American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

June 7, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445–G
Washington, DC 20201

RE: CMS-1750-P, Medicare Program; FY 2022 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2021 (FY 2022), Proposed Rule

Dear Administrator Brooks La-Sure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including our nearly 1,600 psychiatric and substance use disorder provider members, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) inpatient psychiatric facility (IPF) prospective payment system (PPS) proposed rule for fiscal year (FY) 2022.

We support several of the IPF proposals, including alignment of certain provisions of the teaching policy with those used in the inpatient setting as well as the proposed removal of certain chart-abstracted quality measures. In addition, we value the opportunity to respond to CMS' various requests for information (RFIs) on health equity. We have concerns, however, with the proposals to adopt two quality measures, and thus strongly urge CMS to reconsider adopting these measures into the IPF quality reporting program at this time. Details on these recommendations follow.

Changes to IPF Teaching Policy. When a teaching hospital closes a residency program or the hospital closes entirely, Medicare regulations permit the hospital to temporarily transfer a portion of its hospital-specific direct graduate medical education (GME) and indirect medical education full-time equivalent (FTE) resident slots to other hospitals

that are willing to accept and train the displaced residents. The receiving hospitals may then receive a temporary adjustment to their FTE caps for the duration of the displaced resident's training. For IPFs, CMS has previously defined "displaced resident" as one that is physically present at the hospital training on the day prior to or the day of hospital or program closure. However, the agency proposes to modify this definition to be based on the day that the closure was publicly announced, which aligns with a previously finalized changed to the teaching policy used for general acute care hospitals.

In addition, CMS proposes to include as "displaced" those residents in the second and third groups who had not yet started their training, but who intended to train or return to training at the closing hospital/program. **We greatly appreciate CMS' recognition of the efforts made by hospitals that accept and train residents from closed programs and hospitals. We believe that the agency's proposed policy would more accurately account for displaced residents training at receiving hospitals, and therefore support it.**

Adoption of COVID-19 Vaccination among Health Care Personnel (HCP) Measure. This measure would calculate the percentage of HCP eligible to work in the facility for at least one day during the reporting period who received a complete vaccination course. The measure would exclude persons with medical contraindications to the COVID-19 vaccination as described by the Centers for Disease Control and Prevention (CDC), but otherwise all facility personnel — including licensed independent practitioners affiliated with but not directly employed by the facility, students, trainees and volunteers — are included in the denominator, regardless of clinical responsibility or patient contact. The measure would be reported using CDC's National Healthcare Safety Network (NHSN) Healthcare Personnel Safety Component submission framework.

The AHA strongly supports COVID-19 vaccinations of both HCPs and the communities they serve. We have worked closely with our members and the federal government to encourage vaccination within all of our members' to help protect both patients and our health care workforce from this crippling disease. Health care facilities have made remarkable progress in vaccinating large proportions of their teams in a short timeframe, and are working hard to close any remaining gaps. Notwithstanding the remarkable scientific achievement of having three available and highly effective COVID-19 vaccines, we are barely six months into deploying them. The underlying scientific evidence about how to implement the vaccines continues to evolve, and there remain important unanswered questions that would affect both the design and feasibility of any HCP vaccination measure. For example, how long do the vaccines confer immunity? How frequently might booster shots be required? Should one receive the same type of booster shot as the original shot? Will vaccine supply remain sufficient across the nation to ensure all HCP can receive it?

None of these questions detracts from the importance of encouraging COVID-19 vaccinations. However, the answers to all of these questions are of foundational importance to building a meaningful, accurate and fair performance measure whose

results would be shared publicly. The AHA is concerned that a premature mandate to report this measure would lead to unpredictable shifts in reporting requirements that would prove disruptive to hospitals, and result in data that are unhelpful to policymakers, the public and health care providers.

Due to the unique nature of the COVID-19 pandemic and the limited experience the nation has with the vaccine products currently available, we do not recommend implementing this measure for mandatory reporting this year, as its use could have negative unintended consequences and might not be the most useful tool to promote vaccination. Instead, the AHA recommends that CMS either delay adoption of the measure for at least one year (i.e., until Oct. 1, 2022), or adopt the measure for voluntary reporting for at least the first year to allow time for the issues described below to be addressed. Any voluntarily reported data should not be publicly reported.

In its rationale and explanation of the measure's design, CMS relies heavily on the specifications and experience with the Influenza Vaccination among Healthcare Personnel measure (NQF #0431). However, the circumstances around use of the COVID-19 vaccine are not entirely comparable to those of the influenza vaccine, as COVID-19 and the vaccines have had a short and at times, unpredictable implementation. The three vaccine products on the market — from Moderna, Pfizer and Johnson & Johnson — are currently only available under the Food and Drug Administration's (FDA) emergency use authorization. While we are confident in the safety and efficacy of these products and at least one is likely to receive full FDA approval imminently, we find it to be incongruous to adopt a measure into federal quality reporting programs that assesses the use of a product that has not yet received full federal approval.

Another important distinction between the measure proposed in this rule and the influenza measure already in use is that the COVID-19 vaccination measure has not gone through the rigorous testing and National Quality Forum (NQF) endorsement review process to which other measures adopted in CMS quality reporting programs are subject. The measure was presented to the NQF's Measure Applications Partnership (MAP) as a concept, not as a measure ready for implementation. In fact, CMS leadership explained during the MAP meetings that the agency was bringing forward a measure that was not "fully fleshed out" in anticipation of incorporating it into rule-writing in 2022 at the earliest.

While the measure is designed nearly identically to the flu vaccine measure in terms of its calculation and reporting structures, many questions about the specifics of the COVID-19 measure remain (questions that might be answered during the testing and NQF endorsement processes). For example, what are the long-term plans for use of this measure in terms of its reporting period? The flu vaccine measure assesses vaccinations during "flu season," which is defined as October through March; will there be a similar "COVID-19 season," and how will reporting interact with that of the flu

measure? Is this measure in alignment with other COVID-19 vaccination measures under consideration, such as the Merit-based Incentive Payment System measure that was reviewed by the MAP which assessed patients who received at least one dose (as opposed to a complete course)?

Considering the magnitude of changes in the circumstances regarding COVID-19 vaccinations in 2021 alone, additional questions concerning the logistics of this measure may arise. The availability of doses played a major role in vaccination status earlier this year. For example, safety violations at a single plant resulted in millions of unusable doses of the Johnson and Johnson vaccine; variation in distribution strategies, communication between pharmacies and clinics, and site-to-site transfer of unused doses led to confusion, waste and vaccination delays. If the supply chain were disrupted again, health care facilities could be unable to ensure the vaccination status of their employees through no fault of their own. The nation has not yet completed the first wave of complete vaccinations—as of this writing, less than 40% of Americans were fully vaccinated—and thus we have not yet begun to address needs or logistics for "booster" shots. Because of the rapidly changing circumstances in which the COVID-19 vaccines are being deployed, we believe it is unwise to permanently adopt this measure into federal quality reporting programs at this time.

In addition to these logistical concerns, CMS also should consider the potential unintended consequences of the use of this measure. The reporting burden associated with this measure may be high depending on how it interacts with other COVID-19 data reporting requirements. Certain health care settings, such as skilled nursing facilities and inpatient psychiatric facilities, do not use NHSN to report data for quality reporting programs, so the introduction of this measure would require adjustments in workflow for which CMS would need to provide significant technical support. In addition, use of this measure may cause providers to amend other employee-facing policies, which take time to implement.

Moreover, while the measure does not directly compel facilities to ensure that their employees are vaccinated, publicly reporting performance on this measure might incent facilities to adopt mandatory vaccination policies for their personnel. Clearly, a vaccination mandate could be beneficial to measure performance. Yet, the decision about whether to implement a mandate is complex, and in some cases, the decision may be beyond the control of health care facilities. Already, multiple states have introduced or passed legislation prohibiting discrimination based on COVID-19 vaccination status; other existing state laws might also run afoul of mandatory vaccine policies. In practical terms, this could mean that facilities that are unable to mandate the vaccine could be at a systematic performance disadvantage on the measure. We also urge CMS to be mindful of other complex issues that could shape any mandatory vaccination approach. For example, the measure only excludes patients who do not get the vaccine due to medical contraindications. According to the Equal Employment Opportunity Commission, employers must provide a reasonable accommodation if an employee's sincerely held religious belief, practice or observance prevents them from

receiving the vaccination; this policy seems to conflict with the specifications of the proposed measure. A mandatory vaccine policy — with suitable exceptions and employee protections — might be appropriate, but until we have more than eight months of data on the vaccine's safety and side effects, we are unsure whether indirectly encouraging through the mandatory public reporting of COVID-19 vaccination rates is judicious.

The COVID-19 pandemic is not the last public health emergency this nation will face, but our national COVID-19 response will have long-lasting effects on policy. The AHA is concerned about the precedent of adopting a measure assessing COVID-19 vaccination of HCP under these circumstances, and thus recommends that CMS reconsider adopting the measure during this rulemaking cycle. **Instead, CMS should either delay adoption of the measure for at least one year or adopt the measure for voluntary reporting only — without publicly reporting performance — for one year, or at least the first quarter of the measure's use (beginning Oct. 1 of this year) to allow for time to answer the questions raised above regarding feasibility, validity and the incidence of any unintended consequences.**

Replacement of Follow-up after Hospitalization for Mental Illness (FUH) Measure with Follow-up After Psychiatric Hospitalization (FAPH) Measure. CMS proposes to adopt the FAPH measure beginning with the FY 2024 payment determination. This measure would determine the percentage of inpatient discharges from an IPF with a principal diagnosis of select mental illness or substance use disorder (SUD) for which the patient received a follow-up visit for treatment of that diagnosed condition. Two rates would be calculated: visits within seven days and another within 30 days of discharge. Because it is a claims-based measure, IPFs would not need to submit any data.

The FAPH measure is similar to the FUH measure, but the former includes patients with SUD or dementia and does not limit the type of provider with whom the follow-up visit may be completed if the visit is billed with the relevant diagnosis. The NQF declined to endorse the FAPH measure, although the FUH measure is endorsed by the NQF. CMS proposes to remove the FUH measure only if the FAPH is finalized for adoption.

The AHA has repeatedly voiced concerns about both the FUH and the FAPH measures. The FAPH measure has the same conceptual problems as the FUH measure, and also lacks the evidence to demonstrate effectiveness for the expanded patient population. We reiterate these comments here, and **encourage CMS to not only decline to adopt the FAPH measure for the FY 2024 payment determination, but also consider removing the FUH measure from the IPFQR.**

Importance of Measuring Follow-Up after Psychiatric Hospitalization. The AHA agrees that follow-up after psychiatric hospitalization is important for improving short- and long-term patient outcomes. We recognize and uphold the clinical practice guidelines developed by our partners at the American Psychiatric Association and by researchers at the National Institutes for Health that emphasize the importance of continuity of care

between settings for patients with mental illness and SUD. We also appreciate that CMS is considering ways to include patients with SUD and dementia in IPF quality measurement, as most of the measures currently implemented in the IPFQR are specific to mental illness, particularly forms of psychosis. Finally, the AHA supports the work behind CMS' Meaningful Measures initiative, and agrees that the IPFQR should include a measure that addresses the priority areas of *Prevention, Treatment, and Management of Mental Health* and *Prevention and Treatment of Opioid and Substance Use Disorders*, as well as a measure regarding the promotion of effective communication and coordination of care.

However, based on the specifications for the FAPH measure as well as information provided in the Draft Methodology Report, we believe that the proposed measure would not meaningfully achieve its intended purpose. While we agree with several points made by the agency on the measure's importance, such as the association between follow-up care and decreased risk of readmissions, CMS fails to offer sufficient evidence that this association holds true for the newly included patient population (i.e., patients with SUD and patients with dementia). In addition, we do not believe that completed follow-up appointments are fully in the control of IPF providers. Of course IPF providers must do everything in their power to ensure that their patients receive appropriate care post-discharge. At the same time, many factors outside of the facility's control significantly affect the likelihood of a patient completing a follow-up appointment but would not actually reflect the quality of care provided at the IPF, including the availability of enough substance use treatment providers and dementia care providers in the area, and as CMS knows, these providers are in scarce supply in many areas of the country,

The following sections further elaborate upon these points. Again, we agree with the importance of follow-up and that we must hold providers accountable for doing what they can to ensure the continuity of care post-discharge; however, an outcomes measure like FAPH might not be the appropriate method of doing so. We understand that one of the goals of CMS' Meaningful Measures initiative is to avoid process measures that merely record whether a task was done rather than determining if there are true variations in quality; however, we think CMS would agree that there are some instances in which process measures are appropriate. We believe this measure topic—that is, evaluating whether an IPF has made all reasonable efforts to connect a patient with outpatient care following discharge—is such an instance.

Concerns Regarding Measure Development. We are concerned by the incomplete evidence used to support expanding the measure's population to include patients with SUD and dementia. The rationale for using this particular measure appears to hinge on the idea that following up post hospitalization has the potential to reduce readmissions. Yet, every study cited in the methodology report that finds an association between follow-up visits and reduced risk for readmission focuses on patients with schizophrenia and/or bipolar disorder (or psychosis disorders defined more broadly). These studies also were conducted with adult patients, whereas the FAPH measure would include children as young as six (and the dataset analyzed in the methodology report included

too few patients under 18 to assess outcomes). In concept, following up with patients with all types of disorders could be helpful, but unfortunately, CMS does not provide evidence that this intervention is associated with improved outcomes for the patient population in question.

Similarly, we question whether the studies cited show a large enough magnitude of association between follow-up visits and reduced readmissions. One study (Marcus 2017) found that "receipt of a follow-up visit within 30 days of discharge was associated with a *slightly lower* adjusted odds ratio of hospital readmission" (emphasis added), and the strongest association was found for schizophrenia patients whose index admissions were 13 to 30 days long. According to the American Psychiatric Association, the average length of stay for patients with serious mental illness is 12 days; other studies have found it is closer to 10, and some have cited 5- or 6-day stays for facilities whose primary goal is crisis intervention and stabilization. Another cited study (Olfson 1998) found that patients with schizophrenia who had telephone or face-to-face contact with an outpatient clinician before hospital discharge "did not significantly differ" from patients who did not have such contact "in the proportion who were readmitted to the hospital or who made a psychiatric emergency room visit during the follow-up period." Another study cited in the methodology report (Kurdyak 2018) showed only a 4% difference in readmission rates for patients discharged with schizophrenia depending on whether that patient saw a physician within 30 days of discharge.

CMS cites the seemingly low national 7- and 30-day follow-up rates as rationale for the measure's impact; in other words, the developers appear to reason that implementing this measure in the IPFQR would increase the likelihood of patients receiving follow-up care. However, the measure's importance cites the need to reduce readmissions. Because there appears to be only moderate association between follow-up care and reduced readmissions (and no evidence provided to demonstrate this association for patients with SUD or dementia), we seriously question whether the use of this measure will have the impact on outcomes that CMS believes it would.

Equally concerning is whether this measure accurately evaluates the performance of the discharging IPF. The measure assesses the percentage of inpatient discharges for which the patient received appropriate follow-up care in an outpatient setting; conceptually, it is difficult to see how we can accurately evaluate inpatient care based on outpatient experiences. Additionally, there are real-life logistical and patient-level factors that significantly impact the likelihood that a patient will complete an outpatient follow-up visit that are not yet assessed or accounted for in this measure.

Primarily, sociodemographic factors, including but not limited to dual Medicare and Medicaid eligibility, can be indicators of difficulty accessing follow-up care. The methodology report for the FAPH measure notes that Black and Hispanic patients received follow-up care at lower rates than white patients, and dually enrolled patients had a lower 7-day follow-up rate than patients with Medicare only. These disparities are important to highlight, analyze and correct. Yet, there are other factors, such as income,

primary language, homelessness and zip code, that also are likely to show disparate rates of follow-up that were not addressed in the methodology report.

While health care facilities and providers have the responsibility to care for patients regardless of sociodemographic status, the fact is that geographic and patient-level characteristics are likely to influence whether a patient completes a follow-up visit even if the discharging IPF took every reasonable step to connect that patient with an outpatient clinician. One study cited in the FAPH methodology report to demonstrate the effect of inpatient transition intervention on attendance at the first post-discharge appointment (Batscha 2011) excluded patients "if the living situation made it unfeasible to attend appointments (undomiciled, lacking transportation, or living far away), [or] if they did not speak English." Another (Olfson 1998) found that patients with significantly lower total Brief Psychiatric Rating Scale score and less self-assessed difficulty controlling symptoms (i.e., patients who are less severely mentally ill) were more likely to contact the outpatient clinician.

Again, IPFs should be doing everything feasible to connect patients with ongoing care; however, there are circumstances beyond the inpatient facility's control that will affect the ability for patients to complete a post-discharge appointment. Patients who are more severely mentally ill, who live in areas or situations where it is difficult to attend appointments, and who do not speak English are less likely to complete a follow-up appointment because completing that appointment is difficult — not because the IPF provided poor care. Holding IPFs accountable for performance on a measure that fails to account for any of these realities is misguided. For these reasons, we recommend that CMS and its contractors consider other ways to evaluate whether IPFs are following evidence-based guidelines regarding interventions that have been shown effective to connect patients with ongoing care.

Once again, we recognize the unique challenges of developing measures for the inpatient psychiatric population. Patients who receive care in an IPF often have multiple comorbidities, a wide range of severity and functional status, and challenging social risk factors that significantly affect their treatment and long-term outcomes. We appreciate the efforts in which CMS and its contractors have engaged, and are hopeful that the agency can identify measures that accurately and meaningfully address quality of care in IPFs.

Removal of Measures. CMS proposes to remove the following chart-abstracted measures from the IPQFR because the costs associated with the measures outweigh the benefits of their continued use in the program:

- Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB-2/2a)
- Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB-2/2a)
- Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)

CMS has determined that there is little room for improvement in these measures as facility performance across the nation is consistently high; in addition, the agency is attempting to move away from burdensome chart-abstracted measures. If finalized, these measures would be removed from the IPFQR beginning with the FY 2024 payment determination. **We agree that these measures provide little useful information to assess the quality of care provided in IPFs, and support their removal.**

Patient-level Data Submission. CMS proposes to adopt patient-level data submission for chart-abstracted measures beginning with data submitted for the FY 2023 payment determination. Currently, data input forms within the QualityNet secure portal require submission of aggregate data; however, the agency is concerned that aggregate data reporting increases the possibility of human error and does not allow for accuracy validation. Therefore, CMS proposes to transition incrementally to patient-level data submission. The agency would allow voluntary patient-level data submission for the FY 2023 payment determination (data submitted during calendar year (CY) 2022), and then mandatory patient-level submission starting with data submitted during CY 2023.

The AHA understands the utility of capturing patient-level data. However, CMS' proposed "incremental" transition does not allow sufficient time for the agency to ensure that submission is not unduly burdensome; because IPF chart-abstracted measures are reported annually, a single year of voluntary reporting followed immediately after by mandatory reporting would provide a limited opportunity to determine problems with the reporting process or any unforeseen burden. Indeed, the actual submission of voluntary patient-level data would occur almost eight months *after* the mandatory reporting period begins. **Thus, we encourage the agency to consider granting an additional year of voluntary reporting or to be prepared to modify the policy for patient-level data submission if providers encounter significant difficulties during the voluntary reporting period.**

Request for Information: Potential Creation of a Facility Equity Score to Synthesize Results Across Multiple Social Risk Factors. In the proposed rule, CMS also shares its work on and vision for updating and improving the agency's Disparity Methods to address disparities in health outcomes. In this description, CMS relates that it believes a summary score, which aggregates results from multiple measures and multiple social risk factors, "can improve the usefulness of the equity results" provided to facilities. In working with its contractors, CMS recently developed — but has not yet implemented — an equity summary score for Medicare Advantage contracts/plans (the Health Equity Summary Score), and is considering building a similar "Facility Equity Score" off of this concept.

The AHA applauds CMS' commitment to health equity, and appreciates the agency considering creative approaches for data collection and analysis that could better inform health care providers and the public. Our members are working hard to identify and

address health disparities, and close remaining gaps in quality performance across patient populations. Our goal is the same as CMS': to ensure that all patients feel valued and recognized, and that the care provided does not vary due to race, ethnicity, gender, sexual orientation or other demographic or social risk characteristics. We cannot hope to advance our efforts to improve health equity without high-quality data and analysis.

The AHA understands the conceptual appeal of an overarching "facility equity score." However, we question whether the implementation of such a score would be a helpful step in advancing health equity at this time, and recommend that CMS use other avenues to prioritize its health equity-related data efforts. We worry that a facility equity score may inadvertently lead to a reductionist approach to assessing provider efforts related to health equity. We have some concerns that the summary score would only include the imperfect measures in the IPFQR program, the score only would assess for disparities along the lines of race and ethnicity and dual-eligible status, and that a summary score would not be particularly actionable for IPFs.

However, other ideas CMS offers in the RFI hold more promise. For example, we would encourage the agency to continue exploring stratifying performance on quality measures by race and ethnicity and dual eligibility in confidential feedback reports. We believe this approach would result in data that are more actionable by providers, and less susceptible to the methodological challenges of a roll up score highlighted above. In addition, we recognize there are opportunities to improve the consistency and accuracy of demographic and social risk data available to hospitals and CMS. We especially encourage CMS to explore the extent to which there are any demographic data elements collected at the time of Medicare enrollment that could be used more widely across Medicare programs. Lastly, it is vital for CMS to foster consistency and standardization in its approaches to collecting, analyzing and using demographic and social risk data.

Again, we thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Caitlin Gillooley, senior associate director of policy, at cgillooley@aha.org or 202-626-2267.

Sincerely,

/s/

Stacey Hughes
Executive Vice President