data elements.

- b. Our second concern is that CMS does not provide evidence of the new items' capability to predict costs or improve the quality of care in IRFs. Although CMS has noted the inter-rater reliability and TEP feedback on feasibility for these new items, it has not conducted additional analyses to determine whether these new standardized patient assessment data elements are capable of differentiating patient cost or measuring the quality of care provided by IRFs.

We recommend that CMS suspend or delay implementing these new standardized patient assessment data elements until analysis confirms whether these items predict cost or are relevant to the quality of care provided in IRFs.

- c. Our third and final concern with the newly proposed standardized data elements is that CMS does not consider the expertise of physicians and other clinicians in regard to screening and identifying patients. CMS states that the proposed data elements for cognitive status and mental health can distinguish between patients with delirium, confusion, depression, and other behavioral signs and symptoms, but physicians and other clinicians can currently utilize their expertise and other screening tools to document and report the presence of these conditions by recording ICD-10 codes as comorbidities on the IRF-PAI. How will CMS reconcile potential differences identified by comparing the results of these proposed data elements to the presence of a comorbidity supported by the expertise of physicians and other clinicians?

For example, the Patient Health Questionnaire-2 (PHQ-2) is used as an indicator of a patient's potential need for further evaluation of depression. The supporting document provided by CMS states, "In PAC PRD, 11.3 percent of IRF patients screened positive for depressive symptoms as assessed by the PHQ-2," but an analysis of the UDSMR[®] IRF database indicates that nearly 25% of Medicare patients have been identified with an ICD-10 code related to depression. The coding of this diagnosis requires supporting physician documentation, which often includes a screening assessment that may come from a tool other than the PHQ-2. In this scenario, will the PHQ-2 adequately address the patient's depressive state, or should the physician's clinical expertise, as documented via the use of an ICD-10 code, take precedence?

We recommend that CMS suspend or delay implementing these new standardized patient assessment data elements until analysis confirms whether they provide any additional benefit in regard to predicting cost and measuring quality of care beyond the use of the comorbidities currently recorded on the IRF-PAI.

6. **The proposed changes to existing standardized patient assessment data**
 - a. **are not documented in the proposed rule and require careful review of CMS's website to locate and identify,**
 - b. **should require quality measures that utilize these items to be reviewed for continued endorsement and for the reliability and validity of the items, and**
 - c. **will require IRFs to spend time, money, and resources retraining staff and incorporating these items into existing documentation.**

In relation to section XII.J.2.a.1 of CMS-1671-P.

- a. CMS is proposing to make standardized patient assessment data out of the data elements that are part of NQF #2631, but it is also making background changes to these data elements even though this is not stated in the proposed rule. For IRF providers, the only way to identify these changes to already implemented standard patient assessment data is to review CMS's website.

We are especially concerned by the proposed changes to the functional items in sections GG01030, Self-care, and GG0170, Mobility. CMS is making three types of changes that will significantly affect IRFs and their ability to meet quality-reporting standards:

- i. CMS is adding code 10, Not attempted due to environmental limitations, to each of these standardized patient assessment data elements. IRFs have spent considerable time training staff members to understand the current codes for these items, and the addition of a new code will require providers to relearn these coding options.
- ii. CMS is changing the verbiage for the data elements and their responses. Though they may seem minor in nature, these changes can lead to differing interpretations of the function being assessed, as well as the level that correctly represents the patient's functional status. This change will require staff members to relearn codes in order to appropriately assess patients.
- iii. CMS is allowing IRFs to record codes 07, 09, 10, and 88 as discharge goals. Although this change appears to address concerns over the use of a dash value for items without set goals, setting a goal value to "patient refused" or "not attempted" is not consistent with clinical guidelines. Additionally, providers have spent considerable time training staff members to understand how to code the discharge goals, and this change will require IRFs to change their practices significantly.

We recommend that CMS suspend or delay implementing these changes to the standardized patient assessment data elements until (1) they are formally documented as part of the rule-making process and (2) their related effects are discussed in detail with stakeholders.

- b. Our second concern is that these changes to currently collected standardized patient assessment data should require quality measures that utilize these items to be reviewed for continued endorsement and for the reliability and validity of the items. These changes, though they seem minor, may fundamentally change the way the data elements are assessed and the performance of the resulting quality measure. For example, will the addition of code 10 result in identifying more patients as not attempting some of these items, or fewer patients? Will any of the verbiage changes in these items cause patients to appear as being more or less severe in regard to these items than they are when they are assessed with the current versions of these items? And will the use of codes 07, 09, 10, and 88 as discharge goals affect the measurement of NQF #2631? Because of the potential changes in the way these items are assessed, they should be reviewed and evaluated by an endorsement body, both for the reliability and validity of the collected data and for the status of the resulting quality measure.

We recommend that CMS suspend or delay implementing these changes to the standardized patient assessment data elements until they are reviewed by the NQF to determine (1) the reliability and validity of the data elements and (2) the overall effects on the quality measures that utilize these data elements.

- c. Our third and final concern is that the proposed changes to the existing standardized patient assessment data elements will require additional costs to retrain staff and to modify these items in documentation systems, both electronic and paper. As we have noted throughout this comment letter, any changes to the standardized patient assessment data elements incur additional costs, in terms of both time and money, so that providers can not only retrain their

staff on these elements, but also change their documentation to support the values entered for these data elements. Despite this fact, the proposed rule's impact estimates do not account for these costs, and the proposed SPCF increase will not provide sufficient payment to cover these additional costs.

We recommend that CMS revise its estimates to include training and implementation costs and that it add these costs to the SPCF in order to ensure that IRFs have the financial ability to appropriately address these modified data elements. We also recommend that CMS suspend or delay implementing these changes to the standardized patient assessment data elements until the full cost of making these changes has been analyzed and reviewed.

7. The IRF QRP data completion requirements related to the reporting of standardized patient assessment data

- a. use thresholds that differ across the PAC sites, with IRFs having the highest threshold for complete standardized patient assessment data, and**
- b. use only three months of initial data collection for newly implemented standardized patient assessment data, potentially penalizing IRFs that are still adapting to the new requirements.**

As stated in sections XII.M and XII.N of CMS-1671-P.

- a. Our first concern regarding the IRF QRP data completion requirements related to the reporting of standardized patient assessment data is that CMS's thresholds differ across PAC sites, with IRFs having the highest threshold for complete standardized patient assessment data. For assessment-based quality measures and standardized patient assessment data recorded on the IRF-PAI, 95% of an IRF's IRF-PAI submissions must be considered complete. For SNFs and LTCHs, the threshold for data completeness applied to assessment-based quality measures and standardized patient assessment data elements is 80%, which suggests that IRFs are being held to a higher standard for supplying their data to CMS for this purpose.

We recommend that CMS delay or suspend the IRF QRP data completion requirements related to the reporting of standardized patient assessment data until CMS implements a consistent data completion threshold across PAC venues.

- b. Our second concern with these IRF QRP data completion requirements is that CMS uses only three months of initial data collection for newly implemented standardized patient assessment data, potentially penalizing IRFs that are still adapting to the new requirements. Although existing quality measures and standardized patient assessment data use a full calendar year (i.e., twelve months) of data, CMS uses the initial three-month period of data for the purposes of the data completeness requirement whenever it introduces newly implemented standardized patient assessment data. This means that any facility that has difficulty implementing new data elements is at risk for being penalized for this initial three months of data collection. This policy does not allow IRFs to adapt to these new requirements; instead, it penalizes them for CMS's haste in implementing the collection of new data.

We recommend that CMS provide IRFs with a three-month grace period for potential implementation issues related to new standardized patient assessment data. Alternatively, we recommend that CMS base payment penalties off at least twelve months of data.

8. Public reporting of IRF QRP data on IRF COMPARE

- a. does not provide a complete picture of IRF services and the quality of care being provided,**
- b. uses measures that continue to change, and**
- c. displays information for time frames that differ between measures.**

As stated in section XII.O in CMS-1671-P.

- a. Our first concern about the public reporting of IRF QRP data on IRF COMPARE is that the information currently provided does not paint a complete picture of IRF services and the quality of care being delivered. Currently, only three measures—rate of pressure ulcers that are new or worsened, catheter-associated urinary tract infections (CAUTIs), and rate of unplanned readmissions after discharge from an IRF—are being publically displayed on IRF COMPARE. These three measures do not scratch the surface of the care delivered by IRFs and do not represent some of the key IRF outcomes. For example, these measures do not examine patient functional status or the percentage of cases discharged back to the community, both of which are key aspects of IRF care.

Furthermore, although we recognize that CMS is proposing to add more measures to IRF COMPARE in calendar year 2018, we do not believe that the new measures will fill in the previously noted gap. Furthermore, we believe that the proposed items are overly focused on readmissions and claims-based measures that may still misrepresent the quality of care IRFs deliver. Additionally, the proposed functional measure is a process measure that measures only whether assessments were completed, not whether the patient made progress in the IRF.

We recommend that CMS suspend or delay the public display of IRF QRP data on IRF COMPARE until all IMPACT Act domains are implemented to provide a comprehensive comparison of IRF performance.

- b. Our second concern about the public reporting of IRF QRP data on IRF COMPARE is that the information currently provided uses measures that continue to change. As we noted previously in this comment letter, a proposed change to the pressure ulcer measure will fundamentally change the values reported on IRF COMPARE. In addition, as we also noted previously, the changes to section GG of the IRF-PAI will affect NQF #2631, Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.

This proposed rule does not identify a methodology for changing these measures on IRF COMPARE. Will IRF COMPARE report on these measures using blended rates, with one period utilizing the old methodology and data and another period utilizing the new methodology and data? Will IRF COMPARE cut off the reporting of the old methodology and start anew by reporting initial measure results? Without knowing the details about how these changes will appear on IRF COMPARE, providers cannot determine how best to

manage their quality data. In addition, consumers may be shown data that is inconsistent with a provider's actual performance.

We recommend that CMS suspend the public display of measures that are subject to these proposed changes. We also recommend that CMS delay the public display of quality measures until (1) at least a full twelve months of data has been collected and (2) providers are able to review and correct the information on these measures.

- c. Our third and final concern with the public reporting of IRF QRP data on IRF COMPARE is that IRF COMPARE displays information on time frames that differ between measures, creating a situation in which provider performance may be based on completely different populations of cases. Because the claims-based measures are one to two years behind the IRF-PAI and CDC NHSN measures, provider performance between the measures is affected by differences in case mix and patient severity that change over time. Even if an IRF has made improvements to the quality of care it provides, these changes may not show up on IRF COMPARE until one or two years later. This lag will not provide consumers with the information they need to make an informed decision.

We recommend that CMS suspend or delay the public display of IRF QRP data on IRF COMPARE until quality measures are provided on consistent time periods to account for potential differences in the case mix and severity of patient populations over time.

9. The training, data-collection specifications, and support that CMS and its contractors have provided for the implementation of quality measures and standardized patient assessment data have been inconsistent and have not provided the necessary responses to questions from IRFs. As a result, we continue to be concerned that quality data is inaccurate and unreliable and that it lacks the reliability and validity needed to provide clinical standards for quality measurement.

Over the last four to five years, the IRF-PAI has grown from three to eight to eighteen pages in support of both the IMPACT Act and the implementation of quality measures and standardized patient assessment data. Although CMS and its contractors have provided trainings, data collection and quality measure specifications, and e-mail addresses for training and support purposes, we have often found that the responses and the information being provided are inconsistent and may require revision, correction, or changes. As we have noted numerous times previously, perhaps the best example involves pressure ulcer data, which is proposed to change for the fourth time in the past five years. How can CMS and its measure developers provide consistent feedback to IRFs when they are continually changing the items and the calculations involved? And how does CMS expect IRFs to provide reliable and valid information when the data elements change so frequently?

Additionally, because the functional items used for quality differ from the functional items used for payment, an analysis of the data reveals significant disagreement about the patient's functional status, depending on the tool. For example, a large number of patients do not attempt an activity on the quality side but provide a functional status value on the payment side, indicating that the activity was performed. In this instance, the patient may appear to be more severely impaired from a quality standpoint than from a payment standpoint. The opposite situation is occurring as well.

Providers also have had issues with data completeness because of inconsistencies in the data-collection specifications and the training materials provided for these items. For example, section 9 of *The IRF-PAI Training Manual* states that data for healed pressure ulcers is voluntary, but CMS's IRF-PAI data specifications do not allow an IRF to leave these fields blank. In addition, they also generate a warning message if the IRF enters a dash for these voluntary items, suggesting that the IRF may be at risk for a payment penalty due to the entry of the dash. In the absence of additional guidance from CMS, providers have been confused and concerned about these discrepancies. Although CMS appears to be correcting this issue for data collection beginning in October 2017, no one knows how previous data will be handled or whether CMS will clarify whether IRFs will be penalized based on their responses to these voluntary items.

With all the issues noted above, we are concerned that the lack of consistency in CMS's training, materials, and feedback is making IRF-PAI assessment data inaccurate and unreliable. In light of these clear data issues, these quality measures should be considered unreliable and invalid.

We recommend that CMS suspend or delay the public display of IRF QRP data on IRF COMPARE until (1) the issues noted above are resolved and (2) CMS can attest to the data's reliability and validity for the purposes of quality comparisons.

We appreciate both the opportunity to comment on this proposed rule and CMS's careful consideration of the concerns and issues raised in this letter. With thirty years of experience in providing coding, clinical, and quality improvement services to IRFs and other PAC providers, UDSMR welcomes the opportunity to work with CMS to provide ongoing feedback regarding the selection and implementation of standardized and interoperable quality indicators and standardized patient assessment data. If you have any questions about these comments or require additional information, please contact us at 716-817-7800.

Sincerely,



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Troy Hillman, Manager, Analytical Services
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Carol Harper, Manager of Education, Training, and Consultation
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