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SUBMITTED VIA www.regulations.gov

June 16, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445–G
Washington, DC 20201

RE: **CMS–1655–P: Proposed Rule** – "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports" **(RIN 938–AS77)**

Dear Mr. Slavitt,

As an association representing behavioral healthcare provider organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to provide comments on the proposed rule titled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports" as published in the April 27, 2016, *Federal Register*.

We are primarily commenting on **new requirements for quality reporting by inpatient psychiatric facilities (IPFs)** that are participating in Medicare.

Founded in 1933, the National Association of Psychiatric Health Systems (NAPHS) advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. Our members are behavioral healthcare provider organizations that own or manage more than 800 specialty psychiatric hospitals, general hospital psychiatric and addiction treatment units and behavioral healthcare divisions, residential treatment facilities, youth services organizations, and extensive outpatient networks. Our members deliver all levels of care, including partial hospitalization services, outpatient services, residential treatment, and inpatient care.

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COMMENTS: IPF QUALITY REPORTING PROGRAM (IPFQR)

NAPHS has long been committed to quality measurement – working with CMS, accrediting agencies, public and private sectors, consumers, and other stakeholders – to develop and support the ongoing use of inpatient psychiatric performance measures. Our association was one of the original organizations that invested more than 10 years in development of the Hospital-Based Inpatient Psychiatric Services (HBIPS) measures that were among the first CMS performance measures in the IPFQR program (based on testing by CMS). We are pleased that these measures remain a foundation of the IPFQR program.

We applaud CMS for helping the field to focus on collecting, reporting, and analyzing measures that are tested and valid for improving the quality of psychiatric care. We support the CMS IPFQR program, which articulates overall national goals for improved health care. The CMS IPFQR is an opportunity to provide public data for behavioral health – keeping behavioral health on par with the rest of medicine. Other payment systems have required quality reporting to CMS for many years. The *Affordable Care Act* (ACA) extended this requirement to IPF PPS-reimbursed systems.

We agree with CMS's objective in selecting quality measures to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We support CMS's goal to focus on "measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided in IPFs."

Through our representation on the CMS Technical Expert Panel as well as through opportunities to publicly comment, we are committed to continuing to provide perspective from the field on new measures under consideration.

The NAPHS Quality Committee has identified a set of principles by which the association views performance measurement efforts. We believe that all performance measurement and outcomes data-collection efforts must:

1. be for the purpose of improving the effectiveness and efficiency of patient care;

2. focus on indicators that provide the most useful clinical and operational data possible;

3. focus on indicators that support actionable steps that fall within the scope of responsibility and accountability of the organization being measured;

4. provide value in the data generated that is in proportion to the intensity of the data-collection effort. Allocation of limited resources needs to be directed to the collection of the most clinically significant and actionable data – with attention to operational and technical data extraction, feasibility, and burden.

5. have the potential for being used to measurably improve the processes, outcomes, efficiency, and patient experiences of the care being delivered.

Using these criteria as a lens through which to assess proposed IPFQR Program measures for future years, we offer the following comments.

PROPOSED UPDATE TO METABOLIC SCREENING

We support the change in the length of stay to exclude patients with a length of stay equal to or greater than 365 days or less than or equal to 3 days. This change will support the intent of the global sample to allow IPFs to use the same sample for as many measures as possible.

We continue to express concern, as we did in our 2015 comments, that there is no denominator exclusion for patients who refuse the metabolic screen. Patients have every right to refuse treatment and this does not necessarily correspond to a quality of care issue. The proposed rule currently includes "enduring

unstable medical or psychological condition" as an exclusion, and we definitely think this should remain. However, because patient refusal is different from (and not incorporated in the "unstable condition" exclusion), it needs to be an added category. The CMS response in the *2015 Inpatient Psychiatric Facilities Prospective Payment System—Update for Fiscal Year Beginning October 1, 2015* to this concern was, "We believe that patient compliance is indicative of quality care," and, "We encourage providers to educate patients about the importance of these screenings, and we, therefore, will not exclude patients who refuse the screening." We challenge the sweeping statement that patient compliance is indicative of quality care and continue to feel this is an inadequate justification for the decision to not include patient refusal as a denominator exclusion.

We note that this measure still has not been NQF-endorsed. We also note that there has been no pilot testing of the measure after it was developed, and that it will be required of 1,600 facilities with no field testing. Further specification has been done by the contractor, but many questions remain unanswered. **We are concerned about the pattern we see of measures developed by contractors – that are not field tested or not NQF-endorsed – being submitted by CMS to the Measures Under Consideration (MUC) process at NQF, being included in proposed rulemaking, and moving to the final rule with virtually no modification based on input from the field submitted during the comment period.**

PROPOSED NEW QUALITY MEASURES

SUB-3 (Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge) and the **subset SUB-3a measure (Alcohol & Other Drug Use Disorder Treatment at Discharge)**

CMS proposes to add the third component to the set of substance use disorder measures that are currently part of the IPFQR program. The proposed additional components require that, at discharge, patients who screen positive for drug and alcohol abuse are offered treatment options (specifically a prescription for and FDA-approved medications for alcohol or drug abuse disorder, OR a referral for addictions treatment).

We do not support the inclusion of this measure. We continue to have concerns, as we expressed in our comments on the FY2015 proposed rules and before, that the SUB suite of measures does not appropriately address the needs of patients in psychiatric inpatient services. They were developed to be population screening measures. Our members consistently question the value of using a validated screening tool that was designed to determine whether a person is at risk for alcohol use problems. Psychiatric hospitals perform an in-depth assessment of patients' alcohol and substance abuse history and current use. This assessment requires far more than a screening question for alcohol use. Patients who are assessed to have an alcohol disorder (which is often comorbid with other substance use disorders and mental illness) are treated through a multi-disciplinary, multi-model plan.

The FY2016 final rule took the alcohol screening question further by adding the SUB-2 and 2a measures (requiring a brief intervention be offered and provided if the alcohol use screen is positive). We did not support this addition and provided recent literature citations to back our recommendation. The psychiatric literature supports the efficacy of brief intervention in primary care for patients who have screened positive for unhealthy alcohol use. However, it identifies that there is no evidence of efficacy among those with very heavy use or dependence. Brief intervention is not the treatment of choice for persons with severe addictive disorders. They require, as noted above, an intensive, multi-disciplinary plan of care if they are being treated in a psychiatric hospital. CMS disagreed with our comments regarding the efficacy of brief interventions and ruled that there must be a "bedside discussion with the patient" focusing on an extensive list of factors in order to get "credit" for the measure.

The SUB-1 and SUB-2 measures focus on alcohol abuse and SUB-3 focuses on both alcohol and substance abuse. This creates changes in the denominator and raises definitional questions about what constitutes substance use that requires ongoing treatment as distinguished from overall outpatient mental health treatment.

We cannot support adding the proposed SUB-3 and SUB-3a measures to a set about which we have serious concerns and no evidence that they are advancing the quality of the IPF field. CMS states in the proposed rule that there is "value created by the inclusion of the SUB-1 measure and the SUB-2 and 2a

measure…" Yet, in our experience, providers are not seeing the value. Referring patients for treatment of their psychiatric and often co-morbid substance abuse conditions is required of IPFs in many other ways and an inherent part of providers' standards of care. The SUB measures are, in many cases, inappropriate and inadequate interventions. Publicly reporting compliance with this specific set of measures does not, in our opinion, further the CMS goal of evaluating critical processes of care that have significant impact on patient outcomes in order to allow consumers to make informed decisions about providers. In our comments we noted that the SUB measures have not been systematically tested in inpatient psychiatric units and asked that CMS continue to review the usefulness of the SUB for such application. We are not aware that any such review has been conducted.

Recommendation:

NAPHS does not recommend extension of the SUB measures. We further recommend review of the usefulness of SUB-1 and SUB 2 and 2a, based on the literature and providers' experience with it through the past year. We note that substance abuse screening is part of NQF-endorsed HBIPS-1, which has been available since 2008 and is currently in widespread use in inpatient psychiatric facilities. We recommend that HBIPS-1 be enhanced, if necessary, and adopted for the IPFQR program.

Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF)

We acknowledge that readmission to a psychiatric or acute care hospital within 30 days of hospitalization is an event that deserves careful review. As a field, we are committed to developing strategies that assist patients to maintain stability at the most appropriate level of care. Because of the widely-reported inadequacies in the mental health infrastructure, we know patients and providers are severely challenged in moving within the continuum of psychiatric services. Readmissions can be life-saving interventions.

We have concerns with the broad characterization presented in the proposed rule of readmissions as a direct reflection of the quality of care received in an IPF. We think the body of literature used to draw the link between quality of inpatient care and rate of readmission is weak. Citations used to build the cause-and-effect relationship are from international journals (from countries with very different healthcare delivery systems such as Great Britain, Israel, Australia), from populations not covered by the IPF quality reporting program (such as veteran administration hospitals, Medicaid patients), and from general medical literature (such as medical discharges of the hospitalized elderly). Issues related to readmission such as length of stay, availability of resources following discharge, and characteristics of the population (age, diagnosis, acuity) were not accounted for in the literature review. Strategies recommended to decrease readmissions (such as medication reconciliation, assigning a transition manager, and connecting patients to services they will need in an outpatient setting prior to discharge) were drawn as examples from studies and have not been systematically studied across large populations. The effectiveness of the interventions that were reported was interesting, but not compelling. The interventions under the control of IPFs for improving readmission rates are limited.

The characteristics of the Medicare beneficiaries cared for in IPFs are significantly different from the general Medicare population. As noted in the "Inpatient Psychiatric Facility All-Cause Unplanned Readmission Measure Draft Technical Report," approximately 65% of patients accounting for index admissions were less than 65 years old on the day of admission. These beneficiaries qualify for Medicare due to disability. Approximately 58% of all IPF admissions also have Medicaid eligibility, indicating poverty status. These combined factors describe beneficiaries with unique challenges in stabilizing their chronic conditions in the midst of an acute psychiatric crisis. The strategies used to reduce readmissions for many Medicare patients (care in skilled nursing facilities, in-home care) are not available to most of this disabled population.

Because of the relatively small number of IPF discharges meeting the measure inclusion criteria (716,174), we question whether 24 months of data (as proposed in the measure) will provide an adequate facility-level sample size. We know this was chosen for the measure development phase, but because of public reporting, we ask for assurance that the sample is adequate to establish a risk standardized readmission rate for each facility. We also note that, because IPF data is only reported once a year because of limitations to the CMS ability to receive the data, the reported rates lag behind actual rates by a significant

amount of time. We anticipate there will be significant public interest in these data, that they will be used for purposes beyond the IPFQR reporting, and their timeliness and accuracy are of great concern.

The HSAG Technical Report discussed the reasons for designing an All-Cause Readmission measure as opposed to limiting the measure to readmissions to IPFs (approximately one quarter of IPF index readmissions are to acute care hospitals). These reasons included among others: 1) determination of the relationship between the principal discharge diagnosis of the index admission and the principal discharge diagnosis of the readmission is complex because similar clinical presentations might be captured with slightly different principal diagnosis codes, and 2) a focus on all-cause readmissions offers the IPF an opportunity to implement a broader range of quality improvement initiatives with promise for greater impact than measures that focus on a specific cause of readmission. While we acknowledge these are the assumptions of CMS, we question if this is the readmission measure that best captures the quality of care provided in IPFs. Patients are admitted to acute care hospitals for many reasons totally unrelated to their index psychiatric admission. The relationship between the psychiatric admission and a subsequent acute care admission has not been systematically explored. Holding IPFs accountable for these admissions could dilute the clarity and actionability of the measure.

Recommendations:

NAPHS recommends review of the 24-month timeframe for collection of data to determine a facility-level sample size.

We also recommend very careful monitoring of the results of the Medicare claims data review as it relates to readmissions based on our concerns with the strength of empirical evidence of the link between the quality of inpatient care and the rate of readmission.

SUGGESTIONS FOR POSSIBLE NEW MEASURES

We continue to recommend exploring the development of a patients' perception-of-care measure. This measure should be constructed with active engagement of the psychiatric provider field. As we know from the data CMS has collected, most providers use a perception of care measure, yet these have not been standardized.

PUBLIC DISPLAY AND REVIEW REQUIREMENTS

We support the CMS objective to publicly display data as soon as possible on the CMS website. We know it is only possible to post IPFQR data annually because of, as we understand it, CMS resource constraints. We continue to be required to report data in more rudimentary ways than other reporting systems. However, it is very important that each IPF have the opportunity to review its data before public display and to identify errors. We support flexibility rather than regulatory constraints. We think it is imperative that facilities have at least 30 days to review their data, and we would not support any change to that standard.

FOCUS MUST BE ON QUALITY (SUMMARY OF KEY ISSUES)

In reviewing our comments on specific measures, there are recurring themes throughout. As CMS finalizes IPFQR measures, we urge CMS to consider the following:

- **The focus should be on the quality of inpatient psychiatric services.**
- **Limited resources should be directed** to the collection of the most clinically significant and actionable data relative to the provision of psychiatric services – with attention to operational and technical data extraction, feasibility, and burden.
- **Publicly reported data needs to help the consumer make choices on the *psychiatric* care provider they may need.**

Thank you for the opportunity to provide feedback.

If you have any questions, please contact me or NAPHS Director of Quality and Regulatory Affairs Kathleen McCann, R.N., Ph.D., at 202/393-6700, ext. 102.

Sincerely,

/s/

Mark Covall
President/CEO