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June 13, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1647-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: 42 CFR Part 412 (CMS-1647-P) Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017; Proposed Rule

Dear Acting Administrator Slavitt,

On behalf of Uniform Data System for Medical Rehabilitation (UDSMR) and the nearly 850 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 2017; Proposed Rule, which was published on April 25, 2016, 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 CMS, in implementing the IMPACT Act across postacute care (PAC) venues, continues to deploy measures that shift a huge regulatory and financial burden onto facilities without any evidence that these measures increase the quality of care or control costs.

Concerns:

1. The FY 2017 update to the SPCF does not include an increase for the time and resources necessary for IRFs to collect and report the additional ten pages of information added to the IRF-PAI and finalized in the FY 2016 final rule. This proposed increase does not cover the costs of technical implementation, training, and data collection related to the new quality reporting items even though these costs will be significant.
2. We have numerous concerns related to the new quality measures proposed in the FY 2017 proposed rule.
    a. The measures have not been fully developed and tested, and no stakeholder or review panel has provided feedback indicating that they are ready for implementation.
    b. The measures continue to include site-specific inclusion/exclusion criteria, episode adjustments, and risk-adjustment factors. As such, they are neither standardized nor interoperable for PAC sites, as mandated by the IMPACT Act.

   c. The measures include circumstances that are typically outside the control of PAC sites, and we question their inclusion within these quality measures.

   d. Certain measures are duplicative or measure factors already reported in other quality measures.

3. The data collection periods for the quality measures, which are used to determine potential payment penalties and public reporting, are inconsistent and include between one and eight quarters of data. As a result, the use of these measures would result in collecting data from patient populations that differ greatly from one measure or group of measures to another.
4. The proposed public display of IRF QRP data is based on measures that do not define inpatient rehabilitation care, and it uses measures that employ different time frames for collecting data and different minimum patient populations.
5. The training, data collection specifications, and support CMS has provided for the implementation of new quality items beginning in October 2016 have been inconsistent and have not provided the necessary responses to questions from the industry. As a result, we are concerned that quality data will be inaccurate and unreliable and will lack the validity needed to provide clinical standards for quality measurement.
6. Although the proposed rule does not specifically address the "60% rule," IRFs and patients are negatively affected by the changes caused by the transition to ICD-10 codes, the decisions related to excluded etiologic diagnoses for certain impairment group codes (IGCs), and the continued lack of support for the use of BMI in presumptive reporting.

Recommendations:

1. The Secretary should suspend—or CMS should defer implementation of—all quality measures specified for meeting the IMPACT Act's requirements, including those previously finalized in the FY 2016 final rule, until all of the following occur:
   a. The measures are provided in a standardized and interoperable manner.
   b. The measures receive full endorsement for use or implementation for all PAC sites.
   c. CMS's staff provides full support for the measures by providing training materials, data collection specifications, and clear and accurate responses to questions from the industry.
   d. The Secretary and/or CMS implements these measures at a uniform time for all PAC sites.
2. If CMS continues implementing quality measures that add considerable burden and cost to IRFs, it should increase the SPCF to accommodate the additional data collection requirements.
3. CMS should base any potential payment penalties and public reporting on consistent data-collection periods and should make sure that both utilize a consistent amount of information.
4. CMS should delay the public display of IRF QRP data until all IMPACT Act domains are implemented and the patient populations for each measure are standardized.
5. CMS should modify the presumptive methodology and accompanying code lists for compliance period 2 by incorporating all instances in which IRF-PAI data can be used to identify the defined qualifying conditions.

The remainder of this letter addresses our concerns in detail.

1. **The FY 2017 update to the SPCF does not include an increase for the time and resources necessary for IRFs to collect and report the additional ten pages of information added to the IRF-PAI and finalized in the FY 2016 final rule. This proposed increase does not cover the costs of technical implementation, training, and data collection related to the new quality reporting items even though these costs will be significant.**

   As stated in section V, with references to section XIII.C.9 of CMS-1624-F.

Beginning on October 1, 2016, IRFs will be required to collect data for quality reporting purposes that have caused the existing IRF-PAI to expand from ten to eighteen pages. In the FY 2016 final rule (CMS-1624-F), CMS estimated that the additional elements for the newly finalized quality measures would take 41.5 minutes to complete (25.5 minutes for admission data and 16.0 minutes for discharge data), resulting in a total of 96 minutes to collect and record the information for the IRF-PAI. This additional time nearly doubles OMB's estimate of the average time needed to administer this assessment. CMS further states, "[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 this information will severely decrease 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. Finally, the need to train staff and update documentation to collect these items will add up to a financial burden that will go well beyond CMS's estimate of $21,239.33 per IRF.

The proposed SPCF change for FY 2017, after adjusting for all factors detailed in table 4 of section V, is an increase of only 1.27%, or $196 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.[1] The burden of data collection finalized in the FY 2016 final rule would consume nearly 33% of the FY 2017 SPCF increase, leaving an increase of only $132 (0.85%) 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 2017 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.

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

2. We have numerous concerns related to the new quality measures proposed in the FY 2017 proposed rule.

a. The measures have not been fully developed and tested, and no stakeholder or review panel has provided feedback indicating that they are ready for implementation.

As stated in sections VII.F.1–VII.F.4 and VII.G.

As noted in each measure-specific section of this proposed rule, these measures were presented to the National Quality Forum (NQF) Measures Application Partnership (MAP) for consideration roughly six months ago. At that time, the measures were still under development and had not been fully tested within each PAC venue. Because of this, the NQF MAP committees wrote a recommendation, as noted in the proposed rule, of "Encourage further development." However, the proposed rule fails to mention that the various NQF committees also stated that these measures, being neither fully developed nor fully tested, would not be appropriate for implementation in any CMS payment or quality program until their development and testing was completed and they came back to NQF for further review and discussion.

Additionally, CMS notes that they have solicited comments and feedback from various stakeholders and technical expert panels (TEPs). UDSMR has participated in, or has heard from subscribers who have participated in, each of these efforts. At no time were the measures under review finalized or fully tested, and none of the TEPs or stakeholders indicated any desire to have these measures move forward in their current state.

In addition, both the stakeholder opportunities and the comments supplied so far reveal significant disagreement among PAC providers about whether the Drug Regimen Review measure adequately addresses the domain of medication reconciliation and whether it would improve the quality of care.

In another example of not fully developing and testing these measures, CMS is inviting further public comment on this proposed rule regarding risk-adjustment factors, episode definitions, and other aspects related to measure development. Throughout section VII.F, CMS refers to deferring further analysis and additional risk-adjustment factors until additional information becomes available. If more information is needed to develop an adequate quality measure, can providers be confident that they will not be penalized by the implementation of underdeveloped quality measures?

At various points in the measure development process, both CMS's representatives and the contracted measure developers have stated that the IMPACT Act is driving the need to implement these measures by a particular date. Although we understand the desire to meet congressionally mandated deadlines, we ask CMS whether the time and costs spent implementing incomplete and untested measures—measures that may change over time—will provide the clinical standards for quality that are the goal of the program.

Congressionally mandated deadlines are present in the IMPACT Act, but section 1899B, paragraph (h), "Removing, Suspending, or Adding Measures," states: "(1) IN GENERAL.—The Secretary may remove, suspend, or add a quality measure or resource use or other measure described in subsection (c)(1) or (d)(1), so long as, subject to paragraph (2), the Secretary publishes in the Federal Register (with a notice and comment period) a justification for such removal, suspension, or addition."

Furthermore, paragraph (h)(2) of section 1899B states: "EXCEPTION.—In the case of such a quality measure or resource use or other measure for which there is a reason to believe that the continued collection of such measure raises potential safety concerns or would cause other unintended consequences, the Secretary may promptly suspend or remove such measure and satisfy paragraph (1) by publishing in the Federal Register a justification for such suspension or removal in the next rulemaking cycle following such suspension or removal."

UDSMR recommends that the Secretary exercise the power to suspend these measures until feedback from designated stakeholder committees and/or TEPs indicates that they are ready for implementation. Because of the difficulty of identifying potential safety concerns or unintended consequences caused by these measures when (1) they are clearly not finalized and (2) providers lack information related to their individual performance, we request that CMS, prior to finalizing and/or implementing these measures, provide IRFs with the information they need to determine whether such safety concerns or unintended consequences may occur.

2. We have numerous concerns related to the new quality measures proposed in the FY 2017 proposed rule.

b. The measures continue to include site-specific inclusion/exclusion criteria, episode adjustments, and risk-adjustment factors. As such, they are neither standardized nor interoperable for PAC sites, as mandated by the IMPACT Act.

As stated in sections VII.F.1–VII.F.4 and VII.G.

Although each of these measures is described as meeting certain IMPACT Act domains, all of them include unique, site-specific factors that prevent them from being considered "standardized or interoperable." This is why the words "IRF QRP" or "Inpatient Rehabilitation Facility" designations are included in the measures' titles. The proposed rule for the SNF PPS includes similar quality measures intended to support the IMPACT Act but designated "SNF QRP" or "Skilled Nursing Facility." Further reviews of the individual measure specifications indicate that there are differences between these measures' site-specific inclusion/exclusion criteria, episode definitions, and/or risk adjustment factors.

The IMPACT Act specifically requires that quality data "be standardized and interoperable so as to allow for the exchange of such data among such post-acute care providers and other providers and the use by such providers of such data that has been so exchanged, including by **using common standards and definitions**, in order to provide access to longitudinal information for such providers to facilitate coordinated care and improved Medicare beneficiary outcomes." If the proposed measures do not provide common standards and definitions due to differences in their inclusion/exclusion criteria, episode definitions, and risk-adjustment factors, do they meet the requirements identified by the IMPACT Act? Furthermore, implementing the quality measures in an unstandardized fashion, as proposed, will result in additional costs in the future for aligning measures between PAC providers—costs that would be unnecessary with the proper standardization.

We recommend that CMS, in accordance with the IMPACT Act's requirements for data and measures that are standardized and interoperable, suspend implementation of the proposed quality measures until they are calculated in a similar manner for all PAC sites.

2. We have numerous concerns related to the new quality measures proposed in the FY 2017 proposed rule.

c. The measures include circumstances that are typically outside the control of PAC sites, and we question their inclusion within these quality measures.

As stated in sections VII.F.1–VII.F.4 and VII.G.

Each of the proposed measures collects data on and calculates circumstances that typically occur after the patient's discharge and that are often well outside the control of the PAC provider. In most instances, the response of CMS and its measure developers to comments have indicated that risk-adjustment factors will account for these circumstances, but this adjustment becomes very difficult for any PAC provider to determine without completed testing or finalized risk-adjustment coefficients.

The following examples and information will help illustrate this concern:

- **Medicare Spending per Beneficiary (MSPB) measure:** The inclusion of the associated services period creates circumstances in which the initial PAC provider can be held accountable for services that result from activities far outside the provider's control. For example, a patient discharged home with home health can require rehospitalization following a fall or an adverse event between home health visits and within the first thirty days after discharge from the IRF. The initial provider—in this case, the IRF—has no control over this patient when the readmission occurs, but the IRF MSPB measure includes the spending for the initial IRF and home health services, as well as the readmission.
- **Discharge-to-community measure:** The discharge-to-community measure will discount or reduce the actual community discharge rate for patients who have an unplanned readmission to an acute care hospital or LTCH or who expire in the thirty-one days after discharge. Like the MSPB measure, this measure incorporates circumstances that are outside the control of the PAC provider. PAC providers discharge patients back to the community with every expectation of a successful outcome and a belief that the patient will be able to stay at home or in a community setting. They should not be held responsible for the unplanned readmission or death of a patient caused by the inability of the patient and/or the patient's caregiver to provide suitable care in the thirty-one days after discharge. For example, a patient who (1) fails to have a prescription filled in the thirty-one days after discharge and (2) requires readmission for the condition the prescription was meant to prevent would be removed from the PAC provider's discharge-to-community rate even though the provider could not directly control this instance and therefore should not be held responsible for the readmission.
- **Potentially Preventable 30-Day Post-Discharge Readmission measure:** Although PAC providers offer education throughout each patient's stay and provide their patients and their caregivers with information at discharge, their control over potentially preventable readmissions is limited for patients who fit into any of the following categories:
  - Patients with chronic conditions
  - Patients who choose to maintain an unhealthy lifestyle
    - Tobacco/alcohol abuse

    - Dietary habits
- Patients who refuse to comply with treatment regimens and recommendations despite knowing the risks and benefits
    - Patients who refuse influenza and/or pneumonia vaccines
    - Patients who choose not to have their prescriptions filled
- Patients who are unable to comply due to sociodemographic factors
    - Lack of funding to purchase medications/DME and/or healthy foods
    - Lack of community resources:
        - Primary care physician/clinic
        - Appropriate follow-up services (e.g., wound care)
        - Access to transportation

- **Potentially Preventable within Stay Readmission Measure for Inpatient Rehabilitation Facilities:** PAC providers may not be able to control or prevent within-stay discharges to acute care, especially within the first few days of admission, for one or more of the following reasons:
    - The results from diagnostic tests conducted immediately before the patient's admission to the IRF are not available until after the patient's admission to the IRF.
    - Conditions are not recognized or treated in acute care prior to the patient's admission to the IRF.
        - Fractures are not seen on an X-ray due to swelling.
        - Diagnostic tests are not conducted.
    - Resources, such as those identified below, are not available to manage the patients in the IRF.
        - Ventilators or respiratory services
        - Telemetry and cardiac monitoring
        - Medications that require certified clinicians to administer

As stated previously in this letter, we recommend that the Secretary suspend these measures until CMS or its measure developers explain in detail how their measures will treat each of these scenarios. We also ask that CMS and its measure developers continue working with PAC providers to determine whether the quality measures require additional modification in order to properly evaluate factors that PAC providers can control.

2. We have numerous concerns related to the new quality measures proposed in the FY 2017 proposed rule.

d. Certain measures are duplicative or measure factors already reported in other quality measures.

As stated in sections VII.F.1–VII.F.4 and VII.G.

Although we understand the emphasis on reducing readmissions within the Medicare program, we are concerned that CMS is deploying quality metrics that overemphasize reducing readmissions and do not adequately address the domains they are meant to measure. CMS has already finalized an all-cause readmission measure that is currently in use and eligible for public reporting. PAC providers who do not perform well on this readmission measure have a high probability of performing poorly on the currently proposed measures because of the inclusion of unplanned readmissions in each measure's calculation. Within the MSPB measure, any unplanned readmission within the associated services period will increase a PAC provider's value on this measure. Within the discharge-to-community measure, any unplanned readmission within thirty-one days will reduce the provider's performance value. The Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facilities is actually a subset of the all-cause readmission measure.

If CMS wants to measure each of the domains of the IMPACT Act, we suggest that its quality measures exclude aspects measured by other domains and/or quality measures. For the MSPB measure, the associated services period essentially measures additional costs due to readmissions. Wouldn't removing the associated services period and measuring only the spending by the PAC provider allow an MSPB measure and a unique readmissions measure to indicate whether the provider is producing additional costs to the Medicare program? Similarly, the readmission penalty within the discharge-to-community measure is unnecessary because the reporting and/or display of each unique measure would adequately indicate whether the facility was able to get patients back to a community setting, to produce a durable outcome, and to prevent a potential readmission.

We recommend that the Secretary suspend these measures until CMS can evaluate whether the inclusion of readmissions within each quality measure is necessary and whether it produces duplicative results within the various quality reporting programs.

3. The data collection periods for the quality measures, which are used to determine potential payment penalties and public reporting, are inconsistent and include between one and eight quarters of data. As a result, the use of these measures would result in collecting data from patient populations that differ greatly from one measure or group of measures to another.

As stated in section VII.I and displayed in tables 10–19.

We appreciate that CMS is providing PAC providers with information about the form, manner, and timing of quality data submissions, but we are deeply concerned by the variations and differences in the quality measurement data collection time frames and the aggregations tied to fiscal years. These factors are causing unnecessary confusion among PAC providers and producing inconsistent quality measurement values.

For example, the FY 2018 payment determination requires the collection and submission of eleven measures, but some of them will be collected and reported across different time frames, as described below.

- **NQF #0678, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay)**, as displayed in table 10 of the proposed rule, will base the FY 2018 payment determination on **five quarters of data (discharges between October 1, 2015, and December 31, 2016)**.
- **NQF #0680, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine**, as displayed in table 11 of the proposed rule, will base the FY 2018 payment determination on **three quarters of data (discharges between October 1, 2015, and June 30, 2016)**.
- **NQF #0674, Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay); 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; NQF #2633, IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients; NQF #2634, IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients; NQF #2635, IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients;** and **NQF #2636, IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients**, as displayed in table 12 of the proposed rule, will base the FY 2018 payment determination on **one quarter of data (discharges between October 1, 2016, and December 31, 2016)**.
- **NQF #0138, NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure; NQF #1716, NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure;** and **NQF #1717, NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure**, as displayed in table 13 of the proposed rule, will base the FY 2018 payment determination on a single calendar year, or **four quarters of data (discharges between January 1, 2016, and December 31, 2016)**.

As you can see above, an IRF would need to manage and/or review data collection for several different time frames in order to determine whether it would be subject to a 2% payment penalty for FY 2018. Additionally, NQF measures 0674, 2631, 2633, 2634, 2635, and 2636 all require the collection of new IRF-PAI data beginning on October 1, 2016, but utilizing only the first three months of new data collection to determine future payment penalties does not allow IRFs to adapt to new changes before being subjected to these penalties.

For payment determinations for FY 2019 and subsequent years, CMS appears to be moving most of the measures to a standardized data collection period based on the calendar year. However, NQF #0680, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, will utilize data from the third quarter of one calendar year through the second quarter of the following calendar year because the influenza season runs from October through March in most years.

We are concerned that IRFs will be inappropriately penalized for failing to meet poorly constructed requirements that, as illustrated above, are based on varying amounts of information.

We strongly recommend that CMS suspend payment determinations until all quality measures use standardized, consistent periods for data collection.

4. The proposed public display of IRF QRP data is based on measures that do not define inpatient rehabilitation care, and it uses measures that employ different time frames for collecting data and different minimum patient populations.

As stated in section VII.N.1.

In addition to the three measures finalized in the FY 2016 final rule—NQF #0678, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay); NQF #0138, NHSN CAUTI Outcome Measure; and NQF #2502, All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs—CMS is proposing to publicly report data in CY 2017 on four additional quality measures:

1. NQF #1716, Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
2. NQF #1717, Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure
3. NQF #0431, Influenza Vaccination Coverage among Healthcare Personnel[2]
4. NQF #0680, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine[2]

Although we recognize the need and desire to publicly report on quality for all Medicare providers, we are very concerned that the initial public display of quality measure information is based on measures that (1) do not exemplify the IRF experience and (2) target very small populations of cases. For example, the UDSMR® database suggests that less than 1% of all Medicare cases have a new or worsened pressure ulcer. Can a quality measure that affects less than 1% of all Medicare patients truly differentiate the quality of care provided?

Additionally, the influenza vaccination rates, both for healthcare personnel and for patients, do not adequately assess whether quality care was provided; instead, they measure whether vaccinations were offered, provided, and/or administered. CMS has not provided any evidence in the IRF QRP that differences in influenza vaccination rates between facilities affect the quality of outcomes or the patient experience. Furthermore, the ability of staff and patients to refuse vaccinations for various reasons, as well as the coverage of a limited number of influenza strains in each vaccination, complicates both the measurement of vaccination rates and the ability of providers to reduce the incidence of influenza.

We fail to see how these measures are representative of the IRF level of care, where intensive therapy is provided for functional improvement and potential discharge to the community. The aforementioned measures may contribute to negative outcomes for a small percentage of patients, but they do not speak to the quality of care IRFs provide.

We are also concerned that the public display of these measures will provide misleading interpretations of quality, as almost all the measures will be based on different time frames and will use different minimum patient thresholds and potentially varying patient populations. For example, the all-cause unplanned readmission measure will be based on two consecutive years of

[2] Data collection for this measure began with the 2015–2016 influenza vaccination season.

data ending at least a year prior, but the pressure ulcer, CAUTI, MRSA, and CDI measures will be based on four rolling quarters of data, and the influenza measures are based on data from the most recent influenza vaccination seasons, with data collected from October through March. Furthermore, the all-cause unplanned readmission measure has a minimum of twenty-five eligible cases, the patient-level influenza vaccination measure has a minimum of twenty stays for reporting, and none of the other measures identify a potential minimum population.

UDSMR recommends that CMS suspend public display of IRF QRP data until (1) all IMPACT Act domains are implemented and (2) the patient populations for each measure are standardized.

5. The training, data collection specifications, and support CMS has provided for the implementation of new quality items beginning in October 2016 have been inconsistent and have not provided the necessary responses to questions from the industry. As a result, we are concerned that quality data will be inaccurate and unreliable and will lack the validity needed to provide clinical standards for quality measurement.

UDSMR and its subscribers have reviewed all the materials supplied to date and have participated in various training events related to the October 2016 implementation of new quality measures for the IMPACT Act. After reviewing the available information, UDSMR and its subscribers have sent numerous messages and made multiple calls to various CMS staff related to questions about the new IRF-PAI items. CMS and the various representatives participating in this implementation have not responded to some questions and have contradicted some of the available information in responding to others. This has caused a great deal of confusion, and we are concerned that this will lead to the collection of data that is inaccurate and unreliable and that lacks the validity needed to provide clinical standards for quality measurement.

For example, the instructions for completing sections GG0130 and GG0170 state, "If the patient's self-care performance varies during the assessment period, report the patient's usual status, not the patient's most independent performance and not the patient's most dependent episode." Multiple providers have asked CMS's staff and measure developers for additional clarification on this statement regarding the definition of "the patient's usual status." At the IRF QRP training in Dallas, CMS's staff and the measure developer, in response to a question about the need for further clarification on this topic, indicated that the intent was not to collect the most frequently occurring patient status over the assessment period, but to record the patient's status as close to admission as possible—and potentially prior to any services that could improve the patient's status after admission. The clarification provided in the IRF QRP training session does not appear to be consistent with the guidelines defined in *The IRF-PAI Training Manual*, and providers are now questioning whether to base their data collection on the information provided by CMS's staff and measure developers or the instructions in the training manual. Additionally, because the industry's understanding of how to collect this data varies from one provider to the next, we are concerned that the information collected on these items will be inaccurate and unreliable and will lack the validity needed to provide clinical standards for quality measurement.

As another example, the current IRF-PAI allows providers to record a dash (-) for a quality measure item to indicate that the item was not assessed and to record an equal sign (=) to indicate that a response was not provided, either because the item was properly skipped or because it is not mandatory. *The IRF-PAI Training Manual* notes that recording a dash may subject a provider to the 2% payment penalty, but providers cannot record an equal sign for some of the new quality measure items on the October 2016 IRF-PAI even though the items are not required or

can be skipped. Yet CMS's staff and measure developers are instructing providers to record a dash if a response may not be required, but doing so may subject the provider to a 2% payment penalty. This circumstance is causing confusion and concern among providers because CMS is not providing consistent methodology and is potentially penalizing providers who are following regulatory guidelines related to data collection and requirements for quality measures.

Our final example relates to inconsistencies between *The IRF-PAI Training Manual* and the IRF-PAI data submission specifications. On April 29, 2016, CMS released an update to section 9 of the training manual that details whether each IRF-PAI item is required or voluntary. This revised section notes that item M0300A, labeled "Stage 1: Number of Stage 1 pressure ulcers," is voluntary for both the admission assessment and the discharge assessment, yet the IRF-PAI data submission specifications, in reference to both item M0300A1_1 and item M0300A1_2, states, "This item is no longer voluntary, so the response of [=] has been removed." This discrepancy was brought to the attention of CMS's staff at the Dallas training, and they responded that section 9 of the training manual was correct and should take precedence over the data submission specifications. However, if CMS does not update the data submission specifications, providers will not be able to voluntarily skip this item and will be required to enter either an invalid value or a dash that potentially subjects them to an inappropriate 2% payment penalty.

Because of the issues noted above, UDSMR recommends that the Secretary suspend quality measures, and that CMS delay implementation of the new IRF-PAI, until CMS can provide training, data specifications, and support that are consistent, clear, and concise.

6. Although the proposed rule does not specifically address the "60% rule," IRFs and patients are negatively affected by the changes caused by the transition to ICD-10 codes, the decisions related to excluded etiologic diagnoses for certain impairment group codes (IGCs), and the continued lack of support for the use of BMI in presumptive reporting.

CMS and the Centers for Disease Control and Prevention (CDC) created the General Equivalence Mappings (GEMs) as a tool for converting from ICD-9-CM to the best matching ICD-10 code. The implementation of ICD-10-CM codes on October 1, 2015, allowed IRFs to report conditions with more specificity, thereby helping them track quality, record morbidity/mortality, and calculate reimbursement based on the physician documentation in the medical record. At the same time, IRFs faced a change to the IRF classification requirement, otherwise referred to as the 60% rule, for facilities with compliance review periods beginning on or after October 1, 2015.

Although the ICD-10-CM codes have helped IRFs improve their documentation practices by allowing them to tell an accurate story of the patient's conditions and by allowing medical record coders to select more specific codes, UDSMR is concerned about the effect the GEMs code mapping has had on 60% presumptive compliance for cases assigned to IGC 02.21, Traumatic brain dysfunction, open injury, or IGC 02.22, Traumatic brain dysfunction, closed injury. For each of these IGCs, the pairing of the IGC and the etiologic diagnosis will exclude a case from presumptive compliance—regardless of the extent of the brain injury, the associated deficits, the medical prognosis, or the clinical management of the patient—if the documentation in the medical record does not specify whether the patient lost consciousness and does not identify the duration of any such loss. Although UDSMR acknowledges that clinical information should be as specific as possible, this particular information may not be available in the record trail provided

from the time of the injury to the time of the patient's admission to the IRF and thus may be impossible for the rehabilitation physician to obtain.

In addition, despite the addition of fields 25A, Height on admission, and 26A, Weight on admission, to the IRF-PAI, CMS has not recognized a presumptive compliance methodology that makes single-joint replacements presumptively compliant with the 60% rule, thereby making facilities responsible for separately tracking and reporting BMI for each patient considered "extremely obese."

UDSMR recommends that CMS modify the compliance-2 presumptive methodology and the accompanying code lists by incorporating all instances in which IRF-PAI data can be used to identify the defined qualifying conditions. Specifically, we recommend that CMS remove presumptive compliance etiologic diagnosis exclusions for traumatic brain injury patients in IGCs 02.21 and 02.22. Additionally, we ask that CMS update the presumptive compliance status of IGCs 08.51 and 08.61, either by allowing IRFs to use the IRF-PAI's height and weight fields to identify patients with a BMI of 50 or more or by adding ICD-10-CM codes Z68.43–Z68.45 to the list of presumptively compliant codes for these IGCs.

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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. 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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