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Seema Verma, M.P.H.
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1677-P
P. O. Box 8011
Baltimore MD 21244-1850

Re: 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 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Proposed Rule (82 Fed. Reg. 19,796, April 28, 2017)

Dear Ms. Verma:

The American Psychiatric Association (APA), the national medical specialty society representing over 37,000 psychiatric physicians and their patients, would like to take the opportunity to comment on the 2018 proposed rule for the Medicare Inpatient Prospective Payment System (IPPS), the Long-Term Care Hospital (LTCH) Prospective Payment System, Quality Reporting Requirements for Specific Providers, and Medicare and Medicaid Electronic Health Records (EHR) Incentive Program Requirements for Eligible Professionals. Our comments focus specifically on issues that impact the care of patients with mental health and substance use disorders (collectively referred to as "behavioral health" disorders), particularly quality measurement for behavioral health services pursuant to the various hospital quality programs considered in this proposed rule.

Annual Payment Updates for the Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospitals (LTCHs)

The proposed changes outlined in this rule are applicable to approximately 3,330 acute care hospitals and approximately 420 long-term care hospitals, and would affect discharges occurring on or after October 1, 2017. The Centers for Medicare and Medicaid Services (CMS) estimate that the proposed annual IPPS rate increase for acute care hospitals, combined with other proposed changes, will increase inpatient operating payments by approximately 1.7 percent. Additional changes to uncompensated care (Disproportionate Share) payments would increase IPPS operating payments by an additional 1.2 percent—for a total cumulative increase in IPPS operating payments of 2.9 percent in fiscal year (FY) 2018.

For long-term care hospitals (LTCHs), the prospective payments would decrease by approximately 3.75 percent, or \$173 million, in FY 2018.

CMS plans to issue a separate annual payment update for inpatient psychiatric facilities.

Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Long-term care hospitals are statutorily required to report certain quality data to CMS to receive their full annual payment update. In this proposed rule, CMS proposes to adopt two new quality measures which are unrelated to psychiatric care, and to define the standardized patient assessment data that LTCHs must report to comply with the Social Security Act, as well as the requirements for the reporting of these data.

For FY 2020, CMS proposes to add five standardized patient assessment elements to long-term care hospitals' reporting requirements:

- 1. Functional status data
- 2. Special services, treatments, and interventions
- 3. Medical conditions and co-morbidities
- 4. Impairments
- 5. Cognitive function and mental health status data

The proposal language is like that found in the Medicare proposed rules for skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and hospice care. These proposals call for reporting data elements from the following cognitive assessment tools: Brief Interview of Mental Status (BIMS), Confusion Assessment Method (CAM), Patient Health Questionnaire-2 (PHQ-2), and Behavioral Signs and Symptoms.

The APA is pleased that CMS proposes to add these standardized patient assessment elements that will then become harmonized across the Medicare SNF, IRF, and hospice programs. Streamlining these requirements across these programs will reduce the administrative burden of quality reporting for these facilities as well as the physicians and other clinicians who contribute to that reporting.

LTCH QRP Quality Measures under Consideration for Future Years—Patients Who Received Antipsychotic Medication

CMS solicits comments on the proposed quality measure, "Patients Who Received Antipsychotic Medication." The agency assigns this measure to the Patient Safety domain of the National Quality Strategy. The APA is very concerned by the potential inclusion of this quality measure due to the lack of information provided for public review. There are several antipsychotic quality measures in various quality payment programs already and while the APA supports measures that ensure appropriate treatment with the correct psycho-pharmacological interventions, we cannot support a quality measure without details provided for review.

We have several questions about this measure and recommend CMS address these questions in the final rule:

What is the age range for the patients captured in this measure denominator?

- Which psychiatric conditions are included in, or excluded from, the measure denominator?
- Is this a metabolic screening measure for patients on antipsychotics?
- Is this a screening and follow-up measure that identifies patients on multiple antipsychotics?
- Is this a medication adherence measure?
- Is this a quality measure related to readmission rates?
- Does this quality measure examine the prescription rates of antipsychotic medications for patients with dementia?
- Does this quality measure attempt to reduce the prescription of multiple antipsychotics to a single patient?

Because of the lack of details provided by CMS including the utilization, rationale, or specifications of this measure, the APA strongly opposes the addition of the "Patients Who Received an Antipsychotic Medication" quality measure into the LTCH QRP.

Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

Proposed New Quality Measure for the FY 2020 Payment Determination and Subsequent Years— Medication Continuation Following Inpatient Psychiatric Discharge

In the proposed rule, CMS proposes adding an additional quality measure for the IPFQR program. Starting with the FY 2020 payment determination, and continuing into subsequent years, CMS would add the measure, "Medication Continuation Following Inpatient Psychiatric Discharge." The proposal states that the measure would be calculated using Medicare fee-for-service (FFS) claims. These claims would identify whether patients who are admitted to Inpatient Psychiatric Facilities (IPFs) with diagnoses of major depressive disorder (MDD), schizophrenia, or bipolar disorder had filled at least one prescription for an evidence-based medication, within the period from two days prior to discharge through 30 days after discharge.

The APA has concerns regarding the concept that filling prescribed medications one time, without information supporting patients' medication compliance after filling the prescription, is an inadequate unit of measurement to assign as a provision of quality care. Considering the specifications of this measure, the APA is also concerned that IPFs and inpatient clinicians would be held responsible for patient behavior following patient discharge.

Moreover, this measure is not currently endorsed by the National Quality Forum (NQF). It was recently recommended for endorsement during the NQF Behavioral Health Project Phase 4, but with consideration of the integration of risk adjustment. There does not appear to be a current risk adjustment methodology identified for this measure. When patients who have been recently discharged after an inpatient psychiatric hospitalization are measured based upon their medication adherence, it is helpful to understand their socioeconomic status (SES) as well as their connections to social supports, two important data points in risk adjustment.

The supporting materials drafted by the stewards for this measure, and shared by the NQF in the Behavioral Health Project Phase 4 Draft Report, claimed that patients who filled their prescriptions exhibited an increased likelihood to attend follow-up care at seven and 30 days following discharge. These materials also claimed a decreased rate of re-hospitalization, when compared to patients who did not fill

their medication prescriptions following discharge. But the materials failed to provide sufficient evidence to support these claims. Consequently, during the NQF comment period, the APA expressed concerns regarding the lack of transparency and/or citations for some of the supporting evidence. We also expressed concerns about the lack of support for the statement that "Evidence demonstrates that interruption of medication leads to relapse and negative outcomes."

Also, although supporting information for the measure specifications states that performance on this measure equated to "66.7 percent in the 10th percentile," there is no citation or information about whether performance on this measure had been specifically linked to improved outcomes. We noted further confusion stemming from the NQF specification information found in the supporting materials that involved the potential concept of encouraging hospitals to use inpatient pharmacies for their discharged patients, rather than outpatient pharmacies. The concept appears to be that the hospital could track whether its recently discharged patient was filling his/her prescription. This seems an unrealistic endeavor for many facilities, and would be quite problematic for stand-alone inpatient psychiatric facilities, which rarely house an inpatient pharmacy. Rather, these facilities typically contract with other pharmacies for prescription deliveries. In addition, defining successful medication adherence as filling at least one evidence-based medication prescription on a single occasion beginning as early as two days prior to patient discharge, potentially permits an opportunity for inpatient psychiatric units located within a larger hospital system to misuse the measure, given that not all facilities subject to this measure maintain inpatient pharmacies.

While we do agree that this quality measure fills a gap in a high impact area, the APA is interested in learning more about the data collected through this measure and its attribution model, because it directly points to the psychiatric facility and clinicians as the accountable entity.

Quality Measures Regarding the Use of Tobacco, Alcohol, and Other Drugs—IPFQR Program and LTCH ORP

For the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), CMS proposes the addition of six "behavioral health" quality measures that the NQF-convened Measure Applications Partnership (MAP) recently recommended (in its final draft of "Maximizing the Value of Measurement: MAP 2017 Guidance")¹ for removal from the IPFQR Program. In its March 2017 report, the MAP noted the importance of addressing tobacco cessation and substance abuse, but recommended "that CMS prioritize measures that will better address the quality of mental health care."

MAP Recommended Measures for Future Removal from IPFQR Program

- Tobacco Use Treatment Provided or Offered and the subset measure, Tobacco Use Treatment
- Tobacco Use Screening
- Tobacco Use Treatment Provided or Offered at Discharge and the subset measure, Tobacco Use Treatment at Discharge
- Alcohol Use Screening
- Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention

¹ "Maximizing the value of measurement: MAP 2017." Measure Applications Partnership. Final report. National Quality Forum. March 15, 2017. Washington, DC.

 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Disorder Treatment at Discharge

The APA agrees with the MAP's rationale for recommending that these NQF-endorsed measures be recommended for <u>future removal</u> from the IPFQR Program during <u>future rule-making periods</u>. We also agree that the following reasons for removal from the IPFQR Program are also relevant for the LTHC QRP: 1) the inadequate measure testing in these care settings; and 2) the high acuity of patients in these care settings which requires clinicians to focus on stabilizing these patients and reducing their most urgent symptoms (such as reducing suicidal ideation) rather than addressing less acute behavioral health issues (such as smoking cessation).

However, the APA does support the use of these quality measures to assess for these behaviors at the time of discharge, when the patient's condition is no longer considered to be acute. At that point, it would be beneficial for clinicians to utilize:

- NQF #1656: Tobacco Use Treatment Provided or Offered at Discharge and the subset measure,
 Tobacco Use Treatment at Discharge; and
- NQF #1664: Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Disorder Treatment at Discharge.

The above measures can be used at the time of discharge, after application of each of their respective screening tools. While the APA has some reservations about the appropriateness of these measures in these acute care settings, we also want to promote "behavioral health" measures that fill gaps in care while meeting psychiatrists' needs for more meaningful measures. Given these two factors, we agree with the limited addition (at time of discharge) of these quality measures into the LTCH QRP, as these measures fill a need in a high impact area.

Inpatient Psychiatric Facilities Should Not Be Penalized for Deficiencies in Their Electronic Health Record (EHR) Systems or Psychiatrists' Lack of Access to Those EHR Systems

The APA supports the overall goal of the Inpatient Psychiatric Facility Quality Reporting Program, as it focuses on stand-alone inpatient psychiatric facilities and psychiatric units within larger hospital systems and requires the provision of high quality care for this patient population. Within the proposed rule, it is notable that CMS acknowledges that this program includes quality measures relating to services provided by the inpatient psychiatric hospital or unit.

The APA supports the premise of reporting on quality indicators that measure the meaningful effects of care provided in this setting. However, we are concerned that psychiatrists and other clinicians cannot always report this data through facility EHRs. Frequently, psychiatrists who report from inpatient psychiatric units within larger hospital systems do not have access to an EHR interface that provides the ability to report data elements required to fulfill the quality measures assigned by this program. Additionally, unlike hospitals, many stand-alone inpatient psychiatric facilities do not have sufficient resources to invest in and maintain electronic health record systems that meet the evolving standards of certified electronic health record technology (CEHRT). This significantly hinders the ability to capture the provision of psychiatric care.

We appreciate that the goals of this quality reporting program include increasing data collection on the full spectrum of care provided by clinicians within these facilities, and decreasing the data collection burden on these health care providers. However, psychiatrists and these facilities will continue to be at a disadvantage. EHRs and clinical data registries continue to develop into the leading quality data reporting mechanisms for current and future capture of clinical data. Yet the EHRs available to psychiatric facilities and their clinicians have not kept pace or developed in a way that permits measurement of the care provided in this setting. As an example, some inpatient psychiatric hospitals continue to maintain EHRs first purchased in the 1990's. Although others have integrated more current data collection platforms, even those do not uniformly include the data fields required to submit the elements mandatory for quality measure completion in the IPFQR Program.

The APA urges CMS to adopt policies in the Inpatient Psychiatric Facility Quality Reporting Program to avoid penalizing an inpatient psychiatric facility for deficiencies in its EHR system, or for psychiatrists' inability to interface with the EHR system. The APA would also welcome the opportunity to discuss potential solutions for these issues.

Accounting for Social Risk Factors in the IPFQR Program

For application to the Inpatient Psychiatric Facility Quality Reporting Program, CMS asks which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a specific measure. Depending on its intended use, the APA encourages the practice of risk adjusting for certain variables, such as social risk factors/socio-economic status (SES) to prevent "cherry picking" the lower risk patients and inaccurately assigning the provision of poor quality care resultant from psychiatric inpatient readmissions, among other reasons. However, there are several limitations to the currently available data sources from which these risk-related variables are extracted, including the absence of sufficient indicators or psychosocial complexity that will allow the exploration into how quality can vary between these factors.

The APA supports the inclusion of risk adjustment methods in quality measurement for psychiatric settings. But we look forward to the results of the NQF two-year risk adjustment measure testing project, to help inform how to best capture this information. Considering the current climate and the ability to reliably capture certain social risk factors, this could prevent stand-alone psychiatric hospitals and psychiatric units in larger facilities from rejecting higher risk patients. Regarding the concerns over EHR discrepancies, it is unlikely that the information collected at the point of care, or from billing, would adequately include information that would display the full picture of the patient or quality of care provided. The APA recommends further, vigilant examination and identification of any potential, unintended consequences that may result from the application of risk adjustment, when stratifying by SES, by psychiatric condition acuity level, or by insurer. We invite CMS to engage in discussions with APA member experts, so that a comprehensive process that would positively impact patients, clinicians, and facilities, may be identified.

Proposed Considerations in Removing or Retaining Measures in the IPFQR Program

The APA supports CMS' language describing the removal and retention of quality measures (page 20,122) as it involves mirroring the process of other Medicare quality reporting programs. However, the language used to describe a "topped out" measure (defined by indistinguishable performance at the 75th and 90th percentile, i.e., measures that are consistently achieving success by nearly all participants) is not standardized over all public and private quality programs. Considering the wide-reaching efforts made by the multiple entities involved in quality measurement (e.g., CMS, NQF, Physician Consortium for Performance Improvement, National Committee for Quality Assurance, Agency for Healthcare Research and Quality, etc.) to *align* and *harmonize* quality measures and their reporting programs, it would be helpful for the national quality organizations to have a consensus definition of a "topped out" measure. Moreover, identifying a quality measure as "topped out" based on what appears to be an arbitrary choice of quality reporting success—without describing the cause for the success—could be very harmful to the program and to the patients that it serves.

For instance, when reporting rates of a process measure show that users are in the 75-90th percentile for compliance, that could be attributed to the fact that the quality measure is actively being measured ("what gets measured, gets done"). Thus, retiring "topped out" measures from the quality reporting programs could result (or is even likely to result) in a decline of what is being measured. That is a real problem when the process being measured contributes to positive health outcomes. It is also possible, due to the inconsistency of EHRs in these facilities or units, that some systems exist where reporting of compliance is automatic (e.g., required EHR fields for tobacco dependence). APA recommends that CMS further examine the mechanisms that assist in determining a measure is "topped out," before arbitrarily assigning this status and summarily retiring otherwise good quality measures.

Changes to the Medicare and Medicaid EHR Incentive Programs

Significant Hardship Exception for Decertified Certified EHR Technology (CEHRT) for EPs, Eligible Hospitals, and CAHs Seeking to Avoid the Medicare Payment Adjustment

Under the 21st Century Cures Act, Congress added a provision that the Secretary of the Department of Health and Human Services shall allow a one fiscal-year exception (subject to renewal by the Secretary) to the Medicare payment adjustment for eligible professionals (EPs) whose certified electronic health record technology (CEHRT) becomes decertified under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program. In this proposed rule, CMS proposes to revise its regulations for Section 495.102(d) of the 21st Century Cures Act. The revision would allow an EP to qualify for this exception if a) their chosen CEHRT becomes decertified by the Secretary, or b) the developer voluntarily withdraws the certification.

The APA is supportive of the exception for eligible professionals from the EHR Incentive Program whose electronic health record (EHR) systems have been de-certified by the ONC or otherwise discontinued by the vendor. Presently, as listed on the ONC's Certified HIT Product List (CHPL), there are very few EHRs that are certified to the 2015 standard (i.e., approximately 75).² Furthermore, none of these systems are

² See ONC Certified HIT Product List, https://chpl.healthit.gov/#/search.

distinguished by holding itself out as designed explicitly for psychiatric practices. Thus, there is already a dearth of EHR options for psychiatrists, making it difficult for these EPs to report directly to CMS via EHR on electronic clinical quality measures (eCQMs) and submit measures pertaining to EHR functional requirements.

It is further proposed, in this rule, to require EPs to complete an application process when and if their systems become de-certified or otherwise no longer supported by vendors. Specifically, this proposed rule recommends that the application process require EPs to "demonstrate in its application and through supporting documentation if available that the EP intended to attest to Meaningful Use for a certain EHR reporting period and made a good faith effort to adopt and implement another CEHRT in advance of that EHR reporting period." Over the past several years, the number of ONC-certified EHR systems that focus on psychiatry or mental/behavioral health that are available on the marketplace has dwindled significantly. This is clearly evidenced by the number of de-certified EHRs listed on the CHPL web site.

The APA recommends that this application process be more inclusive than restrictive in its requirements. For instance, it should allow for the CEHRT products listed on the CHPL web site to serve as the primary source of evidence for an EP's inability to participate in the Program. We recommend that the proposed application for exception due to the de-certification or discontinuation of a product should require:

- The date that the product was either de-certified, or
- The date the EHR vendor discontinued support of its own product, and the date(s) the EP accessed the CHPL web site to select a new, certified EHR system and subsequently confirmed that none of the CEHRT within the database satisfied the psychiatry-specific reporting needs of the Incentive Program (e.g., lack of eCQMs relevant to psychiatry/mental and behavioral health).

Request for Information on CMS Flexibilities and Efficiencies

The APA would like to address administrative burdens faced by health care providers, physicians, and clinical staff. The burdens have been discussed widely in the context of health care costs, clinical burnout, and adoption and usability of electronic health records. Key organizations, including the American College of Physicians and the American Medical Informatics Association, have developed position papers outlining these issues in detail. The 2015 RAND/American Medical Association report³ also touched on several of these issues.

Many of these issues are more problematic for psychiatry than for other medical specialties due to the additional regulatory and documentation requirements that have traditionally been a part of psychiatric hospital certification (under 42 CFR §482.60ff) and the different admission certification and quality requirements for inpatient psychiatric facilities. For facilities that have general medical as well as psychiatric units, the differences in regulatory and accreditation requirements between psychiatric and non-psychiatric services create added administrative burden and cost, particularly when electronic health

³ Friedberg, M. W., et al. Effects of Health Care Payment Models on Physician Practice in the United States. Santa Monica, CA: RAND Corporation, 2015. https://www.rand.org/pubs/research reports/RR869.html. Also available in print form.

record features must be customized to fit CMS, Joint Commission, and state mental health/substance use treatment requirements.

The APA recommends that CMS lead efforts to establish a consolidated set of requirements across the various state, federal, and accreditation organizations, particularly since accreditors (such as the Joint Commission) are performing inspections that fulfill both state and CMS inspection requirements. Streamlined and coordinated review criteria would reduce costs and burden, particularly if requirements were also aligned with general hospital requirements. One example is the restraint-related requirements. There are distinct requirements for "non-violent" as compared to "violent/self-destructive" restraint, which is reasonable because the purposes and types of restraints that are used are distinct. However, the requirements for documentation and evaluation with "violent/self-destructive" restraint differ, depending on whether they are used on psychiatric services or non-psychiatric services.

Proposed Changes Relating to Survey and Certification Requirements

The APA has concerns about the requirement proposed by CMS that accrediting organizations "make all Medical final accreditation survey reports (including statements of deficiencies) and acceptable plans of correction publicly available on the organization's Web site" and that this "includes all triennial, full, follow-up, focused, and complaint surveys, regardless of whether they are performed onsite or offsite."

The APA is supportive of making meaningful quality information available to the public. However, this proposal does not accomplish that goal. This requirement would negatively impact quality and safety in accredited organizations, and directly increase the regulatory burden on accredited organizations. This requirement also appears to be inconsistent with the intent of Congress as explicitly articulated in section 1865(b) of the Social Security Act: "(b) The Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency) made and released to the Secretary by the American Osteopathic Association or any other national accreditation body, of an entity accredited by such body, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary."

Accreditation reports by themselves are quality improvement tools and represent raw data that do not provide adequate information to understand the quality or the safety of the institution provided. Moreover, we are concerned that the proposed rule undermines the principles of creating a culture of safety and a just culture—things known to improve care. For instance, the aviation industry, as well as the nuclear power industry, have developed extremely effective methods to report errors and mishaps safely and confidentially. These methods have resulted in the United States leading the world in the safety of our aviation and nuclear power industries. By promoting confidential reporting processes led by the National Air and Space Administration (NASA), separate from the Federal Aviation Administration, administrators can analyze and improve processes.

Under current procedure, the Joint Commission (TJC) prepares an individual report for each facility that it surveys. Even facilities receiving a passing grade typically receive "citations" of areas that can be improved. Such citations are extremely common, but often carry a low likelihood of causing harm, and are limited in scope. Furthermore, these may reflect observations from TJC surveyors employing standards that go above and beyond the CMS Conditions of Participation (COP) and do not reflect any violations of the COP. The larger the hospital, the more such observations will be found, which is strictly

a consequence of size. Conversely, the smaller the hospital, the fewer may be found, again a consequence of size. This does not mean that an 18-bed critical access hospital in a rural county that lacks 24-hour inhouse physician coverage is therefore better than a 700-bed teaching hospital with 24-hour inhouse specialty care. But this is what the raw data may seem to say.

Enacting this requirement would unnecessarily increase the burden on physicians and hospitals. In the current process, accredited organizations spend time and effort developing plans to improve quality and safety. If accreditation survey reports and plans of correction are made public, we are concerned that organizations will spend increased time trying to shape the reports so individuals who do not understand the nuances do not misunderstand the raw data. This distracts the organization from the far more important task of improving the quality and safety of the care they provide.

Furthermore, the recommendations within this section of the proposed rule run counter to the explicitly stated intent of Congress. Current law explicitly forbids CMS from disclosing the results of an accreditation survey. We note the proposed change appears to be a specific effort for CMS to force accrediting organizations to do what Congress specifically forbids CMS from performing.

This proposal also undercuts the culture of quality and safety that organizations are building and it would directly weaken the quality of care beneficiaries receive. Measures of quality, such as those used by the Merit-Based Incentive Payment System, provide more meaningful information.

Conclusion

Thank you for your review and consideration of these comments. If you have any questions or would like to discuss any of these comments, please contact Debra Lansey, M.P.A., APA Associate Director for Payment Policy, at <u>DLansey@psych.org</u> or (703) 907-7848.

Sincerely,

Saul Levin, M.D., M.P.A. CEO and Medical Director

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