American Hospital Association™
Advancing Health in America

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The Honorable Chiquita Brooks-La Sure
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

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners and, especially, the 105 psychiatric hospitals and 846 hospitals with dedicated behavioral health beds, 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) 2024.

While we appreciate certain proposed provisions in this rule, we are concerned that CMS' proposed payment adjustment will be inadequate to support the vital services IPFs provide to their communities. In addition, we have a number of concerns about proposals for measures to be adopted in the IPF quality reporting (IPFQR) program.

IPF PAYMENT UPDATES

CMS proposes to increase payments to IPFs by a net 1.9%, or $55 million, in FY 2024 compared to FY 2023. This payment update includes a 3.2% market basket update minus a 0.2% productivity cut as required by the Affordable Care Act, and a cut of one percentage point to keep outlier payments at 2%.

Market Basket Update. CMS's proposed market basket update is woefully inadequate in the face of the enormous cost pressures faced by IPFs, which include inflationary pressures as well as longstanding underpayments by public payers. For example, the Medicare Payment Advisory Commission (MedPAC) determined that Medicare has failed to cover the cost of caring for patients in hospital-based and freestanding nonprofit IPFs since at least 2016. Aggregate Medicare IPF margins across all IPFs

were *negative* 2.1% in 2019, but were almost *negative* 25% for hospital-based nonprofit IPFs that same year. These data demonstrate the intense financial pressures faced by IPFs even before the cataclysmic events of the COVID-19 pandemic and related skyrocketing labor, supply and inflationary costs faced by facilities since then. **For that reason, we suggest that CMS consider other methods and data sources to calculate the market basket update that better reflect the costs incurred by IPFs.**

In addition, recent market basket updates have very clearly been inadequate in measuring input price inflation. Specifically, for FY 2022, CMS finalized a market basket update of 2.7%. However, based on CMS data, the actual IPF PPS market basket update for that year should have been 5.3%. This resulted in IPFs being underpaid relative to inflation by 2.6 percentage points. **Therefore, we urge the agency to adopt a one-time forecast error adjustment of 2.6 percentage points to account for this discrepancy.** Added to the proposed 2024 market basket update of 3.2%, this would result in a 5.6% update before additional cuts and adjustments.

Outlier Fixed-loss Threshold. To accommodate extraordinarily high-cost cases, CMS maintains a policy where cases exceeding a threshold amount receive a portion of the difference between the costs and the threshold. Because this policy is designed to be budget-neutral, CMS sets the threshold annually to ensure that the outlier payments do not exceed 2 percent of the total aggregate payments under the IPF PPS.

In this rule, CMS proposes to use 2021 data to increase the fixed dollar loss threshold from $24,630 to $34,750, an increase of 41% over the threshold used in the previous year. In the FY 2023 IPF PPS final rule, CMS increased the fixed dollar loss threshold from $16,040 to $24,630, an increase of over 50% from the previous year. Part of the reason for the large increases in the threshold in 2023 was due to CMS using data from 2019 claims rather than from 2020 claims to avoid the effects of the COVID-19 pandemic; using the same logic, CMS uses 2021 data to inform the threshold rather than 2020 data in this rule. Because of the larger gaps in time of the data used in this methodology, it is reasonable that there might be a larger changes in the threshold than if CMS were to calculate outlier costs based on charges from the immediate prior year. However, historically, the increase in the threshold from year to year has been at most 10%, so two consecutive payment updates of more than 40% seems extreme.

The AHA understands CMS' goals in avoiding unnecessary overpayments, but the risk of underpayment for the most severely ill and complex patients is far more concerning. As MedPAC noted in their comments on the FY 2023 IPF PPS rule, the large variation in costs among IPFs suggests that CMS needs to conduct additional analysis to determine whether these enormous year-over-year increases are appropriate and whether they threaten access to care. **Thus, we encourage CMS to provide additional information about how this increase would affect the IPF field and its patients, particularly around the characteristics of patients who may not qualify for outlier payments as proposed, but would otherwise qualify if the amount were increased by a more historically consistent percentage (that is, closer to 10% not**

40%). This level of analysis would help us understand the implications for IPFs and how it might affect access to care for very ill patients.

Modification of Regulation on Excluded Units Paid under the IPF PPS. CMS proposes to revise existing regulations to allow hospitals to open a new IPPS-excluded psychiatric unit at any time within the cost reporting period (as long as the hospital meets certain notification requirements), rather than requiring hospitals to wait until the start of a new cost reporting period. **The AHA supports this proposal and believes it will allow for additional flexibility to open needed psychiatric beds.**

Request for Information: Revisions to the IPF PPS. The Consolidated Appropriations Act (CAA) of 2023 requires revisions to the IPF PPS beginning in FY 2025. It also requires the Secretary to collect data on cost reports beginning October 1, 2023 to inform these revisions. In this proposed rule, CMS asks for feedback on the specific additional data and information that psychiatric hospitals and units might report that could be appropriate in informing possible revisions to the payment methodology under the IPF PPS.

The AHA appreciates the directive of the CAA to revise the IPF PPS. As demonstrated by data provided above, IPFs have long been underpaid by public payers due to the inability of the payment system to capture the unique costs of providing psychiatric care. Although the IPF PPS already uses several patient-level adjusters to attempt to account for these variables, the methodology is clearly incomplete. Based on conversations with our members, we urge CMS to investigate how to incorporate the following information into the IPF PPS:

- Source of admission: While CMS provides a positive payment adjustment to IPFs with qualified emergency departments, the adjustment is not applied when a patient is discharged from an acute care hospital or critical access hospital and admitted to the same hospital's psychiatric unit. Patients who are transferred to an IPF from an acute care unit or hospital typically have higher costs per case than patients admitted from the community. We recommend CMS consider how to incorporate differences in cost based on whether patients were admitted from the community or from a prior proximal hospital setting.
- Violence: Patients who exhibit violent behavior often incur greater costs due to increased staffing or other measures taken to ensure the safety of the patient and staff. CMS should consider how to capture information on risk of violent behavior and incorporate it into payment adjustments.
- Comorbidities: The IPF PPS currently includes 17 MS-DRGs. However, there can be considerable cost variability within a single MS-DRG due to factors such as the social drivers of health (discussed below). While the majority of patients receiving care in IPFs can be grouped into these MS-DRGs, that does not make them a homogenous group; patient-level physical and behavioral factors result in unique cases with unique costs.

In addition, CMS asks for more information about IPF industry billing practices pertaining to ancillary services. Specifically, the agency asks for information on the reporting of charges for ancillary services such as labs, imaging and drugs on IPF claims. It states that it is considering whether to require charges for these services to be reported on claims and potentially reject claims with no ancillary services reported as inappropriate or erroneous. Based on analysis by MedPAC in 2018, CMS believes that some IPF claims may be inappropriately missing charges for ancillary services due to stinting on care or otherwise billing incorrectly. **This is misguided – there are legitimate reasons that there may be no ancillary charges on a claim.** For example, freestanding IPFs may not have imaging, labs or pharmacies on site and thus may have to send a patient to a partnering general acute care or other facility to perform those ancillary services; in this case, the latter facility would be billing for the service, not the IPF. In addition, some state Medicaid plans administer mental health benefits separately from physical health in terms of claims, and thus certain non-psychiatric-specific services (like imaging) would be considered outside the scope of the mental health benefit. Thus, a patient receiving care at an IPF who is covered by both Medicare and Medicaid would have ancillary charges billed on a separate claim under state law. **As such, a policy to reject claims without ancillary charges would inappropriately penalize both IPFs and the patients and communities that they serve.**

Request for Information: Social Drivers of Health (SDOH). In this proposed rule, CMS shares that its analysis of the association of ICD-10 codes indicating the presence of certain SDOH demonstrates that specific Z-codes tend to increase relative costliness of IPF stays, while others (including the code for homelessness) are associated with a lower mean cost per diem. These findings do not wholly reflect the experience of our members. One reason that variation in state law as well as organizational policy has led to inconsistent use of Z-codes (e.g. the state of California requires hospitals to screen patients for homelessness, while others do not). In addition, adoption has been limited due to a lack of clarity on who can document a patient's social needs, absence of operational processes for documenting and coding social needs, and unfamiliarity with the Z codes. Indeed, while Z-codes have been available to use since FY 2016, CMS reported in 2019 that providers only used the codes for 1.6% of Medicare fee-for-service beneficiaries.

While we believe that Z-codes have the potential to provide important information to inform the unique care needs of individual patients, their use requires much wider analysis before incorporating into the IPF PPS. We support CMS' work to engage in this investigation and offer the assistance of our coding experts who have produced resources for our members on using these codes in their practice.

IPFQR PROPOSALS

CMS proposes to adopt three quality measures to the IPFQR that are related to health equity, and we offer specific comments on those below.

First, we must express our continuing disappointment **with the lack of proposed new measures for the IPFQR that are specifically designed and tested to measure the provision of inpatient psychiatric care. Since 2018—that is, in the past six rulemaking cycles—CMS has only proposed two new measures and one modified version of an existing measure that were specifically developed and tested for IPFs.** The previously proposed measures focused on post-discharge care rather than care provided within the IPF. In the FY 2022 IPF PPS final rule, CMS finalized the adoption of the Follow-up After Psychiatric Hospitalization measure, which would replace the Follow-up After Hospitalization for Mental Illness measure, assessing the percentage of inpatient discharges from an IPF for which the patient received a follow-up visit in an outpatient setting; in the FY 2020 IPF PPS final rule, CMS finalized the adoption of the Medication Continuation Following Inpatient Psychiatric Discharge, which determines if patients were dispensed at least one medication in a 30-day post-discharge period. Neither of these measures directly evaluates the quality of care provided or patient safety while in an IPF and are thus of limited utility for IPF providers seeking to improve care or patients making decisions on where to go for care. We are aware that CMS and its contracting partners are working to develop additional psychiatric measures, but we are disappointed with the lack of progress in this area and encourage CMS to accelerate its efforts to identify and develop IPF-specific evidence-based measures of quality of care and patient safety.

Facility Commitment to Health Equity Measure. America's hospitals are committed to reducing disparities in health outcomes and promoting diversity, equity and inclusion within their own organizations. We certainly agree that advancing health equity is important across the care continuum, including those services delivered in IPFs. Beginning with the FY 2026 payment determination, based on data reported in calendar year (CY) 2025 which would reflect performance in CY 2024, CMS proposes to adopt a structural measure that assesses whether an IPF demonstrates certain equity-focused organizational competencies. IPFs would be asked to attest to several statements across five domains. The same measure was adopted in the inpatient quality reporting (IQR) program last year and will be required for reporting for the first time this year.

While there is limited information to evaluate the potential impact of this measure on quality of care because it is so new, this measure has potential for future use in CMS programs because it fills a critical gap. When the measure was proposed for adoption in the IQR, AHA was pleased to support the proposal and offered several suggestions for changes that would make the measure more meaningful, actionable and transparent. While we reiterate that America's hospitals, including psychiatric facilities and units, are steadfastly committed to advancing health equity within their organizations and their communities, **we have concerns about the use of this measure in the IPFQR at this time.** CMS declined to make the changes to the measure that we suggested in our comments (that we summarize below), which we believe limits the overall utility of the measure. In addition, IPFs are not entirely comparable to general acute care hospitals in their resources, leadership structures and community footprint. Thus, if CMS moves

forward with its proposal to adopt this measure for the IPFQR, **we again urge the agency to consider our recommendations and pair the implementation of this measure for IPFs with clear guidance on how to attest to the domains comprising the measure.**

IPFs are deeply committed to the important work of improving health equity for the patients and communities they serve. The topics addressed by the questions included in the measure generally represent important actions that hospitals are taking to improve outcomes for all patients. However, the unclear logistics of reporting, calculating and publicly displaying results for this measure as currently specified may detract from its usefulness. Because the measure is so early in its deployment, the measure has not been tested for IPFs specifically, nor has the measure steward engaged stakeholders to determine the usability, acceptability or face validity of the questions for this setting.

Another major concern relates to how performance would be calculated. According to the measure's proposed specifications, performance would be reported as a percentage of questions out of five to which the hospital responded affirmatively to all sub-parts of the question. Suggesting that a hospital is "40% committed to health equity" would be unhelpful—and potentially misleading—to patients, providers, administrators and the community. We therefore recommend that CMS reconsider how to convey to the public what hospitals and health systems are doing to demonstrate their commitment to this essential issue.

Finally, we encourage CMS to work with stakeholders to refine the wording of the questions as well as the content. For example, question 2(c) asks whether the facility inputs information collected into "structured, interoperable data elements using certified electronic health record technology (CEHRT)." While we agree that CEHRT is an important tool for data collection and analysis, it is not yet clear whether CEHRT is the optimal approach to collecting and reporting health equity related data, and it less likely that IPFs have the infrastructure for those data to be "interoperable" as they do not participate in CMS' Promoting Interoperability Program and are not required to adhere to the EHR certification standards from the Office of the National Coordinator.

In our comments to CMS when this measure was proposed for adoption in the FY 2023 inpatient prospective payment system (IPPS) proposed rule, we offered recommendations that we believe would improve the measure's ability to achieve the outcomes it seeks. These recommendations included:

- CMS should provide additional clarifying guidance to facilities—including additional definitions of key terms and examples—so that facilities can answer the attestations in as accurate, complete and consistent a manner as possible. For example, we suggested CMS provide clarification about what it means by "strategic plan," and working definitions of "structured, interoperable data elements." These definitions will have impact on the validity of the results as individual organizations might use different nomenclature than what is used in

the measure, and thus respondents might interpret attestation statements differently.

- CMS should revise the “all or nothing” approach to scoring the measure, and instead award one point for each individual attestation. We believe this approach would make the measure more transparent and useable to both reporting facilities and the public, as the proposed performance calculation approach “rolls up” answers to multiple questions within individual domains.

The AHA agrees with the urgency of making progress on health equity and believes this measure has the potential to serve as a foundational step to advancing this work in IPFs. At the same time, CMS can maximize the potential positive impact of the measure by making the above revisions and clarifications. The AHA believes the best path forward would be to defer finalizing the measure while rapidly testing it in IPFs so that, presuming it demonstrates utility in this setting, it can be re-proposed with appropriate revisions as soon as is practicable. **However, if CMS is intent on adopting the measure in this rule, we encourage the agency to make the first year (CY 2024) of measure reporting voluntary.**

Screening for Social Drivers of Health Measure. Beginning with voluntary reporting in CY 2025 of data collected in CY 2024 and required reporting in CY 2026 of data collected in CY 2025 data (to inform the FY 2027 payment determination), CMS proposes to adopt this structural measure that evaluates whether IPFs are screening patients for certain health-related social needs (HRSNs). CMS explains that IPFs could use a self-selected screening tool to collect these data. The measure was adopted for the IQR in the FY 2023 IPPS final rule with voluntary reporting during CY 2023 and mandatory reporting beginning in CY 2024.

The AHA supported the voluntary reporting of the measure for the IQR, but we also urged CMS to use the voluntary reporting experience to address several important conceptual and operational issues with the measure before mandating it. The AHA also supports the voluntary reporting of this measure for IPFs, but believes it is even more important and urgent that CMS consider the potential challenges with implementing this measure outside of general acute care.

The AHA believes that this measure addresses a critical gap in care but is not sufficiently specified and tested for use in IPFs. We recommend that the measure steward further test this measure in the settings for which it is currently under consideration to determine whether it is feasible and has potential to improve outcomes. While screening for social drivers of health is one important part of a broader push to improve health equity, the measure as currently specified lacks several important details about how the information would be interpreted and used by IPFs.

The measure has only been tested for construct validity; that is, the measure steward has analyzed the psychometric properties of the Accountable Health Communities Health-related Social Needs tool that includes questions addressing topics in the

measure's description. The measure itself has not been formally tested; it has been trialed in certain settings, but as best we can tell, no reliability or validity testing has occurred to show that the measure is feasible in an IPF (as opposed to primary care) setting. In addition, the measure does not require the use of this particular screening tool. The flexibility for providers to choose a tool that aligns with their internal processes is welcome; however, it also raises questions about the consistency and comparability of collected measure data. For a measure to have utility in a quality reporting program, we must be able to count on its reliability and accuracy, and this issue has not yet been sufficiently investigated.

Furthermore, we urge CMS to recognize the limits of what the implementation of this measure in the IPFQR can achieve, and carefully assess its potential long-term value to the program. To be clear, we agree that performing screenings and collecting data on health-related social needs is important for health care providers to do and have been working with our members to encourage them to do so. **However, a measure reflecting the frequency of the screenings alone does not provide information on whether those social drivers were actually met, nor does it indicate whether disparities were eliminated and patients ultimately became healthier as a result of their care.** Furthermore, it is clear that health care providers alone cannot solve the persistent health inequities stemming from social drivers of health. Addressing these challenges takes collaboration and resources from public and private sector partners. In some communities, those partners are willing, able and have the resources to meaningfully address these challenges, but this is not the case everywhere. Providers are willing to accelerate their efforts to effectively screen patients for social drivers of health, but have also expressed concern that screening patients without being able to refer them to meaningful resources could be both unfair to patients and demoralizing to teams.

Fortunately, CMS has an opportunity to quickly gain insights into these questions through the voluntary reporting period for inpatient hospitals. CMS should use that process to solicit information about whether the information has added any value to their efforts to engage public and private community partners on addressing HRSNs and consider it in deciding whether and when to implement the measure in other settings. We also encourage CMS to conduct parallel pilot testing in the facilities to which it intends to expand reporting, and **thus delay implementation of any mandatory reporting for the IPFQR until this pilot testing is completed.**

In addition to these overarching concerns regarding the meaningfulness of the measure for use in any setting, IPFs lack the resources and technological capabilities of general acute care hospitals that might make this measure workable. While these facilities are likely screening for at least some health-related social needs, operationalizing this screening and connecting patients who screen positive for certain needs to necessary community resources—ostensibly the intended outcome for this measure—is an enormous task, particularly for facilities in rural or underserved areas. For these reasons, we encourage CMS to delay mandatory reporting until future rulemaking.

Screen Positive Rate for Social Drivers of Health Measure. Beginning with voluntary reporting in CY 2025 of data collected in CY 2024 and required reporting in CY 2026 of data collected in CY 2025 data (to inform the FY 2027 payment determination), CMS proposes to adopt this measure that assesses the percent of patients admitted to the IPF who were screened for the HRSNs listed above who screen positive for one or more. IPFs would report five separate rates (one for each need). The measure is intended to provide information to IPFs on the level of unmet HRSNs among patients served, "and not for comparison between IPFs." The measure was adopted for the IQR in the FY 2023 IPPS Final Rule.

We agree that screening for HRSNs is an important part of the work our members are taking on to advance health equity; however, we have logistical and conceptual concerns with the use of screening measures in the IPFQR. **Similar to our position on this measure for inpatient hospitals, we support voluntary reporting of this measure, but urge that CMS not set a date certain for mandatory reporting at this time**. In addition to the same issues listed above, we offer additional considerations.

In its description, the measure score interpretation is listed as "lower score is better," suggesting that a smaller percentage of adults who screen positive for certain drivers indicates better performance. This reading is problematic. If hospitals are screening correctly, performance on this measure is only an accurate indicator of the characteristics of the patient population served by the hospital, not a reflection of the performance of the hospital. A lower score could simply mean that the hospital is located in an area with high average income, better public transportation and more accessible nutrition. None of those characteristics is related to quality of care. Further, this kind of misinterpretation of what the measure results actually tell that public is precisely the kind of false reading that everyone should seek to avoid. It raises the likelihood that hospitals serving the most financially challenged neighborhoods will be falsely judged to be of lesser quality.

CMS does not provide data showing a clear causal relationship between quality of care and the proportion of patients with higher social risk scores on this measure. While patient outcomes are often poorer for patients with health-related social needs, nothing in this measure's description makes the connection between a positive screen for a social driver of health and actual utilization—or even availability—of services to address patients' social needs. The measure was developed and is being deployed as a hospital measure, without additional testing or specification for IPFs. The details are important, and without them we fear that this critical information will not be useable to improve outcomes.

We reiterate that identifying social drivers of health is vital, and that hospitals, health systems and society as a whole should engage in addressing inequities in health outcomes and the underlying social pressures that exacerbate these disparities.

However, we are not confident that using this measure as currently specified in the will help make progress on this goal.

Psychiatric Inpatient Experience (PIX) Survey and Measure. Beginning with voluntary reporting in CY 2026 and mandatory reporting in CY 2027, CMS proposes to adopt a specific patient experience of care instrument, the PIX survey, and a measure based on patient responses on a 5-point Likert scale to survey items. The survey comprises 23 items across four domains. Performance on the measure would be reported as five separate rates: one for each of these four domains, and one overall rate. Mean rates would be publicly reported on Care Compare. The survey is distributed to patients, on paper or on a tablet computer, by administrative staff at a time beginning 24 hours prior to planned discharge.

CMS acknowledges that IPFs already administer different patient experience of care survey instruments to their patients and would thus need to transition to the PIX survey. Because of this, the agency proposes a voluntary reporting period during which IPFs would be able to begin administering the PIX survey and collecting survey data in CY 2025 to report on a voluntary basis in CY 2026, and would be required to administer the survey and collect data during CY 2026 to report during CY 2027; this would affect the FY 2028 payment determination.

The Consolidated Appropriations Act of 2023 directed CMS to include a measure on patients' perspective of care by 2031. While we understand that CMS has a statutory duty to adopt a measure on patient experience into the IPFQR, questions remain about whether the PIX survey proposed here is the best method to collect vital information on patient perspectives for use in quality improvement. **We thus encourage CMS to consider implementing the PIX survey on a voluntary basis and defer finalizing a date-certain for mandatory reporting.** This would enable CMS to glean more information on the use of the survey and the measure, the specific guidance needed on survey administration and other changes to workflow, and how the use of the PIX survey for care improvement compares to that of other instruments already in use by IPFs for this purpose.

IPFs have long collected information regarding patient experience of care, albeit not using a standardized tool. Indeed, CMS found that for the FY 2018 IPFQR (the last time IPFs reported an attestation-based measure reflecting whether they used a patient experience assessment), more than 75% of IPFs answered "yes." In past RFIs, CMS has asked whether and how IPFs were using the HCAHPS survey for this purpose. The HCAHPS survey has not been validated for use in the IPF patient population. The needs, concerns, goals and experiences of care of patients receiving care in an IPF are unique and not entirely comparable to those for patients receiving care in a general acute care hospital.

Many of our members operating IPFs have thus developed their own instruments to assess patient experience to tailor it for their patients; it is our impression that many (if

not most) utilize tools developed by Press Ganey. Our members are generally satisfied with their existing processes and often rely upon institutional or system-wide survey tools to collect information that can be comparable across parts of the system. The PIX survey would represent a major departure from processes that our members believe work; if the PIX survey and associated measure are proven to be better indicators of patient experience and the use of the survey and measure are demonstrated to result in better outcomes, then that departure would be worth the effort. However, we do not yet have that evidence.

One particular area where clarity is needed concerns survey administration. During testing, the developer noted (and several participants in the workgroup voiced concerns) that survey results could be influenced by administering the survey before the hospitalization has concluded. We also believe the developer and CMS should consider the influence of patient-level characteristics and on survey results. While IPF discharges generally fall under fewer diagnostic groups than those from general acute care hospitals, those primary reasons for hospitalization as well as underlying patient attributes will almost certainly impact responses. In order to learn from patient feedback and implement changes to improve experience, those details cannot be diluted by averaging top-box scores across all patients. Thus, we encourage further investigation into stratification or adjustment of results based on variables such as diagnostic group (alcohol or substance-related disorders; mood disorders; schizophrenia and other psychotic disorders; anxiety disorders; delirium and other cognitive disorders), age group (geriatric, pediatric, or adult), and/or type of commitment (voluntary or involuntary). These variables, in addition to other social risk factors, could help shine a light on the best way to meet the needs of all IPF patients.

To date, the measure has only been fully tested within the measure developer's own health system, consisting of eight units across three hospitals in a small market. Before CMS mandates its use, the survey must be tested nationally with a wider and more diverse group of patients. As noted above, AHA members have developed many strong and reliable patient experience instruments; the survey that informs the measure under consideration is surely one of them, but before essentially mandating a single tool nation-wide we should make sure it generates information that we can use to improve care for patients in IPFs. Thus, we suggest that CMS not finalize the timeline for mandatory reporting of the PIX survey and measure and instead introduce the measure for voluntary reporting until future rulemaking.

<u>Modified COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) Measure.</u> Beginning with the FY 2025 IPFQR, CMS would adopt a modified version of the COVID-19 Vaccination Coverage among HCP currently used in the IPFQR. While the current measure assesses the number of HCP "who have received a complete vaccination course against COVID-19," CMS would replace this term with "who are up to date" with their vaccination as recommended by the Centers for Disease Control and Prevention at the time of the reporting period.

The AHA strongly supports the vaccination of health care personnel and communities against COVID-19. We also agree with CMS' rationale underlying the proposal to adopt this modified measure that measures in use in its quality reporting programs should reflect the current science. However, the evidence around the optimal cadence for booster doses of COVID-19 vaccination, as well as the seasonality of the virus itself, is evolving rapidly. Over the past several months, CDC and FDA have indicated they are seriously considering the adoption of a once-yearly regimen for COVID-19 vaccinations comparable to the well-established approach used for influenza vaccination. In addition, the AHA is concerned that the administrative complexity of collecting CDC's current definition of "up-to-date" status may outweigh its benefit. For these reasons, **we recommend CMS continue to collect up-to-date vaccination status on a voluntary basis and implement required reporting of up-to-date status after FDA and CDC have completed their recommendations on an updated vaccination schedule.**

We encourage CMS to learn from the experience of implementing the previous version of this measure and take into account the foreseeable logistical challenges of data collection and reporting when considering this new version for inclusion in its various quality reporting programs. As CMS notes in the proposed rule, health care facilities are collecting and reporting data on "up-to-date" COVID-19 vaccination status, though the "up-to-date" data field cannot be used for public reporting unless CMS finalizes the proposed measure specification change. However, facilities have reported that this collection process is administratively burdensome under CDC's current "up-to-date" definition. This is because the collection protocol uses a reference time period for determining up-to-date status that changes every quarter. Practically speaking, this means that a HCP who counted as "up-to-date" in a given quarter may no longer be up-to-date in the next quarter.

Furthermore, CDC's vaccination guidance suggests that some individuals with certain risk factors should consider receiving an additional booster dose within four months of receiving their first bivalent dose. Yet hospitals usually do not have routine access to data to know which of their HCPs may need an additional booster. In fact, collecting accurate data on HCPs underlying risk factors likely would require hospitals to both obtain permission to have such data and a mechanism to keep the data fully secure. The AHA is concerned that the resource intensiveness of collecting data under CDC's current definitions may outweigh its value.

The AHA believes that the adoption of a once-yearly vaccination regime would alleviate much of the administrative complexity of collecting up-to-date vaccination status. While we do not yet know the precise timing, recent discussions from the FDA and CDC's vaccination advisory committees, as well as public statements from the agencies and White House, suggests that such a schedule could be adopted as soon as Fall 2023. By delaying the required reporting of "up-to-date" vaccination status, CMS could align its reporting requirements around this more efficient approach. In practical terms, we believe the soonest facilities could report up-to-date status based on a once-yearly

vaccination regimen is the second quarter of CY 2024, but we recognize that more time may be needed.

As CMS continues to implement the HCP COVID-19 vaccination measure across its programs, we also urge it to consider other important implementation issues. For example, we continue to urge that CMS get the measure endorsed by a consensus-based entity (CBE). A CBE endorsement process will enable a full evaluation of a range of issues affecting measure reliability, accuracy and feasibility. Given the urgency of addressing the COVID-19 pandemic, the current version of the measure never went through a CBE endorsement process and is relatively new to the CMS quality reporting programs. As a result, we have not yet had a holistic evaluation regarding whether the measure is working as intended (e.g., reflecting vaccination rates accurately, achieving CMS's stated goals of encouraging vaccination).

Finally, CMS needs to consider how to implement this measure in a way that is consistent and logical with other sources of information regarding vaccination among healthcare personnel. The time lag between data collection and the publicly reported rate will result in a mismatch between the true rate of healthcare personnel who are up to date with their vaccinations and the rate that is displayed on Care Compare; CMS needs to clearly communicate what publicly reported data reflects. Similarly, the measure under consideration is inconsistent with CMS's recently sunset Condition of Participation (CoP) requiring vaccination among health care personnel in terms of its exceptions for sincerely held religious beliefs. To maintain continuity with the CoP and align with HHS Office of Civil Rights guidance, we recommend that CMS develop an additional exclusion for this measure to account for sincerely-held religious beliefs.

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, director of policy, at cgillooley@aha.org or (202) 626-2267.

Sincerely,

/s/

Stacey Hughes
Executive Vice President