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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-1688-P) Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2019; 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 2019; Proposed Rule, which was published on May 8, 2018, in the *Federal Register*. With thirty years of experience providing coding, clinical, and quality improvement services to IRFs and other PAC providers, UDSMR welcomes the opportunity to provide ongoing feedback to CMS.

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

Executive Summary:

UDSMR appreciates CMS's intended focus on reducing provider burden in this proposed rule. Since the passage of the Improving Medicare Post-Acute Care Act of 2014 (IMPACT Act), CMS has implemented a significant amount of additional assessment items and quality measures that shift a huge regulatory and financial burden onto facilities without sufficient evidence that these measures increase the quality of care or control costs. Over the past three to four years, providers and their clinicians have devoted more and more time to administrative documentation and regulatory requirements in lieu of patient care, which has prevented IRFs from improving the quality of care they deliver and/or reducing costs to the Medicare program.

Although UDSMR and our IRF subscribers appreciate CMS's intent, we believe that the proposed changes to the IRF payment system and requirements will not produce the desired reductions in administrative burden and may instead cause further issues in the delivery of IRF-level care to patients who stand to benefit from this level of service. We also do not believe that the proposed changes will improve the quality of care delivered or control costs within the Medicare program. We strongly urge CMS to reconsider a number of these proposals and work with IRFs in a transparent manner toward the goal of reducing administrative burden.

Concerns:

1. The FY 2019 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 three final rules. The proposed increase does not cover the costs of changes to medical records and documentation, training of clinicians, and data collection related to quality reporting items.
2. The proposed removal of the FIM® instrument and associated function modifiers from the IRF-PAI and proposed refinements to the case-mix classification system
   a. will not reduce administrative burden;
   b. lack sufficient research, testing, and analysis;
   c. will make IRF patients appear "less severe";
   d. will affect patient access to resources and an IRF level of care; and
   e. will not be budget-neutral.
3. The proposed revisions to certain IRF coverage requirements
   a. may put patients at risk due to potentially diminished physician involvement,
   b. may reduce the burden on physicians but place additional burden on other clinicians,
   c. may be unnecessary or handled as a clarification of existing requirements, and
   d. do not address other IRF coverage requirements that have a more significant impact on administrative burden and/or costs.
4. The proposed revisions and updates to the IRF Quality Reporting Program (QRP)
   a. do not identify all the measures that could be subject for removal based on the considerations used for selection of measures and
   b. propose public display of functional quality measures that have yet to provide risk-adjustment information or provider performance previews.

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. The Secretary or CMS should defer removal of the FIM® instrument and implementation of any payment model reform until
    a. standardized patient assessment data not only illustrates that it can be feasibly collected, but also provides evidence that it adequately predicts patient severity and/or cost;
    b. the proposed payment model classifies patients into categories that mirror their current level of severity and provides the proper amount resources needed for patient care; and
    c. CMS provides a transparent process for payment system changes in a manner similar to the development and implementation of quality measures.
3. As part of the effort to reduce provider burden, CMS should remove the 60% rule from the criteria used to classify facilities for payment under the IRF PPS.
4. 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.
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 2019 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 three final rules. The proposed increase does not cover the costs of changes to medical records and documentation, training of clinicians, and data collection related to quality reporting items.**

   As stated in section V of CMS-1688-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 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. 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 continually 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 the FY 2017 IRF PPS final rule, CMS finalized the implementation of the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP measure for discharges beginning on or after October 1, 2018. According to CMS, the proposed estimate is that this will add roughly ten more minutes and will cost IRFs an additional $4,625.46 per IRF 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 2019, after adjusting for all factors detailed in table 5 of section V, is an increase of only 1.15%, or $182, 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 measure in the FY 2017 final rule is roughly $5.2 million, or around $14 per Medicare patient.[*] The burden of data collection finalized in the FY 2016/2017 final rules consumes nearly 43% of the FY 2019 SPCF increase, leaving an increase of only $104 (0.66%) 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 2019 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 removal of the FIM® instrument and associated function modifiers from the IRF-PAI and proposed refinements to the case-mix classification system

a. will not reduce administrative burden;

b. lack sufficient data, research, testing, and analysis;

c. will make IRF patients appear "less severe";

d. will affect patient access to resources and an IRF level of care; and

e. will not be budget-neutral.

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

Before addressing each of the concerns noted above, as previously stated in this comment letter, UDSMR strongly recommends that CMS defer removal of the FIM® instrument and implementation of any payment model reform until

- standardized patient assessment data not only illustrates that it can be feasibly collected, but also provides evidence that it adequately predicts patient severity and/or cost;
- the payment model classifies patients into categories that mirror their current level of severity and provides the proper amount resources needed for patient care; and
- CMS provides a transparent process for payment system changes in a manner similar to the development and implementation of quality measures.

UDSMR and our subscribers would like the opportunity to work with CMS to identify a way forward in reducing the burden related to assessment of a patient's functional status and ensuring that a new payment system accurately accounts for patient severity and provides the necessary resources for patient care.

a. The proposed removal of the FIM® instrument and associated function modifiers from the IRF-PAI and proposed refinements to the case-mix classification system will not reduce administrative burden.

In an effort to reduce administrative burden, CMS is proposing to remove the FIM® instrument and associated function modifiers from the IRF-PAI and proposing refinements to the case-mix classification system. IRFs currently are required to collect functional assessment data two different ways. First, IRFs assess patients and document and collect FIM® instrument data primarily for payment purposes. Second, IRFs assess patients and document and collect standardized patient assessment data elements (SPADEs) that address function currently for quality reporting purposes. Numerous items can be considered duplicative in nature, but the rating scales and the methodology used to collect this information differ.

Although UDSMR and our subscribers agree that additional burden has been placed on them to collect functional status assessment data two different ways, removal of the FIM® instrument and associated function modifiers will not reduce administrative burden. The time and effort required for the underlying documentation and clinician involvement used for these items will remain with the SPADEs. The only burden reduction will be eliminating the choice of a scale value to enter data into the IRF-PAI. As a result, 95% to 99% of the time

needed to assess a patient's functional status will still be required, resulting in an essentially identical amount of administrative burden.

Additionally, the replacement items suggested for the removal of the FIM® instrument and associated function modifiers are not only duplicative items, but also additional items that have placed significantly more burden on IRFs and their clinicians. There are eighteen FIM® items and ten associated function modifiers for a total of twenty-eight items. By contrast, CMS has implemented fifty-seven items for the purposes of assessing patient functional status and quality measurement:

- Two items in IRF-PAI section B related to hearing and speech
- Fifteen items in section C related to cognitive patterns (BIMS and SAMS)
- Ten items in section GG0100 related to prior functioning and device use
- Seven items in section GG0130 related to self-care
- Twenty-one items in section GG0170 related to mobility
- Two items in section H related to bladder and bowel

Is administrative burden reduced by the requirement of documenting and assessing at least twenty-nine additional items related to function?

CMS also has made changes to the training materials, as well as the verbiage and codes of these SPADEs, requiring IRFs to spend additional administrative time and resources to retrain staff and update documentation. Changes to item verbiage will require additional staff training and documentation updates for cases discharged on or after October 1, 2018. In addition, a new response code will be available for use on the section GG items to indicate instances where an activity may not be assessed due to environmental limitations, and providers will need to train their staff on how and when to use this code.

We further note that CMS is continuing to test and evaluate new items related to patient function, especially as it relates to cognitive and mental status, as well as continence, vision, and hearing. Currently, CMS has contracted with the RAND Corporation to conduct the national beta test to evaluate additional candidate standardized patient assessment data elements. As stated on the National Field Test Assessment Protocol:

"The clinical categories being considered for standardized assessment are:

- *Cognitive status (including cognitive function, delirium, expression and understanding, and behavior)*
- *Mental status (including depression and anxiety)*
- *Impairments (including continence, vision, and hearing)*
- *Medical conditions (including pain)*
- *Special Services Treatments and Interventions*
- *Other clinical categories:*
    - *Global health*
    - *Care preferences*
    - *Medication reconciliation"*

We are greatly concerned that this beta test not only will result in additional administrative burden, but also could modify existing items that are currently suggested as replacements for the FIM® instrument and associated function modifiers. For example, the national beta test includes testing of the BIMS, as well as different methods of assessing bladder and bowel function. If these items are actively being tested, how confident can we be that the existing items are reliable and valid?

As a result, we recommend that CMS not remove the FIM® instrument and associated function modifiers from the IRF-PAI until adequate replacement items are finalized that provide suitable evidence that they can adequately predict patient severity and/or cost.

In an effort to further reduce administrative burden, we also recommend that CMS evaluate the opportunity to remove items from the IRF-PAI that do not show the ability to predict patient severity, cost of care, or quality of care. For example, over the past two to three years, IRFs have been collecting and submitting data on therapy minutes for the first two weeks of each patient's stay. To this point, this has simply been an exercise in data collection, and CMS has not provided any evidence that the information is intended to be used for payment or quality purposes.

b. The proposed removal of the FIM® instrument and associated function modifiers from the IRF-PAI and proposed refinements to the case-mix classification system lack sufficient data, research, testing, and analysis.

First and foremost, utilizing the first year of data for newly implemented assessment items does not represent sufficient data for the purposes of removing existing payment data and replacing a payment system. The current payment system is based on FIM® assessment data that has been collected for over thirty years and has been a part of the IRF PPS for nearly twenty. Prior to implementation of the IRF PPS, CMS and their contractor (RAND) analyzed four years' worth of FIM® data in order to show that the payment system would be based on reliable and valid data that accurately predicted cost and patient severity. We suggest that one year's worth of data based on the first twelve months of data collection on new assessment items does not meet the standards necessary for producing a reliable and valid alternative payment model.

Second, the supporting document from RTI related to the research, testing, and analysis of the proposed alternative payment model does not offer sufficient evidence that the selected items and the resulting model are suitable replacements for the existing items and payment system. Although certain analyses were performed to determine the overall financial impact, the document fails to indicate whether each of the nineteen items chosen for the motor score is needed or can predict costs on its own. The analyses also do not indicate whether the resulting motor score measures the severity of patients as consistently as the weighted motor score index does. Without transparency and additional information about how the model was created and why certain selections were made, providers cannot evaluate whether the proposed payment model will provide the resources necessary to care for their patients.

We recommend that CMS and RTI provide evidence that each of the items included in the motor score and payment model can predict cost on its own or improve the prediction of cost when added with other items. We further recommend that CMS and RTI provide information and analyses about the impact on patients and whether their current level of severity is consistent with the existing system. Finally, we recommend that CMS and RTI provide an

opportunity for a technical expert panel (TEP) or subject-matter experts (SMEs) to review the analyses and findings prior to the rulemaking process in order to allow for better stakeholder engagement and opportunities to produce suitable results.

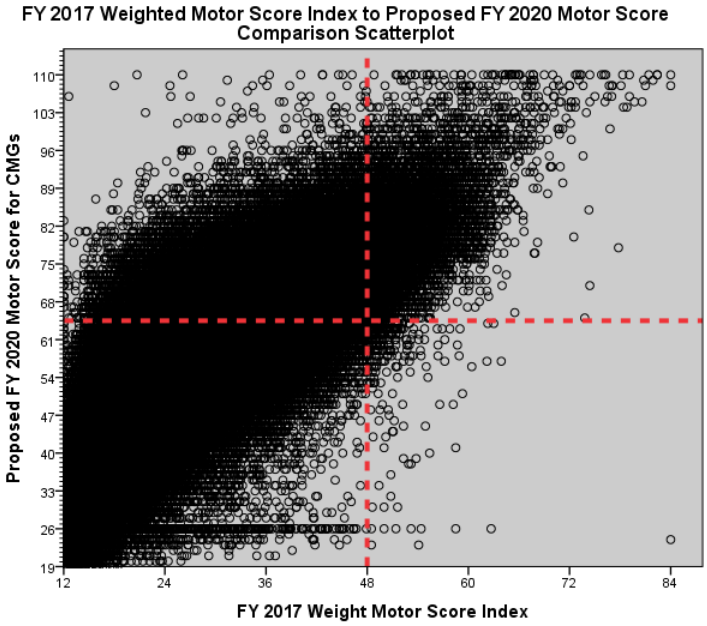
c. The proposed removal of the FIM® instrument and associated function modifiers from the IRF-PAI and proposed refinements to the case-mix classification system will make IRF patients appear "less severe."

Using the UDSMR® IRF database for Medicare Fee-for-Service cases discharged between October 2016 and September 2017, we replicated the proposed motor score used for the proposed CMGs for FY 2020. We then compared these values to the existing weighted motor score index used for the current CMGs. As shown below, for FY 2017 cases we found that, on average, the proposed motor score for the FY 2020 CMGs was indicating that patients were functioning at a higher percentage of total possible function than the current weighted motor score index.

	Maximum Value	Mean (Average)	% of Max. Value
Proposed motor score for FY 2020 CMGs	110	55.5	50.5%
Current weighted motor index for CMGs	84	28.1	33.5%

As shown here, the proposed motor score for FY 2020 CMGs suggests that the average IRF patient is functioning at 50% of maximum function at admission; by contrast, the current weighted motor index suggests that the average IRF patient is functioning at 33%. Such a difference causes us to question whether the proposed payment model will accurately reflect the resource needs of what appears to be a more severe population.

We also produced a scatterplot of these values to examine the amount of variability between the two scores and identify any significant differences in the interpretation of patient severity.



The scatterplot illustrates significant variation between the level of severity represented by the proposed motor score for FY 2020 CMGs and the level represented by the FY 2017 weighted motor score index. For reference purposes, we added the red dotted lines to indicate the values where patients would be at 50% of maximum function. If the proposed payment model was consistent with projecting the level of severity of IRF patients, we would expect to see a relatively tight grouping of patient values moving from low to high and clustering around common values; however, we see a very wide band of patient values that, even at the 50%/50% point, is shifted upward in terms of the proposed motor score for FY 2020 CMGs. From a payment perspective, the upper left quadrant is of particular concern. The cases in this quadrant would be less than 50% of maximum functioning in the existing payment system but considered greater than 50% of maximum functioning in the proposed payment system. For these cases, the probability of reduced payment and lack of resources is high.

To take a closer look at this, we proceeded to evaluate the assessment items currently being used for both the current weighted motor score index and the proposed motor score for FY 2020 CMGs. As shown below, the average patient appears to have a significantly different level of severity based on the items chosen and the methodology behind the assessments.

FIM® Item	Mean (Average)	% of Maximum Function	Quality Indicator Item	Mean (Average)	% of Maximum Function
Eating (39A)	4.71	67.3%	Eating (GG0130A)	4.80	80.0%
Grooming (39B)	3.82	54.6%	Oral hygiene (GG0130B)	4.22	70.3%
Bathing (39C)	2.71	38.7%	Shower/bathe self (GG0130E)	2.71	45.1%
Dressing: Upper Body (39D)	3.13	44.7%	Upper-body dressing (GG0130F)	3.43	57.2%
Dressing: Lower Body (39E)	1.95	27.8%	Lower-body dressing (GG0130G)	2.35	39.2%
			Putting on/taking off footwear (GG0170H)	2.23	37.1%
Toileting (39F)	2.18	31.1%	Toileting hygiene (GG0130C)	2.64	44.0%
			Roll left and right (GG0130A)	3.42	57.1%
			Sit to lying (GG0130B)	3.20	53.3%
			Lying to sitting on side of bed (GG0130C)	3.17	52.8%
			Sit to stand (GG0130D)	2.92	48.7%
Transfers: Bed, Chair, Wheelchair (39I)	2.33	33.3%	Chair/bed-to-chair transfer (GG0170E)	2.81	46.8%
Transfers: Toilet (39J)	2.52	36.0%	Toilet transfer (GG0170F)	2.69	44.8%
Locomotion: Walk, Wheelchair (39L)	1.77	25.3%	Walk 10 feet (GG0170I)	2.60	43.4%
			Walk 50 feet with two turns (GG0170J)	2.12	35.3%
			Walk 150 feet (GG0170K)	1.56	26.0%
Locomotion: Stairs (39M)	1.43	20.5%	One-step curb (GG0170M)	1.76	29.4%

FIM® Item	Mean (Average)	% of Maximum Function	Quality Indicator Item	Mean (Average)	% of Maximum Function
Sphincter Control: Bladder Management (39G)	2.97	42.5%	Bladder continence (H0350)	3.26	81.5%
Sphincter Control: Bowel Management (39H)	3.90	55.7%	Bowel continence (H0400)	3.50	87.6%

With the exception of bladder and bowel function, the average patient appears to be about 10% to 20% higher in terms of the percentage of maximum function for each of the comparable or duplicative items. We believe that these differences are caused by two factors:

- **Assessment methodology:** The FIM® items utilize the lowest value over the three-day admission assessment period. This methodology is designed to capture the burden of care so that IRFs can provide the appropriate amount of resources to meet the patient's needs. The quality indicator items in section GG also have a three-day admission assessment period, but *The IRF-PAI Training Manual*'s instructions for choosing a value indicate that the assessment should occur prior to the start of therapy services, that it should be based on the patient's usual status, and that the patient's best and worst performances should not be recorded. Implementation of the section GG items created a great deal of confusion, as providers have not consistently adopted the assessment methodology noted. If therapy starts on the first day of the stay, providers may only assess a patient once prior to the start of therapy, and that day may be the worst or best performance over the three-day admission assessment period. In this scenario, providers are confused about whether to use the assessment prior to therapy or the usual performance result. In addition, the value used by providers who document only one assessment of these items may not be consistent with the value used by those who document multiple assessments. Either way, this difference in the assessment methodology appears to be causing patients to appear less severe. We ask that CMS and RTI clarify the assessment methodology further and identify whether this methodology captures the burden of care for the purposes of payment.
- **Scale/code differences:** Differences in the item scales/codes can make patients appear less severe. The table below provides details about the scale/code options.

Score	FIM® Level	SPADE Section GG Levels
1	Total assistance (subject performs 25% or less independently or requires assistance from two or more helpers)	Dependent—Helper does ALL of the effort. Patient does none of the effort to complete the activity. Or, the assistance of 2 or more helpers is required for the patient to complete the activity.
2	Maximal assistance (subject performs 25%–50% independently)	Substantial/maximal assistance—Helper does MORE THAN HALF the effort. Helper lifts or holds trunk or limbs and provides more than half the effort
3	Moderate assistance (subject performs 50%–75% independently)	Partial/moderate assistance—Helper does LESS THAN HALF the effort. Helper lifts, holds or supports trunk or limbs, but provides less than half the effort.
4	Minimal assistance (subject performs 75% or more independently)	Supervision or touching assistance—Helper provides VERBAL CUES or TOUCHING/STEADYING assistance as patient completes activity. Assistance may be provided throughout the activity or intermittently.

Score	FIM® Level	SPADE Section GG Levels
5	Supervision (subject performs 100% independently)	Setup or clean-up assistance—Helper SETS UP or CLEANS UP; patient completes activity. Helper assists only prior to or following the activity.
6	Modified independence (device used)	Independent—Patient completes the activity by him/herself with no assistance from a helper.
7	Complete independence	*Patient refused*
88	—	*Not attempted due to medical concern or safety issue*
9	—	*Not applicable*
0	*Activity does not occur (admission only)*	—

In terms of making patients less severe, we are most concerned about the differences in level 1, which is the most severe functional level. For the FIM® instrument, a patient who performs 25% or less of an activity or requires assistance from two or more helpers is assigned a level 1 value. For the section GG items, level 1 is assigned only when a patient does not perform any of the effort to complete the activity or when the patient requires assistance from two or more helpers to complete the activity. For a patient who performs 1% to 24% of an activity, the section GG items require that the patient be coded level 2, along with patients who perform 25% to 49% of an activity. So if patients attempt and complete only a small portion of an activity yet still require a significant amount of assistance, they are now moved from a value of 1 to a value of 2. In terms of the percentage of maximal function value, this change takes these patients from 14.3% of maximal function value to 33.3%. From a resource perspective, these patients will still require a great deal of time and resources, but the scale options are producing a result that may make these patients appear less severe. We ask that CMS and RTI evaluate whether their scale items appropriately capture the burden of care for these patients and whether the scale values represent the actual amount of time and resources needed for these patients.

For bladder management and bowel management, the proposed replacement items are measuring a different construct using a different scale on a different admission assessment period. The FIM® ratings for Bladder Management and Bowel Management are each the result of two function modifiers that assess both the frequency of accidents over the last seven days (the three-day admission assessment period and the four days prior) and the level of assistance provided during the three-day admission assessment period. In contrast, the SPADE bladder and bowel continence items only assess the presence of incontinent episodes over the three-day admission assessment period. Because the SPADE items do not capture the amount of assistance provided to the patient and do not capture incontinent episodes prior to admission, patient severity appears significantly different for these items.

The following tables compare how these items are assessed for FY 2017 discharges:

	Admission FIM Sphincter Control - Bladder (39G)	Cases	%
1	Total Assistance (<25%)	140375	45.3%
2	Maximal Assistance (25-49%)	21449	6.9%
3	Moderate Assistance (50-74%)	21400	6.9%
4	Minimal Assistance (75-99%)	23620	7.6%
5	Supervision	61831	19.9%
6	Modified Independence	19569	6.3%
7	Complete Independence	21931	7.1%
	AVERAGE	2.97	
	Percentage of Maximum Function	42.5%	

	Admission Bladder Continence (H0350)	Cases	%	Recode Value
9	Not applicable	23865	7.7%	1
4	Always incontinent	18711	6.0%	1
3	Incontinent daily	30270	9.8%	2
2	Incontinent less than daily	41574	13.4%	3
1	Stress incontinence only	15278	4.9%	4
0	Always continent	176753	57.0%	4
-	Not assessed	82	0.0%	4
5	No urine output	3642	1.2%	4
	AVERAGE	3.26		
	Percentage of Maximum Function	81.5%		

	Admission FIM Sphincter Control - Bowel (39H)	Cases	%
1	Total Assistance (<25%)	90738	29.3%
2	Maximal Assistance (25-49%)	19494	6.3%
3	Moderate Assistance (50-74%)	17795	5.7%
4	Minimal Assistance (75-99%)	21244	6.8%
5	Supervision	42897	13.8%
6	Modified Independence	99747	32.2%
7	Complete Independence	18260	5.9%
	AVERAGE	3.90	
	Percentage of Maximum Function	55.7%	

	Admission Bowel Continence (H0400)	Cases	%	Recode Value
3	Always incontinent	19189	6.2%	1
2	Frequently incontinent	16885	5.4%	2
9	Not rated	16684	5.4%	2
1	Occasionally incontinent	29520	9.5%	3
0	Always continent	227817	73.4%	4
-	Not assessed	80	0.0%	4
	AVERAGE	3.50		
	Percentage of Maximum Function	87.6%		

In both instances, significantly more patients are coded as "always continent" on the SPADE items, which is recoded to the highest functional level for the purposes of the proposed payment model. Additionally, significantly fewer patients are coded as "always incontinent," which is recoded to the lowest functional level for the purposes of the proposed payment model. In comparison to the FIM® items, it appears that patient severity has completely changed because of the change in items and what they measure. This is causing patients to appear less severe from a payment model standpoint.

We also note that alternative bladder and bowel items are currently being tested as part of the national beta test for additional SPADE items previously mentioned in this comment letter. We question the applicability of the existing bladder and bowel items for payment purposes when alternative items are actively being tested and potentially considered for implementation. We ask that CMS evaluate which bladder and bowel items are most appropriate and which best capture patient severity and burden of care for the purposes of payment.

Finally, in regard to the proposed payment model making patients appear less severe, we would like to point out issues with the chosen items that differ from the current FIM® items or have no comparable FIM® items. These items typically involve "smaller" activities or tasks, and we believe that these items were added as SPADEs at the request of LTCHs and SNFs in order to allow these settings to demonstrate functional change for more severely impaired patients. As previously stated, CMS and RTI have not provided additional information related to an individual item's ability to predict cost on its own, and, as such, some of the choices they have made for inclusion in the motor score significantly affect the level of severity of IRF patients.

- CMS is proposing to replace the existing FIM® item 39L, Locomotion: Walk, Wheelchair, which is based on the patient's ability to walk or wheel 150 feet, with three walking items, each of which assesses a different distance and functional ability. Although item

GG0170K, Walk 150 feet, has the most similar definition and produces a very similar average functional ability for IRF patients, CMS and RTI also included item GG0170I, Walk 10 feet, and item GG0170J, Walk 50 feet with two turns. As shown previously, these two items have a higher average value and represent a higher functional level for IRF patients. The inclusion of these two additional walking items in the payment model motor score makes the patient look less severe because the values of these two items outweigh the value measured by item GG0170K, Walk 150 feet. We ask CMS and RTI to provide evidence related to the inclusion of these two additional walking items and to determine whether they capture an accurate burden of care and patient severity for the purposes of predicting cost and resulting payments.

- CMS is proposing to replace the existing FIM® item 39M, Locomotion: Stairs, which is based on the patient's ability to go up and down twelve to fourteen stairs, with item GG0170M, One step (curb), which is based on the patient's ability to step over a curb or up and down one step. For quality purposes, IRFs are required to collect and submit data on a SPADE item that is equivalent to the existing FIM® item and is based on twelve steps, but CMS and RTI did not choose that item for the purposes of the payment model. When evaluating the twelve-step item, we have noted that average patient performance is more closely aligned to the existing FIM® item. By choosing a one-step item to replace a twelve-step item, as shown previously, average performance on the one-step SPADE item is higher than performance on the twelve-step FIM® item and represents a higher functional ability for IRF patients. CMS and RTI offered little information as to why the twelve-step item was not used in the proposed payment model motor score, suggesting that "excluded elements are typically too challenging for patients on admission to IRFs and therefore are less likely to be assessed on admission. The frequency with which these items are not assessed on admission in the IRF decreases their relevance for predicting costs." We ask that CMS and RTI reevaluate their choice of a replacement for FIM® item 39M, Locomotion: Stairs, and provide evidence that any chosen items capture the true burden of care and patient severity for the purposes of predicting cost and resulting payments.
- CMS is proposing the inclusion of four items in the motor score that have no comparable FIM® instrument items:
  - Roll left and right (GG0130A)
  - Sit to lying (GG0130B)
  - Lying to sitting on side of bed (GG0130C)
  - Sit to stand (GG0130D)

  As shown in the analysis previously presented, these items average at or around level 3 on the SPADE section GG scale, which represents "Partial/moderate assistance—Helper does LESS THAN HALF the effort." In addition, a significant percentage of IRF patients appear to be coded at level 3 or 4. We believe that these items are duplicative in nature, as these smaller activities/tasks are part of the assessment of other SPADE items, such as item GG0170E, Chair/bed-to-chair transfer. The inclusion of these four items in the motor score will outweigh other item values, which produce a much lower average value and represent the level of severity of an IRF patient. We ask that CMS and RTI provide

evidence related to the inclusion of these items and whether they capture the true burden of care and patient severity for the purposes of predicting cost and resulting payments.

For all the reasons we identify above, we believe that the payment model and motor score value that CMS and RTI are proposing are making IRF patients appear less severe. We want to work with CMS and RTI to resolve these issues and produce a payment model and patient classification system that accurately reflects the severity of IRF patients and provides the appropriate amount of resources to meet the burden of care.

d. The proposed removal of the FIM® instrument and associated function modifiers from the IRF-PAI and proposed refinements to the case-mix classification system will affect patient access to resources and an IRF level of care.

After replicating the proposed motor score using the UDSMR® IRF database for Medicare Fee-for-Service cases discharged between October 2016 and September 2017, we proceeded to map these patients into the proposed CMGs for FY 2020 in order to evaluate potential changes in payment and other factors influencing care. We found significant differences in the CMG groupings that may affect patient access to resources and an IRF level of care. Nearly 40% of patients in the UDSMR® IRF database would be subject to a decrease in payment, and over 42% of cases would have a lower CMS average length of stay value. For example, the following chart displays patients with a stroke CMG but without a tiered comorbidity.

			FY 2020 CMG	A0101	A0102	A0103	A0104	A0105	A0106
			FY 2020 Rel. Wgt.	0.8050	1.0182	1.2831	1.6361	1.8382	2.1291
			FY 2020 CMS Avg. LOS	10	12	15	19	20	23
FY 2017 CMG	FY 2017 Rel. Wgt.	FY 2017 CMS Avg. LOS	FY 2017 FPP	$12,644.94	$15,993.89	$20,154.93	$25,699.86	$28,874.45	$33,443.90
A0101	0.6215	8	$9,762.52	1,089	207	15	0	0	3
A0102	0.7877	10	$12,373.19	1,177	1,043	211	3	2	3
A0103	0.9204	12	$14,457.64	304	308	74	5	1	1
A0104	0.9796	12	$15,387.56	777	1,917	1,235	33	1	14
A0105	1.1331	14	$17,798.73	263	1,094	1,907	131	5	14
A0106	1.2671	15	$19,903.61	108	515	1,963	441	18	46
A0107	1.4142	17	$22,214.25	44	264	1,545	915	52	172
A0108	1.7801	20	$27,961.81	5	51	489	790	2,461	0
A0109	1.6005	19	$25,140.65	26	100	723	887	0	562
A0110	2.1243	24	$33,368.50	19	62	578	1,517	0	7,520

The cases in the red shaded areas indicate patients who will see a decrease in both payment and CMS average LOS. Over two thousand patients are currently assigned to the most severe and highest-paying stroke CMG (A0110), and we are very concerned that payment and LOS values may be reduced significantly for these patients. These changes are based solely on the differences in the functional assessment and the use of SPADE items, which, as we noted previously, make IRF patients appear less severe. How will providers handle stroke patients who are clearly severe in today's payment model but who will appear less severe and be paid

less in the proposed model? Will these patients be admitted to IRFs for care if CMS does not make adequate resources available? Will these patients receive a full course of IRF-level care, or will they instead be discharged to a lower level of care for continued services? And will patients in CMG 0101 be targeted for payment denials, as they have been in the past? We are very concerned that this proposed payment model is based on information that makes patients appear less severe and places them into payment categories that may not provide an adequate amount of services or may prohibit them from receiving IRF care. We ask that CMS and RTI analyze these differences and projected effects to produce a payment model that does not affect patient access to resources and care.

e. The proposed removal of the FIM® instrument and associated function modifiers from the IRF-PAI and proposed refinements to the case-mix classification system will not be budget-neutral.

We conducted a financial impact analysis on the UDSMR® IRF database for Medicare Fee-for-Service cases discharged between October 2016 and September 2017 in order to replicate the impact analysis CMS and RTI produced for the proposed rule. Our analysis included 310,175 Medicare Fee-for-Service cases (representing nearly 84% of the cases included in the CMS/RTI analytic sample) from 875 IRFs (representing nearly 79% of the IRFs included in the CMS/RTI analytic sample). As shown below, we project that the proposed payment model will produce a decrease of over $28 million dollars, which represents a payment decrease of 0.5%.

	Medicare FFS (02) Primary Cases	FY 2017 Unadjusted FPP Payment Total	FY 2020 CMGs with FY 2017 SPCF Unadjusted FPP Payment Total	Difference in Unadjusted FPP
UDSMR® IRF Total	310,175	$6,067,210,446.87	$6,039,164,952.10	($28,045,494.77)
Freestanding rehab hospitals	163,596	$3,280,786,074.30	$3,182,873,350.89	($97,912,723.41)
Rehab units in acute care hospitals	146,579	$2,786,424,372.56	$2,856,291,601.20	$69,867,228.64

Freestanding rehabilitation hospitals project to experience a payment decrease of nearly 3%, while rehabilitation units in acute care hospitals project to experience an increase in payment of about 2.5%. We find that the average weighted motor score index value of freestanding rehabilitation hospitals is typically lower than that of rehabilitation units in acute care hospitals and that the issue with the proposed motor score making IRF patients appear less severe significantly affects patients in these settings.

Overall, 348 IRFs (~40%) are projected to see a reduction in payment, with a range of 0.01% to 16.59%, and 85 IRFs (~10%) are projected to see reductions in payment of at least 5%.

CMS and RTI suggested that this proposal would produce a budget-neutral result, but the data in the UDSMR® IRF database does not support this finding. We ask that CMS and RTI provide additional information related to their budget-neutral finding, including provider-level data that allows IRFs to evaluate the effects. We also recommend that CMS and RTI provide further clarification related to their calculations and methodology for producing financial affects, which will allow the IRF industry to more closely examine their proposal.

To summarize these comments, UDSMR does not support the proposed removal of the FIM® instrument and associated function modifiers from the IRF-PAI and does not support the proposed refinements to the case-mix classification system. These proposals will not reduce administrative burden and will not produce a payment system that meets the needs of all IRF patients. As previously stated, UDSMR strongly recommends that CMS defer removal of the FIM® instrument and implementation of any payment model reform until

- standardized patient assessment data not only illustrates that it can be feasibly collected, but also provides evidence that it adequately predicts patient severity and/or cost;
- the payment model classifies patients into categories that mirror their current level of severity and provides the proper amount resources needed for patient care; and
- CMS provides a transparent process for payment system changes in a manner similar to the development and implementation of quality measures.

3. The proposed revisions to certain IRF coverage requirements

a. may put patients at risk due to potentially diminished physician involvement,

b. may reduce the burden on physicians but place additional burden on other clinicians,

c. may be unnecessary or handled as a clarification of existing requirements, and

d. do not address other IRF coverage requirements that have a more significant impact on administrative burden and/or costs.

As stated in section VIII of CMS-1688-P.

Before addressing each of the concerns noted above, UDSMR appreciates CMS's evaluation of opportunities to reduce provider burden through revisions to certain IRF coverage requirements. We generally agree that much needs to be done in this area, but we need to ensure that proposed revisions produce the desired reduction in administrative burden and do not affect patient care. We also need to ensure that any revisions are properly administered by entities that are auditing IRFs and issuing denials of payment. Revisions that are not properly considered and are implemented poorly will not reduce administrative burden and may instead cause greater problems for providers and patients.

a. The proposed revisions to certain IRF coverage requirements may put patients at risk due to potentially diminished physician involvement.

Although we agree with the proposal to include the PAPE as one of the three face-to-face visits in an IRF, we are concerned that this may create a circumstance in which physicians will only be available for three face-to-face visits and will suggest that more face-to-face visits are unnecessary to meet CMS's requirements. Some patients require regular/daily assessments by a rehabilitation physician, and we are concerned that emphasis on this revision to coverage requirements may adversely affect patients.

We are also concerned that the proposal to allow the rehabilitation physician to attend interdisciplinary team meetings remotely is not in the best interest of the patient. Will team discussions about the patient's status, progress, lack of progress, and discharge planning be

as detailed over the phone as it would be in person? Could a lack of discussion result in longer lengths of stay or less organized discharge plans?

Finally, the solicitation of comments related to physician visits being conducted remotely, in addition to the use of non-physician practitioners to fulfill some of the requirements, significantly affects the availability of a physician and may put patients at risk. A physician assessment for patients who require an intense interdisciplinary level of care provided in an IRF cannot be adequately assessed remotely. The medical and functional complexity of IRF patients requires the expertise of an on-site rehabilitation physician to complete assessments in person. This allows them to use their medical judgment to update medications if necessary, update the plan of care, order additional testing, assess the effect of the patient's medical conditions on the patient's function, and counsel the patient about the patient's recovery based on the physical assessment. A virtual assessment cannot result in a comprehensive review of the patient's status that would be of benefit to the patient, and it will not provide adequate leadership to the interdisciplinary team. In addition, neither a physician assistant nor a nurse practitioner has the education or the expertise to fulfill the physician's role in inpatient rehabilitation. Their assistance to the rehabilitation physician is a nice blend that would provide the patient with medical oversight on the days the rehabilitation physician is not required to perform face-to-face assessments, but they cannot take the place of a rehabilitation physician. It would not be reasonable for non-physician practitioners to fulfill CMS's rehabilitation physician requirements, but in light of the severity of IRF patients, their assistance with medical/functional supervision, in addition to the required supervision by the rehabilitation physician, would certainly benefit the patient and would complement the intense level of supervision and services provided by the rehabilitation physician in an IRF.

b. The proposed revisions to certain IRF coverage requirements may reduce the burden on physicians but place additional burden on other clinicians.

The proposal to allow the rehabilitation physician to attend interdisciplinary team meetings remotely may reduce the burden on the rehabilitation physician but will place additional burden on the interdisciplinary team attending in person. The interdisciplinary team may need to provide additional technology to the physician in order to allow the proper remote access to the meeting. Additionally, the team may need to account for technical issues that result from the physician's remote status, such as phone connection issues and access to electronic information. Any issues that arise will require additional time for the meeting, which will prevent the interdisciplinary team from using that time for patient care.

The solicitation of comments related to physician visits being appropriately conducted remotely via another mode of communication, such as video or telephone, would also place additional burden on other clinicians. Depending on how the physician will contact the patient remotely, a clinician will need to be available to either administer the phone call or position a video device for use with the patient. Additionally, a clinician will most likely need to be present in the room in order to ensure the patient's safety during this remote visit.

We believe that CMS needs to further evaluate these proposals in order to assess the additional burden that may be placed on other clinicians.

c. The proposed revisions to certain IRF coverage requirements may be unnecessary or handled as a clarification of existing requirements.

The requirement not to count the PAPE as one of the three face-to-face visits is not a requirement stated in the CFR or the *Medicare Benefit Policy Manual*; it was a separately published clarification. Although we are not opposed to this revision, it does not have to be done and could be accomplished as a clarification of existing requirements. This would leave the facilities/physicians to decide whether or not to use the PAPE as one of the three face-to-face visits, depending on the patient's needs.

d. The proposed revisions to certain IRF coverage requirements do not address other IRF coverage requirements that have a more significant impact on administrative burden and/or costs.

A significant amount of administrative burden is produced by the 60% rule, yet this IRF coverage requirement is not proposed for revision or removal. IRFs spend considerable time and resources managing their compliance. From screening patients at preadmission, to determining whether a 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 the CJR program 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.

4. The proposed revisions and updates to the IRF Quality Reporting Program (QRP)

a. do not identify all the measures that could be subject for removal based on the considerations used for selection of measures and

b. propose public display of functional quality measures that have yet to provide risk-adjustment information or provider performance previews.

As stated in section IX of CMS-1688-P.

Before addressing each of the concerns noted above, UDSMR would like to continue to express our concerns with the IRF QRP and the ongoing implementation of quality measures and SPADEs. Quality measures and SPADEs continue to be developed and implemented without meeting the IMPACT Act requirements of being standardized and interoperable across all PAC sites. In countless instances, quality measures and SPADEs have been adopted and endorsed for only one PAC setting but have been implemented across all PAC settings without further testing or analysis to support their implementation. IRFs continue to be presented with quality measures and SPADEs that lack training materials, data-collection specifications, and clear and accurate responses to questions from the industry. Finally, IRFs continue to see changes to quality measures and SPADEs whose standardization and interoperability are questionable.

Because of these issues, UDSMR recommends that the Secretary suspend—or that CMS 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:

- Quality measures are standardized and interoperable for all PAC sites.
- Quality measures receive endorsement for the specified PAC site prior to use or implementation.
- 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.
- 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.

Furthermore, UDSMR recommends 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 and
- quality measures are provided on consistent time periods to account for potential differences in the case mix and severity of patient populations over time.

We would like to continue working with CMS and their contractors on the implementation of the IMPACT Act in order to ensure that quality measures and SPADEs provide standardized and interoperable information across PAC sites and that they do not create undue administrative burden for PAC providers.

a. The proposed revisions and updates to the IRF QRP do not identify all the measures that could be subject for removal based on the considerations used for selection of measures.

UDSMR agrees with the following CMS proposals:

- Adoption of an additional factor to consider when evaluating measures for removal from the IRF QRP measure set:
  - Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.
- Removal of two measures from the IRF QRP Measure Set:
  - National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)
  - Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680)

Although we agree with the removal of these two measures from the IRF QRP, we are concerned that CMS did not identify all the measures that could be subject to removal based on the eight factors presented for consideration. The following is a list of measures we feel should be considered for removal, citing one or more of the removal factors:

- Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)
  - Factor 1. Measure performance among IRFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.
  - Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

  This measure currently has an IRF average value of 0.1%, and over 75% of IRFs report it at 0%. IRFs are required to assess and input data on six IRF-PAI items related to falls in support of this measure even though the reported values are significantly low and provide little opportunity for improvement.
- Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
  - Factor 1. Measure performance among IRFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.
  - Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

  This measure currently has an IRF average value of 99.4%, and nearly 75% of IRFs report it at 100%. IRFs are required to assess and input data on twenty-eight IRF-PAI items at admission, at discharge, and for discharge goals in order to provide information for this measure. Additionally, because this information is tied to a 2% payment penalty

for IRFs that fail to provide IRF-PAI information on 95% of cases, we do not anticipate this measure ever having an average below 95% or providing any additional opportunity for substantial improvement.

We ask that CMS review these measures to determine whether they meet the measure removal criteria and whether they can be removed from the IRF QRP as soon as possible. This will reduce significant provider burden and will allow for the collection and reporting of data for more meaningful measures.

b. The proposed revisions and updates to the IRF Quality Reporting Program (QRP) propose public display of functional quality measures that have yet to provide risk-adjustment information or provider performance previews.

UDSMR does not agree with the proposal to begin publicly displaying data on the following four assessment-based measures in CY 2020, or as soon thereafter as technically feasible:

1. Change in Self-Care (NQF #2633)
2. Change in Mobility Score (NQF #2634)
3. Discharge Self-Care Score (NQF #2635)
4. Discharge Mobility Score (NQF #2636)

Although data is currently being collected, CMS has yet to provide adequate information related to how these measures will be risk-adjusted and how provider performance may appear upon publication to IRF COMPARE. These measures are specified to include a significant number of risk-adjustment factors as part of determining expected performance in the calculation of each measure. Without risk-adjustment information from CMS, IRFs are currently unable to track or determine their performance or to set goals for their patients in order to meet CMS's quality measure expectations. CMS has been asked about the availability of this information but has not yet supplied a date for providing it to the industry. Additionally, because risk-adjustment values are not available, the current CASPER reporting of these measures only provides observed values. With the proposed CY 2020 publication of this information based on CY 2019 data, we do not believe that providers will be given sufficient information to ensure that their provider-level performance is accurately represented on IRF COMPARE for these measures.

We ask that CMS defer or suspend the public display of these measures until all the necessary measure information is publicly available and providers have had sufficient opportunity to evaluate their performance prior to public display.

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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 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,

Kathy Dann
Director of Operations

Cc: Fran Hagerty, Associate Director
Troy Hillman, Manager, Analytical Services
Brigid Greenberg, Manager of Postdischarge Services and Appeals
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