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President and CEO

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Via electronic submission at *https://www.regulations.gov*

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Unleashing Prosperity Through Deregulation of the Medicare Program (Executive Order 14192); Request for Information:
Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes; 90 Fed. Reg. 18,002 (April 30, 2025)
Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2026 and Updates to the IRF Quality Reporting Program; 90 Fed. Reg. 18,534 (April 30, 2025)
Medicare Program; FY 2026 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update; 90 Fed. Reg. 18,494 (April 30, 2025)

Dear Dr. Oz:

The FAH is the national representative of nearly 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

Pursuant to the January 31, 2025, Executive Order (EO) 14192 "Unleashing Prosperity Through Deregulation," the Centers for Medicare and Medicaid Services (CMS) has issued a Request for Information (RFI) to solicit public feedback on potential changes to Medicare regulations, with the goal of reducing the costly private healthcare expenditures required to comply with federal regulations. CMS seeks public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, Medicare Advantage and Part D plans, and other stakeholders participating in Medicare.

The FAH appreciates CMS' leadership in issuing this RFI to reducing regulatory requirements that, while intended to protect the health and safety of the beneficiaries, often result in duplicative efforts and unnecessary administrative burdens. We agree with CMS that these requirements divert resources from patient care, contribute to inefficiencies, and can create financial strain on providers, including hospitals. The FAH also appreciates the opportunity to provide our comments regarding this critical effort to reduce burdensome and unnecessary regulations that divert the focus on patient care.

Rein in Abuses of Prior Authorization in Medicare Advantage Plans

The FAH and our members support the Medicare Advantage (MA) program and the way the program can offer private options and flexibility beyond the benefit structure of the Traditional Medicare program. Our members increasingly serve more seniors with MA coverage than through Traditional Medicare fee-for-service. However, we are increasingly concerned by the alarming practices of MA plans that harm patients by eroding access to and affordability of medically necessary care. Abusive practices by MA plans include systematically inappropriately denying, limiting, and delaying the delivery of services and care. This behavior often requires hospitals and caregivers to divert precious resources and time to respond to care denials and delay tactics and away from their core mission of patient care.

MA delays and denials through prior authorization and inconsistent administrative processes add tremendous costs to the health care system. Hospitals and physicians must hire teams of clinical and non-clinical staff, as well as costly information systems, to keep up with the prior authorization and payment hurdles that MA plans erect to slow down patient care and provider payment. By design, these practices lead to Medicare Advantage beneficiaries receiving a lower standard of appropriate care than those in Traditional Medicare. **We urge the Administration to improve MA by taking steps that would simplify these administrative barriers by requiring plans to ensure that MA patients receive at least the same levels of coverage as patients in Traditional Medicare. One easy way to do this that would significantly reduce burdensome paperwork, processes, and costs would be to ensure that plans comply with the Medicare Two-Midnight Rule and Inpatient Only List.** This would save time and money for hospitals, physicians, nursing staff, and plans – as well as for Medicare overall.

However, Medicare beneficiaries that ultimately receive authorization for inpatient admission often face additional hurdles upon discharge. MA patients that need post-acute care (PAC) often have much longer lengths of stay in the inpatient setting due to a combination of lengthy PAC prior authorization delays as well as inadequate PAC networks. For patients, it means they are stuck in the hospital longer than they want or need to be. For hospitals, it means increased administrative costs trying to access PAC for the patient and unreimbursed costs for care since most inpatients are paid at a per case rate (using DRGs). In some cases, it can also lead to denied claims as MA plans deny care that isn't "medically necessary" at the end of the stay – even though their inadequate PAC provider networks and lengthy prior authorization processes cause the delay.

These overly burdensome and varied MA practices are a rich opportunity for the Administration's regulatory relief efforts. **We also urge CMS to track and report prior authorization denials and appeals at discrete service levels and provide this information to Medicare enrollees.** Doing this will add transparency to the MA prior authorization processes and allow seniors to be informed of their practices and more easily choose plans they know will cover the care they need.

Eliminate the Inpatient Rehabilitation Facility (IRF) Review Choice Demonstration (RCD)

The Administration should eliminate CMS' IRF RCD program that requires pre-payment review of 100 percent of all IRF admissions in Alabama and Pennsylvania. The IRF RCD program began in Alabama with 100 percent prior authorization review of all IRF admissions. More than 85 percent of claims received during the first one and a half years of this program receive approval – and appeals raise the total approval rate even higher. This program is administratively burdensome for CMS and IRFs and is unnecessary. The program is slated for expansion to California and Texas IRFs and will ultimately be expanded to IRFs in other states that use the same MACs in the four RCD states. The Administration should eliminate this costly and unnecessary program.

Enforce No Surprises Act (NSA) Independent Dispute Resolution (IDR) Process

Hospitals fully support the surprise billing patient protections under the NSA. **We urge the Administration, however, to enforce health insurer compliance with the NSA, including the IDR process which establishes a mechanism intended to resolve insurer-provider disputes over payment for certain out-of-network services.** Appropriate incentives must be implemented to ensure that health insurers: provide greater payment transparency; meaningfully participate in the IDR 30-day open negotiation process; and timely, appropriately, and efficiently pay out-of-network amounts and any related IDR awards; and are subject to enforcement for noncompliance.

Without appropriate incentives for health insurers, the NSA's IDR process is broken, ineffective, and anticompetitive for hospitals vis-à-vis health insurers. Insurers' ability to bypass the requirements for the NSA IDR process presents an anticompetitive dynamic in hospital and other provider negotiations with insurers because insurers can threaten to bar provider participation in their networks knowing the provider would then be subject to the broken and anticompetitive IDR dispute resolution for out-of-network claims. We urge the Agencies to support adoption by the Department of Health and Human Services of a proposed rule containing provisions intended to establish an IDR process, with appropriate incentives, for health insurers as envisioned by the NSA when enacted in December 2020.

Nursing Staff Ratio Interpretations in Conditions of Participation

CMS has issued interpretive guidance under 42 C.F.R. § 482.23(b), governing nursing services, that increasingly reflect rigid expectations around nurse-to-patient ratios. **The FAH strongly opposes any move toward implementing specific ratios in regulation or sub-regulatory guidance**. Section 1861(e) of the Social Security Act allows CMS to ensure that

hospitals maintain adequate nursing services to meet patient needs. Still, it does not authorize the agency to mandate fixed ratios irrespective of staffing realities, patient acuity, or local market conditions.

As detailed in our FY 2023 IPPS comments, the imposition of nurse staffing ratios would severely burden hospitals struggling with nursing workforce shortages. Such mandates may lead to care delays or temporary closures of units, particularly in rural and underserved areas. Rather than improving care, rigid ratios reduce flexibility and could result in unintended safety risks. **CMS should rescind interpretive guidance implying ratio requirements and confirm hospital discretion in establishing staffing plans responsive to patient needs.**

Remove Patient-Reported Outcomes Measure for Hip/Knee Arthroplasty (PRO-PM)

The PRO-PM for Total Hip and Knee Arthroplasty, adopted under the Hospital IQR Program requires hospitals to collect and submit survey-based patient-reported outcomes before and after surgery. Although CMS adopted this under the same statutory authority as other IQR measures, the FAH has raised strong concerns in multiple IPPS comment cycles regarding its feasibility, fairness, and alignment with statutory intent.

The implementation of this measure is complex and costly. Hospitals must procure survey platforms, maintain consistent follow-up processes, and manage response rate bias. Moreover, these data are heavily influenced by social and demographic variables unrelated to hospital care quality. Smaller and rural hospitals may lack the technical or staffing capacity to comply, raising significant rural-urban equity issues. These challenges render the measure incompatible with Section 1886(b)(3)(B)(viii), which envisions accurate and equitable quality assessment across all hospitals. **Until methodological concerns are addressed, CMS should withdraw the PRO-PM.**

Remove Low-Value Structural Measures in the Hospital IQR and VBP Programs

CMS has adopted a range of structural measures in the Hospital IQR and Value-Based Purchasing (VBP) Programs, also authorized under Section 1886(b)(3)(B)(viii) of the Social Security Act. While initially intended to incentivize quality infrastructure, these measures now impose a significant reporting burden with little utility for hospital performance differentiation. Key structural measures currently implemented in the IQR Program include:

- Maternal Morbidity Structural Measure (hospital participation in PQCs and use of safety bundles)
- Patient Safety Structural Measure (attestation of safety culture strategies across five domains)
- Age-Friendly Hospital Measure (five-domain assessment of geriatric care practices)

Although these measures are well-intentioned, the FAH's IPPS comments noted that they present limited variation across hospitals and add burdensome documentation requirements. Many hospitals already meet the basic expectations of these measures, and there is minimal evidence that they lead to improved outcomes. For example, the Age-Friendly Hospital measure

is primarily a self-attestation exercise, prone to subjective interpretation and lacking rigorous validation.

CMS' continued use of these structural measures raises questions about statutory alignment. Section 1886(b)(3)(B)(viii) authorizes the collection of "measures of quality of care," which are more accurately represented by patient outcome measures rather than attestation-based infrastructure inputs. **The FAH recommends that the measures be removed and that outcomes-based, actionable quality indicators be implemented.**

Remove Hybrid Clinical/Claims-Based Quality Measures

CMS implemented hybrid measures in the Hospital Inpatient Quality Reporting (IQR) Program under the authority of Section 1886(b)(3)(B)(viii) of the Social Security Act. These measures, including the Hybrid Hospital-Wide Readmission and Mortality Measures, require hospitals to extract and report structured clinical data elements from electronic health records (EHRs) alongside claims data.

The FAH stated in comments on the FY 2023 IPPS proposed rule that these measures present a disproportionate burden with little evidence of added clinical value. Data elements such as troponin levels, blood pressure, and oxygen saturation are often not captured in structured fields, necessitating costly manual abstraction. **These measures unfairly penalize smaller, resource-constrained hospitals and should be withdrawn until standardized EHR interoperability and infrastructure are universally available.**

Suspend Hospital Star Ratings and Develop Better Model

The FAH urges CMS to suspend the Hospital Star Ratings program and initiate a transparent, collaborative process to develop a more accurate and equitable model. The current Star Ratings oversimplify complex hospital performance data and often mislead patients by failing to reflect important contextual factors, such as the hospital's case mix, social risk factors, and service lines. The program's methodology remains volatile—particularly for smaller, rural, and critical access hospitals—due to the limited number of measures reported and inconsistent peer grouping.

Additionally, hospitals are scored on differing combinations of measure groups, making direct comparisons unreliable and confusing. Public display of these ratings can unintentionally penalize hospitals that serve high-risk or underserved populations, potentially exacerbating disparities in access and perception. The FAH recommends that CMS replace the existing system with one that promotes transparency, reflects clinical realities, and supports informed decision-making without distorting public perception or undermining hospitals committed to serving vulnerable communities.

Remove eCQMs from Mandatory Reporting

The FAH urges CMS to remove the mandatory reporting requirements for electronic clinical quality measures (eCQMs) under both the Hospital Inpatient Quality

Reporting (IQR) Program and the Medicare Promoting Interoperability Program. While the FAH supports the broader goal of advancing digital measurement, the current mandates place an outsized burden on hospitals—particularly small, rural, and critical access facilities—that often lack the health IT infrastructure and technical support needed to comply. Many of these hospitals use electronic health record systems that are not fully interoperable or cannot extract standardized data without manual abstraction, undermining the efficiency and reliability of the process. Additionally, the complex data requirements of eCQMs often span multiple clinical domains and care settings, further straining limited staff and resources. The FAH recommends that CMS make eCQM reporting voluntary across both programs, allowing hospitals to adopt digital quality reporting in a manner aligned with their technical readiness and resource capacity.

Ensure Appropriate Pre-Deployment Testing of all Federal Systems for Collecting and Reporting Hospital Quality Data Both at CMS and CDC

The Administration should ensure full testing of any changes to quality measures and the reporting structures to which the data is reported before the new/updated systems are deployed. Hospitals are required to report a series of quality measures to CMS and Centers for Disease Control and Prevention (CDC). FAH members welcome the opportunity to improve patient care and value the feedback received from reporting data. However, inordinate resources are expended in reporting data to and retrieving data from faulty federal reporting systems. This year alone, CMS has had to recall preview reports, suspend reporting for several weeks, or change reporting deadlines three times in the first quarter due to problems with QualityNet reporting. Deploying systems that cannot either accurately receive the data or report data back to hospitals costs both the government and hospitals hundreds of thousands of dollars each year.

Additionally, more robust testing of CDC National Healthcare Safety Network (NHSN) quality reporting systems prior to deployment of any new upgrade would avoid the challenges, downtime, and inability of hospitals to effectively and efficiently retrieve their data to either check that it was recorded appropriately or inform improved patient care. Each time an upgrade is issued, hospitals experience significant challenges and down time in submitting and retrieving data at CDC.

Right-Size CMMI Models and Halt Mandatory Approaches

The FAH urges CMS to halt the implementation of mandatory models developed by the Center for Medicare and Medicaid Innovation (CMMI), including the Transforming Episode Accountability Model (TEAM) and the Increasing Organ Transplant Access (IOTA) Model. The FAH does not believe that section 1115A authorizes CMS to mandate provider participation in CMMI models such as the TEAM and the IOTA. As such, CMS should make them voluntary**.** CMMI authority is designed to test models and make recommendations to Congress for permanent or mandatory changes to the Medicare program. Specifically, CMMI's general authority is to test innovative payment and services delivery models to reduce program expenditures while preserving or enhancing quality of care. The law further directs CMS to evaluate CMMI models and, if appropriate, allows CMS to expand "the scope and duration" of an existing model to a "Phase II," provided certain requirements are met. CMS is required to report periodically to Congress on CMMI models and make proposals for legislative action on

models it deems appropriate. Notably, nowhere does the law expressly state that CMS can make models mandatory.

While the FAH supports innovation in care delivery and payment, mandating participation in untested or underdeveloped models imposes significant financial and operational risk on providers, especially during a time of workforce shortages, inflationary cost pressures, and regulatory fatigue. The TEAM model, scheduled to begin on January 1, 2026, is a mandatory, episode-based payment model that requires selected acute care hospitals to coordinate care for patients undergoing specific surgical procedures and assume responsibility for the cost and quality of care from surgery through the first 30 days post-discharge. Despite minor technical updates proposed in the FY 2026 IPPS Proposed Rule—such as adjustments to quality measures and risk adjustment methodologies—the model's fundamental structure remains unchanged, maintaining significant financial risk for participating hospitals without adequate piloting or stakeholder engagement.

Similarly, the IOTA model, set to commence on July 1, 2025, is a six-year mandatory model aimed at increasing access to kidney transplants for patients with end-stage renal disease. While CMS has made some adjustments in response to stakeholder feedback—such as delaying the start date and modifying performance metrics—the model still imposes substantial operational and financial burdens on transplant hospitals. Concerns remain regarding the model's potential to incentivize inappropriate organ-recipient matches due to an overemphasis on transplant volume, as well as the lack of sufficient risk adjustment to ensure equity

Provide Payment and Regulatory Flexibility for IRFs in CMMI Bundling Programs

CMS should provide IRFs an optional, voluntary discount to the standard payment amount, or otherwise enable them to assume more risk, for relevant IRF cases discharged from an acute care hospital participating in a CMMI bundling program. At the same time, regulatory relief under the 60 Percent Rule and Three-hour Rule should be granted to provide IRFs treating these patients at payments below the current IRF prospective payment system rates with the flexibility needed to participate in the program without jeopardizing their Medicare status. This shared accountability payment model would strengthen the relationship between acute care hospitals and IRFs and reduce costs by enabling IRFs to pass along savings from accepting payments lower than the IRF discharge-based PPS.

Promoting Interoperability Program: SAFER Guides

SAFER Guides Measure

The FAH supports the goal of enhancing EHR safety and appreciates CMS' effort to update the Safety Assurance Factors for EHR Resilience (SAFER) Guides. However, we continue to have significant concerns regarding the SAFER guides and **recommend making the attestation requirements for the SAFER Guides measure optional beginning in CY2026, due to the following concerns:**

- **Duplicative Requirements and Limited Added Benefit:** The SAFER Guides assessment contains duplicative content and considerations already addressed through other facets of the Promoting Interoperability Program, particularly within the Protect Patient Health Information objective through the Security Risk Analysis (SRA). Performing both assessments annually creates unnecessary administrative burden without commensurate benefit to providers or their EHR systems.
- **Resource Intensive:** The comprehensive assessment of all required SAFER Guides places a substantial burden on providers and personnel, diverting valuable time and resources from direct patient care and other essential activities.
- **Lack of Clarity and Potential for Inconsistent Implementation:** Ambiguity in several recommended practices within the SAFER Guides poses significant challenges and necessitates additional resources for proper completion.

To address these concerns and promote a more streamlined and effective approach to EHR safety assessment, we recommend CMS consider the following alternatives:

1. **Reconsider Measure Requirements**: Reconsider mandating the SAFER Guides measure due to the above concerns.
2. **Recognize Alternative EHR Safety Demonstrations:** Allow organizations to submit evidence of their participation in recognized EHR safety programs or certifications as an alternative means of demonstrating compliance. Providers and vendors already attest to many of the existing best practices through ASTP/ONC's health IT certification program. As an example, the Office of Civil Rights (OCR) also requires consideration of "recognized security practices" when determining HIPAA fines.
3. **Share Responsibility with Certified Health IT Vendors:** Re-evaluate the requirements for hospitals and providers to be a shared responsibility with certified health IT vendors. Both parties should be accountable for attesting "Yes" to the SAFER Guides and their functional assessment.

We urge CMS to carefully consider these concerns and alternative proposals to ensure that the SAFER Guides measure is streamlined in a manner that promotes EHR safety without placing an undue burden on healthcare providers.

Expand 60 Percent Rule Data Transparency

CMS should provide IRFs with access to their patient-level data submitted for presumptive testing under the 60 Percent Rule. Currently, IRFs do not know which cases satisfied the rule and which cases did not and have been unable to access this patient-level data from CMS. This information would enable IRFs to reconcile their internal 60 Percent Rule testing procedures against CMS' presumptive testing procedures and thus reduce the burden and cost of compliance.

Harmonize IRF Appeal Rights Under the PRRB

CMS should grant IRFs access to the Provider Reimbursement Review Board (PRRB) process for Low-Income Patient (LIP) appeals. While acute care hospitals can appeal

DSH payment determinations by their contractors to the PRRB, IRFs cannot appeal parallel LIP payment adjustment determinations by their contractors. Instead, IRFs are forced to seek such appeals through the federal court system, which is more burdensome, costly, and time-consuming.

CMS Conditions of Participation (CoPs) on Respiratory Illness Reporting

The COVID-19 public health emergency prompted CMS to establish new requirements under 42 C.F.R. § 482.42(e), mandating that hospitals report data on respiratory illnesses such as COVID-19, influenza, and RSV. While appropriate in the context of a national emergency, these provisions were extended beyond the statutory emergency authority and now continue without a clear statutory mandate under Section 1861(e) of the Social Security Act. That section authorizes the Secretary to impose hospital Conditions of Participation to ensure the health and safety of patients receiving services, not to require duplicative, long-term epidemiological surveillance.

The FAH has highlighted in prior IPPS rulemaking (FY 2023) that these CoPs duplicate data submissions already required by the CDC under the National Healthcare Safety Network (NHSN) and add administrative burden without improving patient care or clinical operations. Hospitals must dedicate health information technology (HIT), clinical, and compliance resources to maintain daily reporting, which is an inefficient use of personnel post the public health emergency. **We urge CMS to rescind §42 C.F.R. § 482.42(e) as an outdated and burdensome provision inconsistent with statutory authority.**

Maternal Health CoPs

CMS has finalized new CoPs for maternal health under 42 C.F.R. § 482.82, which require hospitals to establish and maintain policies and procedures addressing obstetric emergencies such as severe hypertension and obstetric hemorrhage. While these are critical issues, Section 1861(e) of the Social Security Act does not authorize CMS to impose clinical protocol mandates under CoPs. That section provides facility standards to protect patient health and safety but does not empower CMS to standardize clinical decision-making across vastly diverse hospital settings.

In comments on the CY 2024 and 2025 OPPS proposed rules, the FAH cautioned that such regulations disproportionately affect small, low-volume, or rural hospitals that may not offer labor and delivery services or have the infrastructure to comply with one-size-fits-all mandates. These hospitals are already engaged in evidence-based maternal safety work through the Alliance for Innovation on Maternal Health (AIM) or state perinatal collaboratives. The proposed CoPs risk closure of obstetric services in areas where maternal care access is already limited, thus undermining the very safety goals the rule seeks to advance. **These provisions should be withdrawn to align with CMS' statutory limits.**

Conditions of Participation (CoP)

We urge CMS to narrow the focus of new CoPs issued in late 2024 for hospital emergency services, focusing on emergency readiness, including staff training on the emergency protocols and a call-in system for each patient in the emergency services treatment area. These requirements are unnecessary and extremely burdensome for providers while diverting resources away from patient care.

In addition, we urge CMS to update life safety code CoPs to allow hospitals to comply with more up-to-date requirements and reduce potential conflicts with State and local requirements.

Streamline Care Plan Documentation Requirements

To provide higher quality, more holistic care, patients are increasingly cared for by interdisciplinary teams, with clinical professionals ranging, for example, from nurses and therapists to social workers. These teams develop what an "interdisciplinary care plan" although outdated regulations require nursing-specific care plans. As care delivery trends increasingly move toward interdisciplinary teams that work collaboratively to address a patient's needs from a more patient-centered approach framework, clinicians must create duplicate paperwork to document the care plan. **Therefore, we urge that the care plan documentation requirements at 42 CFR 483.23(b)(4) be streamlined.**

Repeal Information Blocking/Provider Disincentive Regulations

We urge CMS to repeal the excessive and confusing provider disincentives included in *21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking*" (July 1, 2024). This final rule provides that hospitals and providers determined to have engaged in information blocking may face reductions in Medicare payment updates, adjustments to payment rates, lower performance scores, and potential ineligibility for certain incentive programs.

The FAH supports ensuring that critical health information is available to patients, clinicians treating those patients, and those with appropriate reasons for having access, among which are payment, care oversight, and research. However, the disincentive structure in this rule is excessive and puts hospitals' stability at risk, especially for small and rural hospitals. Further, the Office of the Inspector General processes for determining whether information blocking has occurred are not sufficiently clear and lack transparency, including the appeals process, thus making providers subject to a rule that seems arbitrary and capricious.

Withdraw Cybersecurity Proposed Regulations

The FAH urges the Administration to withdraw the HHS OCR HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information, proposed on December 27, 2024, with comments due on March 7, 2025. The rule proposes

cybersecurity standards for HIPAA-covered 6 entities and their business associates. However, many provisions in the proposal are not operationally feasible and do not recognize the nuance and complexities of applying cyber protections in a complex health IT environment; are not scalable to multiple types and sizes of hospitals and health care systems; drastically underestimate implementation costs; and impose prohibitively costly and unnecessary burden. Therefore, we urge the Administration to withdraw the proposed rule and engage in a stakeholder process to develop a new approach for a cybersecurity regulatory framework.

Expand Eligibility for 340B Drug Pricing Program to Tax-Paying Hospitals

The FAH urges CMS to consider reforms to the 340B Drug Pricing Program that would expand eligibility to tax-paying hospitals and protect 340B status during hospital acquisitions. Currently, approximately 20% of community hospitals—those that are tax-paying—are categorically excluded from the program, even when they serve high concentrations of Medicaid and uninsured patients and exceed the Medicare low-income thresholds. This arbitrary tax status-based restriction undermines the original intent of the 340B program, which is to stretch federal resources and improve access to care for vulnerable populations.

FAH data show that our member hospitals provide greater levels of charity and uncompensated care, as a percentage of operating costs, than many current 340B participants. To promote continuity of care and preserve community benefit, we recommend that CMS support legislative or regulatory action to allow tax-paying hospitals serving low-income populations to participate in the 340B program and to grandfather 340B eligibility for hospitals that are acquired by tax-paying systems, provided that the safety-net services and patient mix remain substantially the same post-acquisition. This policy would extend critical cost savings to underserved communities regardless of tax status and reinforce the program's intent to improve access and affordability for those most in need.

Telehealth

The FAH supports the value of telehealth in providing critically needed services to Medicare beneficiaries, especially as technology has evolved. Telehealth flexibilities help ensure that hospitals are able to meet the needs of their patients and communities. **To continue to leverage value of telehealth and make it accessible on a widespread basis to Medicare beneficiaries, we urge that CMS support legislation to achieve the following:**

- Remove telehealth originating site restrictions within the Medicare program at Sec. 1834(m)(4)(C)(ii)(X) of the Social Security Act (42 U.S.C. 1395m) and 42 CFR 410.78(b)(3) to enable patients to receive telehealth in their homes.
- Remove telehealth geographic site restrictions within the Medicare program at Sec. 1834(m)(4)(C)(i) of the Social Security Act (42 U.S.C. 1395m) and 42 CFR 410.78(b)(4) to enable beneficiaries in non-rural areas to have the same access to virtual care as those in rural areas.
- Remove the in-person visit requirements for behavioral health telehealth at Sec. 1834(m)(7) of the Social Security Act (42 U.S.C. 1395m) and 42 CFR 410.78(b)(3)(xiv),

which is unnecessary, is a barrier to accessing care and on a timely basis, and creates a disparity between physical and mental health services.

Medicare Parts A and B Overpayment Provisions of the Affordable Care Act

The FAH broadly supports CMS' policy that applies the False Claims Act standard of "knowing" and "knowingly" to the identification of overpayments and suspends the report and return deadline during a timely, good-faith investigation of related overpayments. The FAH, however, is concerned that the suspension provision assumes a relatively straightforward investigation of related overpayments and the 180-day proposed period is insufficient for more complicated overpayment investigations**. Therefore, the FAH urges CMS to revise proposed 42 C.F.R. § 401.305(b)(3)(ii) to provide that the deadline is suspended for the entirety of a timely, good-faith investigation to minimize the piecemeal report and return of overpayments.** The 180-day limit proposed in subsection (b)(3)(ii)(B) may be a useful benchmark for many simple overpayment investigations, but it is not uncommon for a good-faith investigation conducted with reasonable diligence to necessitate additional time, particularly where the overpayment issue involves complex factual and legal questions.

If a timely, good-faith investigation cannot be concluded in the 180-day period, the provider would likely revert to the piecemeal report and return of overpayments, addressing the initially identified overpayments with an initial report and return while continuing its larger investigation and then subsequently reporting and returning any further overpayments that are later identified. Certainly, there are situations where a timely, good-faith investigation can be concluded within 180 days such that the related overpayments can be identified within this time frame and then reported and returned along with the initially identified overpayments. But providers frequently confront circumstances where the underlying facts and circumstances are sufficiently complicated that a reasonable, good-faith investigation would not conclude within 180 days. For example, in some cases the investigation of related overpayments requires complex factual development, including the clinical review of individual medical charts and interviews of staff. These complicated, multi-stage investigations are particularly common for hospitals given the breadth and complexity of their operations.

In order to appropriately minimize piecemeal reports and returns of overpayments, the FAH strongly urges CMS to revise 42 C.F.R. § 401.305(b)(3)(ii) to provide for the reasonable suspension of deadlines over the entirety of a timely, good-faith investigation. In the alternative, CMS should provide a process for reasonably extending the 180-day period in appropriate circumstances. Flexibility to go beyond 180 days in appropriate cases is necessary in light of the range of complexity in investigations of related overpayments.

Accrediting Organizations (AOs) and Preventing AO Conflict of Interest

Last April, the FAH provided comments to CMS regarding a proposed rule addressing *Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions*. Our hospital system members demonstrate compliance with Conditions of Participation (CoPs) by achieving accreditation through a CMS-approved national AO that is authorized to "deem" compliance, rather than through a State Survey Agency

certification, in accordance with Section 1865(a) of the Social Security Act. Our members have established effective working relationships with the AOs, which ensures that Medicare's health and safety requirements for beneficiaries are met or exceeded. While the proposed rule reference above has not been finalized, we urge the Administration to ensure the following:

The Definition of "Fee-Based Consulting Services" Should Not Include Subscription-Based Generic Consultative Tools

CMS has proposed to restrict AOs from providing "fee-based consulting services" prior to a provider's initial survey and providing such services to their accredited providers during the 12-month period prior to each provider's reaccreditation survey. **The FAH urges CMS to clarify that the definition of "fee-based consulting services" does not include use of AOs' subscription-based generic consultative tools.** If "fee-based consulting services" is defined too broadly, this could prove detrimental and undermine hospital efforts to ensure they meet the CoPs and appropriately advance quality and safety initiatives. Our members often utilize annual subscription web-based, generic tools and seminars offered by an AO or its consulting arm, including during the 12 months prior to a survey, to generate self-assessment reports that help hospitals meet the CoPs and prepare for a survey. These commonly used AO tools and seminars would not represent a conflict of interest because they do not result in the: (i) AO or its consulting arm facilitating or advising on hospital-specific situations or complaints being evaluated by an AO; or (ii) development of a material personal relationship with a representative of the AO or its consulting arm. Hospitals may contact technical or tool navigation support at the AO consulting arm, including within 12 months prior to an initial or reaccreditation survey, but these interactions are on a sporadic, as needed basis, and are not tailored to a hospital's individual survey needs or a specific complaint being assessed about a hospital.

Hospitals would be adversely impacted if these types of resources could no longer be used during the 12-month period prior to a survey. Such a restriction would leave hospitals without a source of guidance to self-assess and ensure appropriate compliance with the quality and safety requirements of the Medicare CoPs.

CMS Should Reconsider the Parameters of an "Unannounced Survey"

Under the proposed rule, the AO would be required to cease any advance notification to the hospital and its staff so that the facility would be unaware of the survey until the time that the survey team arrives. AOs also would be required to schedule surveys so that their timing or occurrence would not be predictable to the facility being surveyed. Further, in June 2023, CMS released guidance that parallels the intentions of the proposed rule, with similar requirements for "unannounced surveys."

The proposed rule's new definition of "unannounced survey" reinforces an inefficient policy that overestimates the value of providing a facility a brief advance notice of a survey. Both the June 2023 guidance and the proposed rule give too much credence to what a facility could do to improve the results of an impending survey in the short amount of advance notice that an AO may provide, often inadvertently.

The FAH recommends that CMS encourage AOs to provide hospitals 24 hours' advance notice of a survey which would allow time for hospitals to ensure appropriate staff are available for the survey. While there may be instances in which a hospital's staff members may not be available for the survey due to travel or illness, for example, providing the hospital with a brief advance notice would allow the hospital to resolve simple scheduling issues that could ensure maximum access to hospital leadership and other staff who could better facilitate a smooth survey process and answer surveyors' questions accurately and completely. This would allow surveyors to garner robust feedback in a more efficient manner, making the survey results more useful and reflective of the care the hospital provides for the facility, public, and CMS' consideration.

CMS discusses in the proposed rule its concern that unannounced surveys are required "to prevent the provider or supplier from making unusual preparations for the survey that would not represent the ongoing typical condition of the provider and true nature and quality of care provided." 89 *Fed. Reg.* 12,004. Yet, a 24-hour window of time would represent an appropriate balance to these concerns – this window would not allow enough time to make unusual preparations while at the same time it would allow hospitals an opportunity to ensure a more efficient, robust, and smoother survey process.

Surveys Need Greater Transparency

Lastly, we note that AOs often combine the triennial deemed status surveys with a complaint survey during a survey visit. Each of these surveys has very different rules and requirements. Combining them into one evaluation, especially when each type of survey is not identified by the surveyor, is confusing for hospital staff and risks conflating results against varying standards, increasing the possibility that a hospital will receive inaccurate results. **Thus, we urge CMS to ensure that surveyors clearly identify the purpose of each survey being conducted, along with providing appropriate instruction for each such survey, with outreach to hospital staff to assess any issues that arise and develop a plan to address them.**

National Health Insurance Portability and Accountability Act (HIPAA) Privacy Standard

We urge CMS to support Congressional enactment of a national privacy law under HIPAA that pre-empts all state privacy laws that apply to protected health information (PHI). The FAH has long advocated for strong national privacy standards and believes this is the best approach for both PHI and personal health data that falls outside HIPAA. Covered entities and their business associates have struggled for many years with the patchwork of different, sometimes conflicting state laws governing PHI, especially as many more states have enacted comprehensive privacy laws. While some of these laws carve out PHI, others do not or are unclear as to the application to PHI, which makes compliance a significant challenge, for both large and small hospital systems that operate in multiple states. Requiring organizations to comply with multiple different, often inconsistent, privacy laws for the same health data creates complexities and compliance challenges that take away from patient care.

The FAH therefore urges: (i) a national privacy standard under HIPAA that pre-empts all state privacy laws that apply to PHI; and (ii) any federal privacy law for non-

HIPAA personal health data should similarly preempt state privacy laws that might otherwise apply to that data.

Eliminate 96-Hour Rule

The 96-hour average length of stay requirement for Critical Access Hospitals (CAHs), originally enacted in the Balanced Budget Act of 1997, is outdated and no longer reflects the realities of rural health care. While intended to limit costs and define the scope of CAH services, this statutory provision — along with the regulatory 96-hour physician certification requirement — imposes unnecessary administrative burdens and limits flexibility in care delivery. Today, CAHs often manage higher-acuity patients, face limited transfer options due to hospital closures, and leverage technology to provide safe, effective care beyond the original 96-hour assumption. The 96-hour average inpatient stay limit is too restrictive and not clinically appropriate for many patients, particularly those with more complex needs or in areas with limited access to higher-level care. Realizing the challenges for rural providers, CMS announced in 2014 it would not enforce the requirement that physicians certify at admission that a patient will likely be discharged or transferred within 96 hours (per 42 CFR § 412.3). CMS justified this moratorium by saying it would reduce administrative burden and preserve access to care in rural areas. Further, during the first Trump Administration, CMS granted waivers during COVID-19 and other public health emergencies that suspended enforcement of the 96-hour rule entirely, reinforcing arguments that the requirement is not essential for quality or safety. This regulation is outdated and administratively burdensome.

The FAH urges CMS to work with Congress to amend the statute to eliminate the length-of-stay requirement (42 U.S.C. § 1395i–4(c)(2)(B)(iii)). Moreover, we urge CMS to take immediate steps to remove the corresponding Conditions of Participation (42 CFR § 485.620(a)), which mandates that the average annual length of stay not exceed 96 hours and to eliminate the separate 96-hour payment condition that obligates physicians to certify at admission that a patient is likely to be discharged or transferred within 96 hours (42 CFR § 412.3).

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The FAH appreciates this opportunity to submit these comments. If you have any questions or if we can assist CMS as it considers these recommendations, please contact me or any member of my staff at (202) 624-1500.

Sincerely,