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June 9, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1624-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: 42 CFR Part 412(CMS-1624-P) Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2016; Proposed Rule

Dear Acting Administrator Slavitt,

On behalf of Uniform Data System for Medical Rehabilitation (UDSMR) and the nearly 830 inpatient rehabilitation facilities we serve, we are pleased to present our comments on 42 CFR Part 412 Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2016; Proposed Rule, which was published on April 27, 2015, in the *Federal Register*.

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

Executive Summary:

We appreciate CMS's continuing efforts to measure quality in healthcare and its emphasis on developing standardized and interoperable measures within postacute care settings, but we are very concerned that these efforts, as presently proposed, will create additional and unnecessary administrative and financial burden on IRFs and their staff, negatively affecting their ability to provide the necessary patient care that results in quality outcomes.

Concerns:

1. The proposed new quality measures will require critical IRF staff (OTs, PTs, SLPs, and nurses) to spend an additional 41.5 minutes of administrative data collection for each Medicare beneficiary's IRF stay. These minutes will take time away from direct patient care.
2. Implementation of process measure NQF #2631 is redundant for IRFs because admission and discharge assessments of the patient's functional status and an interdisciplinary plan of care are already requirements for IRF PPS participation.
3. Four of the proposed NQF measures (#2633, #2634, #2635, and #2636) do not meet the IMPACT Act's requirement of being "standardized and interoperable." These specific measures were not included or proposed for SNFs or LTCHs.
4. The amount of duplication and similarity between the proposed new functional items and the existing IRF-PAI functional items increases the risk of confusion and the subsequent potential for errors in the payment and quality systems.
    a. Duplication of items with different functional rating scales (seven levels vs. six levels) and only minor adjustments to item definitions for Eating; Bathing;

Toileting; Dressing – Upper Body; Dressing – Lower Body; Transfers: Bed, Chair, Wheelchair; and Transfers: Toilet

   b. Measurement of the same functional constructs with different or multiple items versus one item (e.g., IRF-PAI item 39M, Locomotion: Stairs, vs. proposed items GG0170M, 1 step [curb]; GG0170N, 4 steps; and GG0170O, 12 steps)

5. The proposed "public display" of IRF QRP data includes the following:
   a. Indicators that are not representative of IRF quality
   b. Measures whose data collection periods are inconsistent, thus using different patient populations to define quality
6. The costs of the technical implementation of EMRs and training for the proposed new items will be significant. We are very concerned that these costs will flow back to CMS as additional operational costs at the facility level.

Recommendations:

1. Defer the implementation of NQF measures #2633, #2634, #2635, and #2636 until one or both of the following occur:
   a. The measures are endorsed by NQF for all postacute care sites.
   b. The Secretary implements the measures for all postacute care sites.
2. Remove the new IRF-PAI items related to NQF #2631, and utilize the existing functional assessment items for facilitation of measure. Use of the existing functional items will still allow the Secretary to meet the IMPACT Act's requirement for a quality measure related to functional status by October 1, 2016.
3. Where item duplication or similarity exists between proposed items and existing IRF-PAI items, utilize existing IRF-PAI functional status items for quality measures, avoiding potential effects on current payment policy.
4. Delay the public display of IRF QRP data until all IMPACT Act domains are implemented.

The remainder of this letter addresses our concerns in detail and concludes with additional comments.

1. **The proposed new quality measures will require critical IRF staff (OTs, PTs, SLPs, and nurses) to spend an additional 41.5 minutes of administrative data collection for each Medicare beneficiary's IRF stay. These minutes will take time away from direct patient care.**

   As stated in section IX.B, with references to proposed changes detailed in section VIII.G.

The IRF-PAI went from its original three pages to eight pages in FY 2014. Additional data-entry requirements for recording therapy minutes were added for FY 2015, and the proposed addition of another ten pages will produce an eighteen-page IRF-PAI for FY 2016. CMS estimates that IRFs will need 41.5 minutes to complete the additional elements for the six newly proposed quality measures (25.5 minutes for admission data and 16.0 minutes for discharge data), which will result in a total of 96.0 minutes to complete the information collection for the IRF-PAI. This additional time nearly doubles OMB's current estimate of the average time needed to administer this assessment. CMS further notes, "[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 will spend collecting information will severely decrease their ability to perform the patient-care activities necessary for improving the quality of care. Additionally, facilities with multiple admissions/discharges per day will need to increase staffing levels to accommodate the additional administrative workload, adding a financial burden that will go well beyond CMS's estimate of $21,239.33 per IRF.

2. **Implementation of process measure NQF #2631 is redundant for IRFs because admission and discharge assessments of the patient's functional status and an interdisciplinary plan of care are already requirements for IRF PPS participation.**

   As stated in section VIII.G.2.

The proposed measure (NQF #2631, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function) is a process measure that provides very little information about the quality of patient care while requiring the assessment of twelve "new" IRF-PAI functional items at admission and discharge. To satisfy the concept of a care plan that addresses function, the measure also will require that only one of the twelve items contain a numerical value for a goal. NQF is currently reviewing the proposed measure for use for long-term care patients but is not evaluating its applicability to the IRF and SNF populations.

IRF conditions of participation require IRFs to assess patients at admission and discharge with the IRF-PAI, which currently uses a seven-level scale to assess/measure cognitive and motor function. IRFs are also required to create an interdisciplinary plan of care for each patient and to file this document, which identifies individual functional goals, in the patient's medical record.

Requiring IRFs to collect additional information for twelve new functional items is redundant. Based on current requirements, IRFs will answer yes to this process measure 100% of the time. We believe that the intent of this measure is already being fulfilled as part of the IRF PPS and that no additional information should be required.

In a comment letter dated May 27, 2015, the Medicare Payment Advisory Commission (MedPAC) strongly urged CMS to move away from process measures that minimally improve patient care and to move toward the use of meaningful outcome measures. MedPAC urged CMS

not to burden providers with too many measures that take away from patient care. MedPAC is not in favor of requiring IRFs to implement NQF #2631 because IRFs are already required to assess each patient's function at admission and discharge. UDSMR wholeheartedly concurs with these statements.

3. Four of the proposed NQF measures (#2633, #2634, #2635, and #2636) do not meet the IMPACT Act's requirement of being "standardized and interoperable." These specific measures were not included or proposed for SNFs or LTCHs.

As proposed in sections VIII.G.3–VIII.G.6.

As stated in sections VIII.F.1 and VIII.G.1 of the proposed rule, "The IMPACT Act requires the specification of quality measures and resource use and other measures that are standardized and interoperable across PAC settings." We are concerned that the proposed quality measures are not aligned across the postacute settings and therefore do not meet the intended purpose of the IMPACT Act.

These four NQF measures—#2633, IRF Functional Outcome Measure: Change in Self-Care; #2635, IRF Functional Outcome Measure: Discharge Self Care Score; #2634, IRF Functional Outcome Measure: Change in Mobility Score; and #2636, IRF Functional Outcome Measure: Discharge Mobility Score—are being proposed specifically for IRFs, not for SNFs or LTCHs. Unless a measure is capable of being used across all settings, we suggest that data for it should not be collected at all.

These four proposed measures introduce seven "new" functional items related to self-care and fifteen "new" functional items related to mobility, all of which will be assessed at both admission and discharge to meet the requirements of the proposed measures. As we note in section 4 below, a number of these "new" functional items are duplicative of or similar to functional items in the current IRF-PAI. These measures also will require the assessment of fifteen to thirty additional IRF-PAI fields for risk-adjustment purposes. Because these measures have not been introduced for all postacute care settings, we question whether IRFs need the additional burden of collecting data for forty to fifty new IRF-PAI items.

These measures, which are still under review by NQF, have been found to be related to or to compete with the following measures that UDSMR previously submitted to NQF's Person- and Family-Centered Care Committee (PFCC):

- Measure #2287, Functional Change: Change in Motor Score
- Measure #2286, Functional Change: Change in Self-Care
- Measure #2321, Functional Change in Mobility

The PFCC considered these quality measures but was unable to reach a consensus about "best in class." As a result, these measures are now being referred to the Consensus Standards Approval Committee for a vote on June 9, 2015. UDSMR proposes to use existing IRF-PAI functional items, thereby eliminating the additional burden required with implementing the proposed quality measures.

We recommend that CMS defer implementation of NQF measures #2633, #2634, #2635, and #2636 until either they receive NQF endorsement for all postacute care sites or the Secretary implements the measures for all postacute care sites.

We further urge the Secretary, as enabled by the IMPACT Act, to consider using quality measures established on existing functional assessment items to meet the requirements of functional and cognitive outcome measurement. This decision will relieve the impending financial burden and data collection burden of duplicative measures.

4. The amount of duplication and similarity between the proposed new functional items and the existing IRF-PAI functional items increases the risk of confusion and the subsequent potential for errors in the payment and quality systems.

In reference to the quality measures proposed in sections VIII.G.2–VIII.G.6.

The rating scales for these sets of functional items use different values to represent different functional ability. The proposed functional items for use in the quality measures use a six-level scale with three additional responses if the item was not assessed. The existing IRF-PAI functional items use a seven-level scale with one additional response if the item was not assessed. Certain levels on each scale have very similar labels, although the values may differ. For example, level 04 is labeled "Supervision" for the proposed functional items, but that label corresponds with level 5 for the functional items on the current IRF-PAI. As another example, both level 03 for the proposed functional items and level 3 for the existing IRF-PAI functional items are labeled "Moderate Assistance," but the definitions differ to such an extent that level 03 for the proposed functional items corresponds to both level 3 and level 4 for the functional items on the current IRF-PAI. These examples demonstrate the potential for confusion when clinicians attempt to accurately rate for payment versus quality, calling the value of the resulting data into question.

In addition, the two rating scales differ in both their level of specificity and their ability to show functional differences between patients. Levels 6 and 7 for the current IRF-PAI functional items have been collapsed into level 06 for the proposed functional items. The proposal to collapse functional levels into one combined level does not allow IRFs to demonstrate the functional improvement of patients who no longer depend on adaptive or assistive devices. This level of specificity was previously requested by the industry, and collapsing these values may reduce the ability to differentiate higher levels of quality between postacute care providers.

UDSMR's subscribing facilities have suggested that they may need to ask different staff members to rate the payment and quality measures independently in order to ensure the validity of the data they are providing. This practice will further add to the potential staffing burden placed on IRFs.

We further believe that inpatient rehabilitation facilities, already short-staffed, will try to conserve resources and attempt to create a crosswalk between these functional items. This arbitrary assignment of presumedly equivalent ratings is obviously both unscientific and unproven, and it would produce substandard data for the purposes of both quality and payment. The possibility for multiple crosswalks exists, and the resulting substandard data would then form the basis for future policy decisions and clinical decisions.

4. The amount of duplication and similarity between the proposed new functional items and the existing IRF-PAI functional items increases the risk of confusion and the subsequent potential for errors in the payment and quality systems.

a. Duplication of items with different functional rating scales (seven levels vs. six levels) and only minor adjustments to item definitions for Eating; Bathing; Toileting; Dressing – Upper Body; Dressing – Lower Body; Transfers: Bed, Chair, Wheelchair; and Transfers: Toilet

In reference to the quality measures proposed in sections VIII.G.2–VIII.G.6.

According to the IMPACT Act, "In the case of patient assessment data being used with respect to a PAC assessment instrument that duplicates or overlaps with standardized patient assessment data . . . the Secretary shall, as soon as practicable, revise or replace such existing data with the standardized data." As the table below clearly demonstrates, duplication exists between the proposed and current functional items. However, CMS cannot currently replace the existing PAC assessment instrument in favor of standardized patient assessment data without negatively affecting the existing payment system. Because of this, the proposal will increase the burden on IRFs, producing additional costs to the IRF PPS by mandating duplicative data collection instead of using the existing items to facilitate the proposed quality measurement.

A review of the DRAFT IRF-PAI Version 1.4 can easily identify the overlap between the proposed functional items for use in the proposed quality measures and the existing IRF-PAI functional items used for payment. The table below identifies these instances of potential duplication.

Existing IRF-PAI Items		Proposed New Items	
Item	**Description**	**Item**	**Description**
39A Eating	Includes the ability to use suitable utensils to bring food to the mouth, as well as the ability to chew and swallow the food once the meal is presented in the customary manner on a table or tray.	GG0130A Eating	The ability to use suitable utensils to bring food to the mouth and swallow food once the meal is presented on a table/tray. Includes modified food consistency.
39C Bathing	Includes washing, rinsing, and drying the body from the neck down (excluding the back) in either a tub, shower, or sponge/bed bath.	GG0130E Shower/Bathe Self	The ability to bathe self in shower or tub, including washing, rinsing, and drying self. Does not include transferring in/out of tub/shower.
39F Toileting	Includes maintaining perineal hygiene and adjusting clothing before and after using a toilet, commode, bedpan, or urinal.	GG0130C Toileting Hygiene	The ability to maintain perineal hygiene, adjust clothes before and after using the toilet, commode, bedpan or urinal. If managing an ostomy, include wiping the opening but not managing equipment.

Existing IRF-PAI Items		Proposed New Items	
Item	**Description**	**Item**	**Description**
39D Dressing – Upper Body	Includes dressing and undressing above the waist, as well as applying and removing a prosthesis or orthosis when applicable.	GG0130F Upper Body Dressing	The ability to put on and remove shirt or pajama top; includes buttoning, if applicable.
39E Dressing – Lower Body	Includes dressing and undressing from the waist down, as well as applying and removing a prosthesis or orthosis when applicable.	GG0130G Lower Body Dressing	The ability to dress and undress below the waist, including fasteners; does not include footwear.
39I Transfers: Bed, Chair, Wheelchair	Includes all aspects of transferring to a chair and back, or from a bed to a wheelchair and back, or coming to a standing position if walking is the typical mode of locomotion.	GG0170E Chair/Bed-to-Chair Transfer	The ability to safely transfer to and from a bed to a chair (or wheelchair).
39J Transfers: Toilet	Includes safely getting on and off a standard toilet.	GG0170F Toilet Transfer	The ability to safely get on and off a toilet or commode.

Where item duplication exists between proposed items and IRF-PAI items, we recommend that CMS discard the proposed new functional items in favor of the existing IRF-PAI functional status items for quality measures, thereby avoiding potential effects on current payment policy.

4. The amount of duplication and similarity between the proposed new functional items and the existing IRF-PAI functional items increases the risk of confusion and the subsequent potential for errors in the payment and quality systems.

b. Measurement of the same functional constructs with different or multiple items versus one item (e.g., IRF-PAI item 39M, Locomotion: Stairs, vs. items GG0170M, 1 step [curb]; GG0170N, 4 steps; and GG0170O, 12 steps)

In reference to the quality measures proposed in sections VIII.G.2–VIII.G.6.

For functional items relating to stairs and steps and a patient's ability to walk and use a wheelchair, CMS appears to propose expanding data collection in order to obtain more details about a patient's functional capacity. However, the additional functional quality items have not demonstrated any ability to increase the accuracy of functional measurement or to provide any additional benefit to the patient. Is the assessment of multiple items that measure the same functional ability truly necessary?

Additionally, expanding from one functional item to many in the effort to assess more specific functional capability may cause the quality measures to provide an inflated interpretation of functional progress.

To detail this further, item 39M of the existing IRF-PAI is labeled "Stairs," and it includes going up and down twelve to fourteen stairs (one flight) indoors in a safe manner. This definition may suggest that the patient must try to manage all twelve to fourteen stairs to complete the assessment of this item, but a review of *The IRF-PAI Training Manual* shows that certain exceptions are already in place for this item—for example, an exception that allows the patient to perform this function on only four to six stairs, with or without a device. The proposed new functional items for quality measurement of stairs include item GG0170M, 1 step (curb); item GG0170N, 4 steps; and item GG0170O, 12 steps. The use of three items forces IRF staff members to evaluate the patient's functional independence for each item independently.

An analysis of current IRF-PAI data for Medicare beneficiaries in the UDSMR® database suggests that item 39M, Stairs, is not assessed at admission on roughly 60% of the population due to the patient's inability to perform the activity safely, the patient's inability to perform the activity because of a medical condition or medical treatment, or the patient's refusal to perform the activity. If this single item is expanded to three specific items, how will CMS handle information that is not assessed at admission for 60% of their patients for three of the fifteen functional items used in a quality measure of mobility?

Additionally, a patient who performs this function for twelve steps should, in theory, be able to perform it for both one step and four steps. Will an improvement in all three items illustrate unique changes in the patient's functional ability, or do all three actually measure the same functional construct, which is the ability to navigate stairs?

The same comparisons and concerns can be examined for item 39L, Locomotion: Walk, Wheelchair, and the following proposed items:

- GG0170I, Walk 10 feet
- GG0170J, Walk 50 feet with two turns
- GG0170K, Walk 150 feet
- GG0170R, Wheel 50 feet with two turns
- GG0170S, Wheel 150 feet

Does the addition of specific distances as new items truly display unique changes in the patient's functional ability, or does it simply measure the same functional construct that the existing single functional item does?

Where item similarity or expansion exists between proposed items and existing IRF-PAI items, we recommend that CMS not add the proposed new functional items to the IRF-PAI and that it instead utilize the existing IRF-PAI functional status items for quality measures, thereby avoiding the potential inflation of measures of functional improvement.

5. The proposed "public display" of IRF QRP data includes the following:

a. Indicators that are not representative of IRF quality

As stated in section VIII.O.

Although we recognize that CMS intends to publicly report on IRF QRP data, the industry does not believe that the three initially proposed measures represent the quality of care provided by IRFs. For example, an analysis of current IRF-PAI data for Medicare beneficiaries in the UDSMR® database suggests that less than 1% of Medicare IRF cases are identified with a new or worsened pressure ulcer at discharge. This quality measure (NQF #0678) has been suggested for the IMPACT Act domain for skin integrity, but we question whether any improvement in less than 1% of the existing population truly represents an improvement of the quality of care within IRFs. As such, public display of this measure does not add value to consumer decisions.

Additionally, we are concerned about the display of NQF measure #2502, All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs. IRFs currently have no way to monitor patient readmission status in order to improve this outcome. The use of claims data that facilities cannot access in real time and cannot interpret does not provide appropriate guidance or meaningful insight about clinical quality improvement initiatives that could be implemented to alter the outcome. In addition, this measure does not risk-adjust for socioeconomic factors, which can greatly influence a patient's outcomes after discharge from an IRF.

Because these initial items do not accurately reflect the quality of IRF care, we recommend that CMS delay the public display of IRF QRP data until all IMPACT Act domains are implemented.

5. The proposed "public display" of IRF QRP data includes the following:

b. Measures whose data collection periods are inconsistent, thus using different patient populations to define quality

As stated in section VIII.O.

The proposed data collection period for the initial public display of IRF QRP data for both the pressure ulcer measure and the CAUTI measure is January to December 2015, but the data collection period for the all-cause unplanned readmission measure is January 2013 to December 2014. Additionally, each proposed measure for public display specifically states that both Medicare Part A and Part C patients are included for IRFs. However, SNFs include only Medicare fee-for-service residents for these measures, and LTCHs do not make any specific reference to payer source for data collection for these measures.

The variance in collection periods and payer sources is a concern because the differing patient populations may result in conflicting indicator data or representations.

6. **The costs of the technical implementation of EMRs and training for the proposed new items will be significant. We are very concerned that these costs will flow back to CMS as additional operational costs at the facility level.**

   In reference to the quality measures proposed in section VIII.G.

At a time when CMS is attempting to mitigate the various costs for providing care within the postacute care programs, we are very concerned that CMS has not considered additional implementation costs as part of its quality strategy. We believe that CMS has severely underestimated the actual cost to facilities of implementing the additional IRF-PAI items. The proposed rule does not refer to the amount of training and education that staff will need to become proficient at rating these additional items. We also believe that CMS did not consider the cost of updating and testing EMRs to comply with the new requirements or the cost of adding to and altering facilities' current documentation forms and processes.

CMS has not adjusted payment in FY 2016 to account for the various changes facilities have needed to make as part of the implementation of ICD-10. We recommend that CMS consider additional implementation costs when making updates to the IRF PPS in FY 2017, when the proposed changes to the IRF-PAI and quality measurement will be implemented.

Additional Comments:

1. The proposed modification of the IRF-PAI items used for new or worsened pressure ulcers (M0800A, M0800B, and M0800C) in order "to further harmonize data elements across PAC providers" is yet another change to this quality measure. CMS should consider the financial burden of accommodated such changes. For the most part, IRFs do not receive any financial incentives for EMR implementation. Each change to the IRF-PAI results in tremendous costs associated with updating EMRs and training staff members. The pressure ulcer measure (NQF #0678) has now been changed for the third time in three years, and a future update to the measure's numerator has been proposed as well. CMS may not consider these changes significant, but the cost to the facility is. We respectfully request that CMS propose for inclusion in the IRF QRP only those measures that have been fully endorsed and validated for all postacute settings.
2. UDSMR agrees that falls with injury represent a significant physical risk to the patient and a significant financial burden to the rehabilitation facility, but falls are not a one-size-fits-all measure. All patients admitted to an IRF are at risk of falling, and many factors, including cognitive impairment, diagnosis, and staffing ratios, influence the rate of falls. The proposed measure (NQF #0674) is currently NQF-endorsed for skilled nursing facilities, whose patient mix differs from that of IRFs in several ways, including age, diagnosis, and functional and cognitive abilities. We recommend NQF validate and endorse this measure for the IRF population prior to implementation, allowing for risk adjustment specific to IRF patients in order to provide quality data that can be used for improvement initiatives.
3. The decision to use alternative functional measures in postacute rehabilitation will negate the ability to reference generations of functional research that has been painstakingly collected and examined and that has provided the industry with reliable benchmarks for monitoring not only individual improvement, but also the industry's progress toward quality patient care.

4. We believe that the PAC-PRD did not produce enough data or scientific evidence to suggest that the proposed functional status indicators based on the CARE tool can be used for quality systems and payment systems. As a result, IRFs and other postacute care providers are being saddled with the administrative and financial burden of collecting additional data for these purposes.
5. We urge CMS to use the successful implementation of the IRF PPS and the IRF-PAI as a model or starting point for meeting the needs of the IMPACT Act. The IRF-PAI currently includes information that can be utilized to meet multiple IMPACT Act domains (functional status, skin integrity, resource use, and discharge to community), and the IRF PPS already accounts for differences in impairment, comorbidities, and functional status. Although we recognize the investment CMS has made into the PAC-PRD, we still believe that expanding the IRF PPS and the IRF-PAI to all postacute care sites will produce the easiest transition and implementation while meeting the requirements outlined in the IMPACT Act.

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. We welcome the opportunity to work with CMS to provide ongoing research regarding the selection and implementation of standardized and interoperable quality indicators. If you have any questions about these comments or require additional information, please contact us at 716-817-7800.

Sincerely,

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