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SUBMITTED VIA www.regulations.gov

June 23, 2015

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: <u>CMS-1627-P: Proposed Rule</u> – "Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System—Update for Fiscal Year Beginning October 1, 2015 (FY2016)"

RIN 0938-AS47

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; Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS)—Update for Fiscal Year Beginning October 1, 2015 (FY2016)" as published in the May 1, 2015, Federal Register.

We are specifically commenting on 1) the **inpatient psychiatric prospective payment system (IPF PPS) update for FY16** and 2) **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.

SUMMARY OF MAJOR RECOMMENDATIONS:

NAPHS recommends that, if an IPF-specific Market Basket is adopted, it be phased-in over two years.

NAPHS strongly recommends that the discharge measure 0647 not be implemented because this domain of care is adequately covered by 42 CFR 482.43, Discharge Planning. The proposed measure has not been studied in the IPF PPS population, and its implementation would be very expensive, technically burdensome, and duplicative of processes already in place in hospitals. There is no data presented to demonstrate it would improve care.

Page 2 - NAPHS

NAPHS strongly recommends that the Timely Transmission of Transition Record (0648) not be implemented and that HBIPS-6 and HBIPS-7 be retained. We would be open to working with the HBIPS measure steward (The Joint Commission) to refine the measure if there is a need to do so.

NAPHS recommends that any decision about the inclusion of a metabolic screening measure be delayed until the measure can be fully developed, tested, NQF-endorsed, and evaluated for appropriateness for use in the IPFQR program.

Recommendations on other aspects of the proposed rule and further discussion of our comments may be found below.

COMMENTS: IPF PPS UPDATE FOR FY16

IPF-Specific Market Basket

We note the significant work CMS has done in the development of a potential IPF-specific market basket. The proposed rule, for the first time, would establish a specific market basket for inpatient psychiatric facilities instead of using the combined Rehabilitation, Psychiatric, and Long-Term Care (RPL) market basket. In past years, CMS has expressed interest in exploring the possibility of creating a stand-alone or IPF-specific market basket that reflects the cost structures of only IPF providers.

NAPHS has supported the efforts by CMS to continue to work on the establishment of an IPF-specific market basket. We also have said that we cannot take a position on a separate market basket until further analysis was made available by CMS.

It is our view that it is preferable to use the best and most accurate data to determine the specific costs on which to base payment for inpatient psychiatric facilities. In that regard, if a separate market basket would better predict the actual costs in inpatient psychiatric facilities, that would be a good next step. We have not conducted our own analysis of the CMS proposed market basket, but we have been made aware of a Dobson/Davanzo analysis of the CMS proposed Inpatient Rehabilitation Facility Specific Market Basket. We understand that this study did identify some possible areas that may need further study and analysis by CMS. We encourage CMS to review the Dobson/Davanzo findings related to IRFs to determine if there needs to be further analysis done by CMS before finalizing a specific market basket for IPFs (given that the methodology used for the proposed IPF market basket is similar to the IRF methodology).

Phase-In

In developing the IPF-specific market basket, CMS calculations resulted in the wage and salary portion of the IPF market basket increasing from the current proportion of 69% to the proposed proportion of 74%. This change is material and would have a redistributive financial impact on IPFs across the country. For that reason, and consistent with prior CMS actions in these types of payment situations, we recommend that CMS, if it does decide to implement the IPF-specific market basket, phase-in the wage and salary portion of the market basket over a two-year period to limit the redistributive effect on IPFs.

Recommendation:

NAPHS recommends that, if an IPF-specific market basket is adopted, it be phased-in over two years (rather than being fully implemented in 2016, as proposed).

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 ADDITIONS TO THE FY2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS:

Measure: NQF 1663 (SUB-2 and SUB-2a) Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention

This measure expands the SUB set of measures to include the offering of brief intervention (BI) and referral. Our members have long been committed to providing the highest quality of care to persons with all types of substance use disorders. However, we continue to have concerns, as we expressed in our comments on the FY2015 Proposed Rule, 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. We perform an in-depth assessment of patients' alcohol and substance abuse history and current use. Their thorough 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 proposed rule takes the alcohol screening question further and requires a brief intervention be offered and provided if the alcohol use screen is positive. 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.

A study published in *Drug and Alcohol Review* (Saitz, R.¹) concluded that "Alcohol screening and BI has efficacy in primary care for patients with unhealthy alcohol use, but there is no evidence for efficacy among those with very heavy use or dependence. As alcohol screening identifies both dependent and non-dependent unhealthy use, the absence of evidence for the efficacy of BI among primary care patients with screening-identified alcohol dependence raises questions regarding the efficiency of screening and BI, particularly in settings where dependence is common."

A recent article in *Addiction*² states that "Despite the widespread support for [Screening, Brief Intervention and Referral to Treatment] implementation as a public health program to address all forms of unhealthy alcohol use, there is a lack of evidence from existing studies of brief alcohol interventions to support the assumption that SBIRT, as currently implemented, is efficacious in linking individuals to higher levels of alcohol-related care." This meta-analysis of 13 randomized controlled trials involving 993 intervention patients and 937 controls, found no evidence that SBIRT for alcohol has any efficacy for increasing treatment for alcohol use disorders.

SUB-2 and SUB-2a have not been systematically tested in a psychiatric hospital setting. In addition, more recent clinical review is documenting that SBIRT has limitations not previously identified.

Recommendation:

NAPHS does not recommend extension of the SUB measures. We further recommend review of the usefulness of SUB-1, 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.

Measure: NQF 1656 (TOB-3 and TOB-3a) Tobacco Use

We acknowledge that use of tobacco is a significant public health issue and patients with mental illness are disproportionately represented in the tobacco use population. We note that the TOB measures were developed for population screening, and that they have not been systematically tested in inpatient psychiatric settings. Data is lacking on the best strategies to use in helping acutely ill psychiatric patients address their smoking behaviors.

Screening for tobacco use (TOB-1) and provision/offering of tobacco use treatment (TOB-2, 2a) are currently included in the IPFQR measure set. Offering treatment at discharge seems like a natural

¹ Saitz R. (2010), "Alcohol screening and brief intervention in primary care: Absence of evidence for efficacy in people with dependence or very heavy drinking," *Drug and Alcohol Review*. 29:631-640. DOI: 10.1111/j.1465-3362.2010.00217.x. See http://onlinelibrary.wiley.com/doi/10.1111/j.1465-3362.2010.00217.x/abstract.

² Glass JE, Hamilton AM, Powell BJ, Perron BE, Brown RT, Ilgen MA. "Specialty substance use disorder services following brief alcohol intervention: a meta-analysis of randomized controlled trials," *Addiction*, online ahead of print April 2015. DOI: 10.1111/add.12950. See http://onlinelibrary.wiley.com/doi/10.1111/add.12950/abstract.

extension of the requirements. We note that, through the use of this measure, the field is developing data that could be very informative in better understanding the appropriate adaptation and application of tobacco use measures in the inpatient psychiatric setting.

Recommendation:

If CMS moves forward with using these measures, NAPHS recommends that CMS engage the field in a process to review the effectiveness and appropriateness of the application of the measures in the inpatient setting in order to determine if the measures are meeting the goals of the IPFQR program.

Measure 0647: Transition Record with Specified Elements Received by Discharged Patients

NAPHS strongly supports the importance of effective transition from one treatment setting to another in support of continuity of care. Communication of relevant information in understandable ways is a key component of this transition. In the current proposed rule, CMS says it intends to implement a new measure titled, "The Transition Record with Specified Elements Received by Discharged Patients" (NQF 0647). Measure 0647 was developed by the American Medical Association-convened Physician Consortium for Performance Improvement (PCPI) and designed for use with a broad range of patients, with focus on patients cared for in medical settings (as noted in language such as major procedures, surrogate decision making, studies pending at discharge). The measures contain specific elements that, at a minimum, need to be included in a transition record that is received by a patient at the time of discharge. The hospitals covered by the IPFQR measures are required to submit data on all age groups of patients. While the measures say they were developed for all ages, references and supporting statistics are definitely weighted toward the adult population. We note there were no members of the PCPI workgroup who appear to represent either psychiatric or child and adolescent patients.

NAPHS maintains that measure 0647 was not designed for – nor does it meet the specialty-focused needs of – the psychiatric patients addressed under the IPFQR program. It would create a duplicative burden for providers because comprehensive information at the point of discharge is already required by the Medicare Condition of Participation (CoP), Discharge Planning. The CoP gives organizations the flexibility to tailor information to the needs of specific populations.

As a Condition of Participation in the Medicare program, hospitals are required to provide patients with detailed discharge information as part of a comprehensive process of discharge planning. CMS has provided recent and extensive guidance through its Interpretive Guidelines for 42 CFR 482.43, Discharge Planning (which is applicable to all facilities that bill under IPF PPS). Among other things, the CoP requires that written discharge instructions (in non-technical language) be developed for, discussed with, and given to patients. Elements to be included in the discharge summary include: a list of medications; evidence of patient (and when appropriate, family) education; referrals for follow-up care; and the sending of necessary medical information to providers to whom the patient was referred prior to the first post-discharge appointment (or within seven days of discharge, whichever comes first). The CoP also requires a hospital to have a process in place to track its readmissions as part of its review of the discharge planning process, and evaluate whether the readmissions were potentially due to problems in discharge planning or the implementation of discharge plans.

See http://www.cms.gov/Medicare/Provider-Enrollment-and-Cert-Letter-13-32.pdf. Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-32.pdf.

This Condition of Participation is routinely surveyed by CMS (if the hospital is not accredited) or The Joint Commission (TJC) under its deemed status responsibilities. If a facility fails to meet the requirements, it is cited for non-compliance by Medicare and risks losing Medicare reimbursement. Results of these surveys are publicly reported and available for use by consumers for decision making. Requiring a quality measure that is well-addressed in (and, in certain aspects, misaligned with) the CoPs is burdensome and duplicative and is not consistent with the goals of the IPFQR program. We think the Conditions of Participation for discharge planning meet the goals addressed in the proposed rule of "promoting appropriate care coordination by specifying that patients discharged from an inpatient facility receive relevant and meaningful transition information." The CoP has specific elements that promote person and family engagement and encourage patient empowerment.

The PCPI 0647 measure was never developed with consideration for the specialty needs of psychiatric patients. It is not in use in psychiatric facilities. The elements that CMS identifies in the proposed rule as superior in the 0647 measure (such as pending test results) are not germane to the vast majority of psychiatric patients. The proposed rule cites an article (Kripalani, 2007) that reports on a study of communication deficits between hospital-based and primary care physicians. It quotes that 40% of discharged patients have test results pending and a quarter of these require further action to avoid potential negative consequences. This article did not study the psychiatric population. From clinical experience, our experts report that having pending test results is very rare. Should there be pending results, these can easily be incorporated into the current requirements for recommendations for next level of care (HBIPS-5 and HBIPS-6). The PCPI measure requires that "at a minimum, all of the specified elements" be included. With so many elements not being a part of the patient's care, it would be unnecessarily burdensome for data abstractors to review the entire record and document that information was not in the record—even when we would not expect it to be. Lack of required elements would place providers (and the public) at a disadvantage when data was compared with care provided in organizations for which the measure was actually developed. It might not be a document that would be helpful to patients.

In the proposed rule, CMS cites one of the advantages of the 0647 is that it would include an advance care plan. While IPFs are responsible for following the Conditions of Participation regarding advance directives, psychiatric patients in the midst of acute stabilizing treatment are often not in the best position to formulate an advance care plan (for example, a patient who is acutely psychotic or is having suicidal thoughts and impulses). We do not think making this a requirement is a measure of quality in the care of psychiatric inpatients.

In the proposed rule, CMS compares 0647 to HBIPS-6. HBIPS-6 is intended to address information that goes to the next level of care provider, not the patient. We comply with the Conditions of Participation regarding patient discharge information. Quality measures are not intended to audit compliance with the Conditions of Participation. We maintain that the information that goes to the patient, in many circumstances, is appropriately different from what goes to the next provider. Since this measure has not been used in psychiatric inpatient settings, it is impossible to answer many of these questions.

CMS notes there is better alignment with 0647 and the requirements of the Electronic Health Record (EHR) Incentive Program for eligible hospitals. Psychiatric hospitals are not eligible for the EHR Incentive program (and are statutorily excluded from it). In addition, the vast majority of organizations to which we discharge patients do not have electronic records, so issues of interoperability make it almost impossible to transmit information electronically. Information we give to patients is in paper format, with rare exceptions. Preparing for a future state that could be many years away – when the measure itself and the IPFQR program may have undergone significant change – is not a good use of resources.

Recommendation:

NAPHS recommends that the discharge measure 0647 not be implemented because this domain of care is adequately covered by 42 CFR 482.43, Discharge Planning. The proposed measure has not been studied in the IPF PPS population, and its implementation would be very expensive, technically burdensome, and duplicative of processes already in place in hospitals. There is no data to demonstrate it would improve care.

Measures: 0648: Timely Transmission of Transition Record

While NAPHS strongly supports the importance of effective care transitions in the provision of high-quality behavioral health care, we have very serious concerns about the introduction of the Timely Transmission of Transition Record as a proposed measure. We are convinced the 0648 measure would not address an unmet program need, and could disrupt important improvement efforts that use data from the NQF-endorsed continuity of care measures already adopted for use in the IPFQR program.

The behavioral health field identified the tremendous importance of communication between the hospital and next level of care several years ago. The field (including public and private psychiatric hospitals and units in general hospitals) worked hard to identify the essential elements in that communication and the

relevant timeframe. We worked together to specify, test, re-evaluate, and imbed the measures (HBIPS-6 and HBIPS-7) into relevant accreditation activities. The field continues to strongly support these measures and to demonstrate ever-improving compliance.

The proposed measure (0648) has a prescribed list of elements that CMS suggests is superior to the HBIPS elements. Several of the elements (reason for hospitalization, diagnosis, medication list, and plan for follow-up care) overlap with those in the HBIPS list. Most other elements in measure 0648 have very little relevance to psychiatric patients (e.g., major procedures, studies pending at discharge, medical advance directive). Medical records would have to be reviewed for each element of the proposed measure—even when significant numbers of the elements would never be expected to be found.

Knowing that a significant majority of psychiatric patients are not seen by an outpatient provider within 24 hours of discharge, the field determined that a longer timeframe gave the hospital a better opportunity to complete the required information so that the receiving site of care would be better informed. It also gave organizations more control over when information was transmitted in order to better comply with the added confidentiality requirements for behavioral health and substance abuse records. Since much communication with outpatient providers is through FAX, a longer period of time gives organizations more control over when materials are sent and who receives them. We have tested the current timeframe over the eight years these measures have been in use and feel it continues to be appropriate. Providers report that the timeframe works well in the field and is acceptable to community providers who are receiving information. If a patient is going to be seen sooner, hospitals have the responsibility to make the appropriate adjustments in the timeframe when sending the information. HBIPS-6 and 7 outline the essential minimal areas of communication between settings for all patients. Hospitals regularly communicate additional information when it is relevant to a particular patient.

As noted above, the psychiatric hospital field is not a part of meaningful use and is potentially many years away from being able to use electronically specified measures. The outpatient providers to whom we send information are often in the same situation and are not interoperable with hospital electronic health records.

CMS states that, "We believe that the Transition Record with Specified Elements Received by Discharged Patients measure is a more effective and robust measure than HBIPS-6 for use in the IPF setting." CMS does not support this claim with data. The measures were not developed for – nor have they never been, to our knowledge, tested in – a psychiatric setting. We do not know how widely they are in use in the field and are not aware of hospitals using the measures with the IPF population.

Here is a summary of our concerns about substituting the Transition Record Measure (0648) for HBIPS 6-7:

- The HBIPS measures were developed with significant input from the psychiatric field and fully tested for validity and reliability in the psychiatric setting by both CMS and The Joint Commission. They are endorsed by NQF. They have been available from The Joint Commission, as a condition of accreditation for psychiatric hospitals, for seven years. Based on a commitment to the importance of continuity of care, hospitals using the measures have developed important strategies to improve care at the point of discharge.
- 2. Since the HBIPS measures were developed for use in psychiatric specialty facilities (those covered by the CMS requirements for the IPFQR program), they focus on elements of specific importance in the care of psychiatric patients, known to be related to outcomes. An example of this is the rigorous communication of details pertaining to medication (including name of medication, dosage, and indication for use) and recommendations for continuing care based on an overview of the current hospitalization. In contrast, 0647 and 0648 pertain to all patients who are discharged from a general hospital or observation unit, skilled nursing facility, or rehabilitation facility. It is impossible to identify good benchmarks for psychiatric specialty providers when data for the measure potentially includes all providers. The AMA-PCPI measures have never been tested in the psychiatric population and contain elements that do not apply to this population. Moreover, national comparative rates for the HBIPS measures are much more meaningful because all users are psychiatric inpatient specialty providers (rather than all hospitals, skilled nursing facilities, and rehabilitation hospitals). The value of the information to the public could be compromised by the many users.

- 3. Due to their widespread use, there is an extensive database in existence for the HBIPS measures that can be used for further analysis and refinement. Changing the requirement at this time would make the existing data irrelevant to the IPFQR program as well as hinder the quality initiatives that facilities have started to address their performance in the area of continuity of care.
- 4. The use of the HBIPS measures has promoted significant improvements in IPFs, and their continued use would help the field close the remaining performance gap. The HBIPS measures have been required of psychiatric hospitals accredited by The Joint Commission since 2011, although hospitals had the option of reporting the measures since October 2008. Within The Joint Commission reporting system, the overall performance of IPFs on HBIPS-7 began at 56% in the fourth quarter of 2008 with 155 facilities, improving to 85% in the second quarter of 2014 with 663 facilities. All units in general hospitals reimbursed under the IPF PPS system were added to the measure pool in October 2012. Overall compliance reported by CMS in April 2014 for HBIPS-7 was 62.7%. By comparison, one-third of these facilities also reported to The Joint Commission for the same time period and had a compliance rate of 87.8%. This translates to a compliance rate of only 44% for the two-thirds of psychiatric facilities that began using the measures based on the CMS requirement. In short, there remains significant additional room for improvement, and we believe the continued use of the HBIPS measure would help foster such improvement.
- 5. The inclusion of IPF PPS facilities in the CMS Quality Reporting initiative is still very new. Facilities have been challenged to report to CMS a very significant number of measures with complex data specifications using local data systems (predominantly paper records) with relatively few having certified EHRs. It has been a very steep learning curve. The quality of publicly reported data needs time to improve and stabilize. Changing measures of the same domain of care without compelling reasons to do so has the potential to impede provider progress toward the goals of delivering quality care.
- 6. If CMS replaced the current HBIPS measures with the proposed measures, psychiatric hospitals would still need to report information on the same dimension of care, but in a different way, to The Joint Commission. The use of such competing measures adds to reporting burden, creates confusion and potential inaccuracy in interpreting performance results, and diffuses the valuable learning that is possible when large numbers of providers report data in exactly the same way. It adds complexity to the public's ability to interpret data for decision making. There has been a long tradition of trying to align measure specifications between CMS and The Joint Commission, as much as possible, while keeping the focus of the measures specific to the patient populations.

Recommendation:

NAPHS recommends that the Timely Transmission of Transition Record (0648) not be implemented and that HBIPS-6 and HBIPS-7 be retained. We would be open to working with the HBIPS measure steward (The Joint Commission) to refine the measure if there is a need to do so.

Measures: Screening for Metabolic Disorders

We recognize that antipsychotic medications increase the risk for metabolic syndrome in some patients. We also recognize that there are practice guidelines that point out the association between specific second-generation antipsychotics and diabetes, coronary artery disease, and obesity. The proposed rule states that "screening for metabolic syndrome may reduce the risk of preventable adverse events and improve the physical health of the patient. Therefore we believe it is necessary to include a measure of metabolic syndrome screening in the IPFQR program." We think the move from identifying a risk profile for a specific medication to a publicly reported compliance rate with a set of physical measures and laboratory values for the purpose of determination of quality and payment is a significant one.

We have engaged in extensive discussion with our members about the usefulness of a screening measure for metabolic syndrome as part of the IPFQR requirements and note the following:

- 1) The metabolic screening measure is still in development. NAPHS members are part of the IPF Technical Expert Panel (TEP) for the IPFQR program and know that the measure, as of the writing of these comments, has not been fully specified nor presented to the full CMS IPF PPS TEP. This makes it impossible for clinicians to fully assess the appropriateness of the measure at this time.
- 2) The measure has not been tested in the field. CMS notes in the proposed rule that "testing of this measure demonstrated that performance on the metabolic screening measure was low, on average, across the tested IPFs." The CMS testing referred to, we believe, was a general review within six facilities of whether they included the proposed elements (BMI, BP, glucose, and lipid panel) in the care of their patients. We do not think this constitutes rigorous testing of measurement specifications (and refinement based on testing, including input from the field) that is the usual standard for measure development. We further question whether this can be truly taken as a measure of the quality of care patients in the six facilities reviewed or that an average performance rate that represents the field can be generated from a sample of six organizations (reported at 42%).
- 3) The measure is not NQF-endorsed. CMS has the latitude to accept measures that are not NQF-endorsed if there are no measures in existence. CMS has researched the NQF database and cannot find an appropriate measure. While we understand the non-NQF-endorsed exception is available to CMS, we are also aware of the strong preference in the Quality Reporting system for using NQF-endorsed measures. Because of the timeframe for implementation of data collection for the measure (patients discharged on or after January 1, 2016), it is hard to conceive there would be time to obtain NQF endorsement before that time. Facilities must begin preparing to have everything in place to implement the measure (such as policies and procedures, education, data retrieval strategies, and EMR adaptations) immediately when the final rule is promulgated (summer 2015). When NQF reviews the measure, it could propose changes to it that would immediately create discrepancies between the CMS-required and the NQF-endorsed measures. This is a complication and burden that points to the importance of using NQF-endorsed measures and that could be avoided by delaying implementation of the CMS-developed measure.
- 4) There are clinical implications to implementation of the measure that have not been fully explored. Have all appropriate patient exclusions from the measure been identified? What is the provider burden involved in collection and reporting? Are there potential medical necessity issues to be addressed? What is actionable about the measure during a short-term hospitalization? What is the patient's acceptance of the screening? Is the public reporting of a screening rate a measure of quality that will help the public differentiate among treatment settings? Is this an appropriate application of the various practice guidelines from the perspective of the guideline developers?
- 5) There are financial implications to adoption of the measure that have not been quantified. Conservative estimates of the cost of doing the required lab tests are between \$30 and \$50 (the 2015 Medicare Lab Fee Schedule reimburses approximately \$43). The number of patients discharged on at least one antipsychotic medication in the fourth quarter of 2014 from psychiatric hospitals that reported the antipsychotic measures (HBIPS-4) to The Joint Commission was 66,211. That equates to an annual number of approximately 265,000 cases. There are about 675 hospitals reporting the measures to The Joint Commission. There are approximately 1,500 hospitals that would be required to implement the Metabolic Screening Measure. Conservatively estimating that the tests cost \$40 each, and that the 265,000 cases captured by TJC represent half the number of tests that would need to be done, the total number of tests for all hospitals for a year could be approximately 530,000. A certain percentage of patients would not need the test because they met one of the exceptions. While it is difficult to estimate those numbers, it is reasonable to say that the cost of doing the required lab work during inpatient stays could be near \$20,000,000 (530,000 patients times \$40 per test) every year the measure requirement is in place. While these costs may be determined to be necessary, they are not inconsequential. It seems that the financial implications deserve discussion.
- 6) Based on the specifications listed in the proposed rule, we think it is essential to add patient refusal as one of the approved exclusions. Patients have a right to refuse treatment under any

circumstances. The proposed rule currently includes "enduring unstable medical or psychological condition" as an exclusion, and we think this should definitely remain. However, because patient refusal is different from (and not incorporated in the "unstable condition" exclusion), it needs to be an added category.

- 7) The denominator for the metabolic screening measure in the proposed rule includes patients who had the complete screening within the past year or during the index IPF stay. The proposed rule accepts documented data from outside sources for tests done within 12 months from the patient's discharge date. NAPHS members noted that getting information from outside sources is very complex and usually cannot be obtained in a timely way. In order to assure compliance with the measure, facilities would, in many circumstances, opt to do the glucose and lipid panel routinely.
- 8) CMS concludes that, "We believe this measure promotes the National Quality Strategy (NQS) priority of Making Care Safer, which seeks to reduce risk that is caused by the delivery of healthcare." We agree that antipsychotics are related to metabolic syndrome, but their use is a constant risk-benefit analysis. For many patients they are life-saving and are prescribed in spite of the risk, as are many medications. Patients must often be stabilized on medication before they are able to understand and implement the life-style interventions (diet, exercise, lipid-lowering medication, etc.) that may be required to manage potential side effects. This is most often accomplished in outpatient follow-up rather than in a crisis-stabilization environment.

Recommendation:

NAPHS recommends that any decision about the inclusion of a metabolic screening measure be delayed until the measure can be fully developed, tested, NQF-endorsed, and evaluated for appropriateness for use in the IPFQR program.

FUTURE MEASURES:

CMS has said that it intends to develop a 30-day psychiatric readmission measure, and we know this process is well underway. We know such measures have been developed for other payment systems. The specific reasons for psychiatric readmissions, predictive factors including socioeconomic status, homelessness, etc. and the level of availability of adequate outpatient treatment resources are all important factors with special applicability to the potential readmission of psychiatric patients. Issues around involuntary commitment, lack of patient insight into disease process, unique characteristics of the psychiatric Medicare population, etc. need to be taken into consideration. An all-cause measure seems to not be appropriate for the IPFQR program. We will follow this development of the readmission measure and look forward to proposed measures being subject to the same rigorous development and testing standards as the readmission measures that have been developed for other populations.

In the last rule-making cycle, CMS discussed its interest in developing a patient perception of care measure. The field acknowledged its relevance to the CMS goals of quality measurement and indicated its interest in working on such a project. We know Assessment of Patient Experience of Care data, which will be used to inform this process, will be collected in the upcoming data reporting period (July 1 to August 15, 2015). We continue to want to work with relevant partners to develop such a measure which is specified for psychiatric patients. We support its development with the rigor of other perception of care tools.

CHANGES TO REPORTING REQUIREMENTS

We are very grateful to CMS for their efforts to reduce IPFs provider reporting burden through changes in sampling, population counts, and age breakouts by quarter. We have heard feedback from our members that the changes might inadvertently increase the complexity of the data reporting. We would be happy to convene some of our members who have been working with the data to share their specific concerns with CMS.

Page 11 - NAPHS

Recommendation:

NAPHS recommends that CMS convene technical experts who have been working with the IPFQR measures to identify the ways to best reduce provider reporting burden.

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