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President and CEO

September 9, 2024

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

RE: CMS-1809-P; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities ; 89 Fed. Reg. 59,186 (July 22, 2024).

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 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.

The FAH appreciates the opportunity to provide our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Calendar Year (CY) 2025 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems proposed rule (Proposed Rule). This letter details FAH's comments on several issues in the proposed rule. Among other issues, our comments to CMS:

- Urge that CMS provide a forecast error adjustment to the CY 2025 OPPS market basket update to ensure that Medicare OPPS payments are sufficient to support access to care.
- Strongly support CMS’ proposal to keep the submission of Core Clinical Data Elements (CCDEs) and linking variables voluntary for the fiscal year (FY) 2026 payment determination under the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause risk Standardized Mortality Measures.
- Raise substantial concerns with CMS’ proposed conditions of participation regarding efforts to improve labor and delivery, prenatal, and post-partum care for newborns and mothers which we believe will exacerbate the growing issue of "OB deserts"—areas where no maternity care is available—especially in rural and underserved regions, further limiting access to essential obstetrical services and potentially increasing maternal morbidity and mortality.

Our detailed comments on these and other proposals in the rule are below.

II.B. Proposed CY 2025 Outpatient Hospital Update

Under section 1833(t)(3)(C)(iv) of the Act, CMS states that:

“the OPD fee schedule increase factor” for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) [the IPPS update] to hospital discharges occurring during the fiscal year ending in such year”

The update is subject to the productivity adjustment and further adjustments for hospitals that fail to submit quality information.¹ While CMS proposed to use a hospital market basket of 3.0 percent to update OPPS rates for CY 2025, it has already finalized an FY 2025 Inpatient Prospective Payment System (IPPS) update of 2.9 percent based on a market basket of 3.4 percent less 0.5 percentage points for total factor productivity. This market basket is based on the forecast of CMS’ contractor, IHS Global Insight, Inc. (IGI). IGI’s 2nd quarter 2024 forecast (with historical data through the 1st quarter of 2024). Therefore, absent any intervention on the part of CMS to provide a different update under the OPPS than the IPPS, we are expecting that CY 2024 OPPS update will be 2.9 percent.

Nevertheless, the FAH reiterates our prior comments that CMS should account for prior year understatements of the market basket that have permanently resulted in updated IPPS and OPPS rates that are well below the rate of inflation. As the FAH has previously noted, prior year market baskets from FY 2021 through FY 2023 did not capture profoundly aberrant and historic economic forces that fueled rapid cost increases for goods and services purchased by hospitals. As shown in the below table, the hospital market basket for these three years was understated by a total of 4.3 percentage points relative to the update hospitals received based on a projected market basket.

¹Sections 1833(t)(3)(F) and (t)(17) of the Act.

This update means the increase in hospital IPPS and OPSS rates has been a combined 4.3 percentage points below the rate of inflation resulting in a permanent loss of hospital purchasing power. While forecast error for FY 2024 appears to be less based on only one calendar quarter of data, it remains at -0.2 percentage points suggesting that the market basket for FY 2024 will have been understated for the 4th consecutive year.

Hospital Market Basket	FY 2021	FY 2022	FY 2023	FY 2024²
Forecast Used in the Update	2.4	2.7	4.1	3.3
Actual Based on Later Data	3.0	5.7	4.8	3.5
Difference	-0.6	-3.0	-0.7	-0.2

To address the permanent underpayment to hospitals by an update below the rate of inflation, the FAH urges CMS to do a one-time adjustment to the market basket update of 4.3 percentage points to account for the difference between projected market basket and actual market basket between FY 2021 and FY 2023.

In addition, CMS proposed reducing the proposed market basket update with a 0.4 percentage point total factor productivity adjustment. This total productivity adjustment is inappropriate in that it contemplates improbable and overstated gains in productivity for the hospital sector as noted by the CMS Office of the Actuary (OACT) itself and detailed below.

CMS’ Understatement of Prior Year Hospital Inflation

In our public comments on the FY 2023 IPPS proposed rule, the FAH provided several sources of data indicating that the historical data upon which the proposed FY 2023 forecast of the market basket was based was less than the rate of increase that hospitals were experiencing at that time.³ The evidence in these data that CMS’ forecasts of the market basket during a time of high inflation and economic instability understate the actual rate of increase have been borne out by CMS’ own data as shown in the table on the prior page.

These data show that CMS has understated the market basket by a combined 4.3 percentage points for these three years. CMS’ forecast of the market basket for FY 2024 in the FY 2024 IPPS final rule (3.3 percent) and its current forecast (3.5 percent) based on actual inflation data through the 1st quarter of FY 2024 appears to be closer than in prior years but remains understated by an additional 0.2 percentage points.⁴ Taken together for these four years, hospital rates appear likely to remain understated due to the aggregate 4.5 percentage point

² OACT, 1st quarter 2024 release of the market basket information with historical data through the 4th quarter of 2023 ([Market Basket Data | CMS](#)) for the actual update based on later utilization. Data for FY 2024 remains an estimate as it only reflects data through the 4th quarter of 2023 (or the 1st quarter of FY 2023).

³ These data came from the KaufmanHall, National Hospital Flash Report, p.4 (Jan. 2021) and Premier, Inc. (PINC) AI™ Data: CMS Data Underestimates Hospital Labor Spending (Apr. 12, 2022) and demonstrated that the latest data that CMS uses for the market basket in the proposed rule seriously underestimated cost increases hospitals were experiencing using other data sources.

⁴ The FY 2024 update is from the FY 2024 IPPS final rule (88 FR 5035)

understatement for FYs 2021 through FY 2024 (while acknowledging that FY 2024 remains a forecast).

One reason that CMS' market basket data may be reflecting lower increases in staffing costs compared to what hospitals are experiencing relates to use of contract labor. Hospitals confronted worsening shortages of hospital workers during the COVID-19 pandemic, necessitating an outsized reliance on contract staff – particularly travel nurses – to meet patient demand.

In 2019, hospitals spent a median of 4.7 percent of their total nurse labor expenses for contract travel nurses, which skyrocketed to a median of 38.6 percent in January 2022. A quarter of hospitals – those who have had to rely disproportionately on contract travel nurses in order to serve their communities during a global pandemic – saw their costs for contract travel nurses account for over 50 percent of their total nurse labor expenses. We understand that the Bureau of Labor Statistics' (BLS) Employment Cost Index (ECI) only captures the salary increases associated with employed staff, and thus wholly fails to capture the extraordinary growth in labor costs associated with hospitals' necessary reliance on nursing personnel that are contracted through staffing agencies during a time of labor supply shortages. This discrepancy may explain why the ECI data is so divergent from data being reported to Premier Inc (PINC) AI™. It is unreasonable to rely on the ECI data for labor expenses without appropriate adjustments that reflect the profound increase in hospital expenses for contract and travel nurses.

As we noted in our previous public comments, the FAH and the American Hospital Association (AHA) provided a report from FTI Consulting that likewise recognized that hospital use of contracted staff has increased markedly since 2019. According to FTI:

[H]ospitals face more competition than ever from travel and temporary nurse staffing firms that are attracting a greater share of the workforce with higher pay and more generous benefits, a trend driving up hospital labor costs. The cost of contract labor relative to total labor expenses increased five-fold in 2022 compared to 2019, primarily due to the need to replace departing staff nurses with travel or agency nurses. Median wages for contract nurses reached triple the median wages of employed nurses in March 2022.⁵

In this analysis jointly undertaken by FAH and AHA, we found that the ECI is unlikely to catch up with overall level of hospital labor cost increases. Since contract labor use and general workforce composition will not likely revert to its earlier levels, growth in the ECI will continue to lag behind growth in hospital labor costs.⁶ This report relies on many of the sources we provided in our FY 2023 IPPS proposed rule comments documenting that the ECI understates the growth in hospital labor costs because it does not account for contract labor being a higher proportion of total hospital costs.

⁵ FTI Consulting, Report: Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, page 4.

⁶ Federation of American Hospitals and the American Hospital Association, Hospital Employment Cost Index Undermeasures Labor Cost Growth in Recent Years, page 4.

This report found that a closely related measure—the Employer Costs for Employee Compensation (ECEC) may better and more timely account for growth in hospital compensation costs than the ECI. As explained in the report, the ECI is constructed through a multi-step process that is intended to smooth short-term fluctuations in the labor pool. However, when the underlying hospital employment structures are changing rapidly and permanently, the ECI will understate labor costs by relying on a job type that is only in the sample for two consecutive quarters, using a sampling weight for when a job first enters the sample and holding the mix of occupations fixed before there is a rebasing.⁷

The ECEC, however, is dynamic and will reflect increases in compensation and changes in the mix of labor inputs on a timelier basis. For the wages and salaries component, the ECI and the ECEC show a growth rate of 13.3 percent and 20.0 percent respectively, a 6.7 percentage point gap between the 4th quarter of 2019 and the 4th quarter of 2022. The growth in the total compensation component, which CMS uses to track benefits, is slightly lower with the ECI and the ECEC recording growth of 12.4 percent and 16.6 percent, respectively, a 4.2 percentage point gap.

Combining wages and salaries and employee benefits into a single composite measure shows the ECEC was 6 percentage points higher during this period than the ECI for items that account for 52.9 percent of the total hospital market basket. All else equal, if the hospital ECI growth had matched the hospital ECEC growth, this would have meant an additional three percentage point increase in the IPPS hospital market basket over this period. Given the parallel trends to CMS’ own market basket data, these data clearly show that the ECI is too low, not that the ECEC is too high.

In the FY 2024 IPPS final rule, CMS rejected use of the ECEC as an alternative to the ECI as a measure of change in hospital wage costs because it includes both changes in compensation as well as changes in employment.⁸ While CMS’ response is accurate, such as it is, the response earlier indicates that the increase in hospital wages that are resulting from higher use of contract labor are also not being accounted for by the ECI.

Therefore, the choice is between two measures of the change in hospital compensation – each of which has a weakness. The ECI does not account for increases in hospital wage compensation associated with more expensive contract labor while the ECEC which does not hold employment constant. Given the ECEC has better predicted the change in hospital compensation based on after-the-fact data, the FAH posits that the ECEC remains the better measure for CMS to rely on for determining the hospital update in a period of high inflation and unstable changes in prices and labor mix.

At this point post-pandemic, it appears that inflation is stabilizing and forecast error may be less of an issue going forward than it has been in the past. Nevertheless, IPPS and OPSS rates remain understated because of the large understatement of the projected market basket between FY 2021 and FY 2023 (and a potentially additional understatement for FY 2024). In light of the foregoing, the FAH urges CMS to do a one-time adjustment to the market basket update methodology to account for forecast error where the difference between

⁷ See pages 6-7 of the FAH and AHA Report for more detail on this issue.

⁸ 88 FR 59032.

projected market basket is more than 0.5 percentage points—the same threshold that the skilled nursing facility (SNF) prospective payment system (PPS) uses for determining when to apply a forecast error correction.⁹

CMS rejected applying a similar forecast error adjustment for the FY 2024 and FY 2025 IPPS rule updates. Nevertheless, we believe that three (and potentially four) consecutive years of understatement in the hospital market basket necessitates applying an adjustment for past year forecast errors in applying the CY 2025 update. CMS' continued denial of appropriate payment updates is creating significant financial pressures for hospitals and threatens patient access as hospitals struggle to maintain services with ongoing inadequate reimbursement.

Total Factor Productivity

Pursuant to section 1833(t)(3)(F) of the Act, the Secretary reduces the OPPS market basket pursuant to section 1886(b)(3)(B)(xi)(II) by the “10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as produced by the Secretary for the 10-year period ending with the applicable fiscal year).” The theory behind the offset for economy wide total productivity is that the hospital sector should be able to realize the same productivity gains as the general economy.

However, CMS itself takes issue with the assumption that hospitals can recognize the same kinds of productivity gains as the general economy. In a memorandum dated June 2, 2022, OACT stated: “over the period 1990-2019, the average growth rate of hospital TFP using the two methodologies ranges from 0.2 percent to 0.5 percent, compared to the average growth of private nonfarm business TFP of 0.8 percent.” The memorandum also indicates that an assumed future rate of hospital industry productivity growth of 0.4 percent per year remains reasonable compared to an assumed rate of productivity growth in the private nonfarm business sector of 1.0 percent.¹⁰

The FAH shares OACT's skepticism regarding the offset to the hospital market basket for the 10-year average in economy-wide nonfarm total factor productivity. One reason that hospitals may not be able to realize the same growth in general economy wide productivity is that hospital services are highly labor intensive. As labor represents nearly 70 percent of the index, hospitals have little opportunity to obtain productivity gains from non-labor inputs as may be occurring in other industries that are less labor intensive.

The FAH understands that CMS is required by law to adjust the market basket update for total factor productivity. However, the FAH asks CMS to consider that the adjustment for total factor productivity reduces the update below what even OACT says is reasonable for hospitals to achieve when deciding on our request for a forecast error correction in its application of an update for hospital outpatient services for CY 2025.

⁹ 89 Federal Register (FR), 23428, April 3, 2024

¹⁰ Paul Spitalnic, Stephen Heffler, Bridget Dickensheets and Mollie Knight, “Hospital Multifactor Productivity: An Update Presentation of Two Methodologies Using Data through 2019.” [Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies Using Data through 2019 \(cms.gov\)](https://www.cms.gov/medicare/medicare-claim-operations-and-payment/medicare-coverage-determinations/medicare-coverage-determinations-2019/hospital-multifactor-productivity).

VII. Proposed OPSS Payment for Hospital Outpatient Visits

The Proposed Rule would continue CMS' 60% payment adjustment for clinic visit services (HCPCS Code G0463) provided at excepted, off-campus provider-based departments (*i.e.*, departments that bill with the modifier "PO"). 89 Fed. Reg. at 59,380. CMS has asserted that it has the authority to implement this significant payment adjustment in a non-budget neutral manner under 42 U.S.C. § 1395l(t)(2)(F), which requires CMS to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department (OPD)] services." ***The FAH strongly opposes continuing this payment reduction because it is not a method for controlling unnecessary increases in volume, it addresses a purported volume increase that Congress has already addressed under section 603 of the Bipartisan Budget Act of 2015 ("Section 603"), and it fails to provide any deference to physician's judgment as to the clinical necessity of the hospital outpatient setting.*** For these reasons, the FAH strongly urges CMS not to eliminate the payment reduction. ***Furthermore, the FAH maintains that the 60% payment cut constitutes an "adjustment" that is subject to the budget neutrality requirements set forth in 42 U.S.C. § 1395l(t)(9)(B) and urges CMS to return the OPSS to the budget neutral payment system required by Congress.***¹¹

In *American Hospital Association v. Azar*, the United States District Court for the District of Columbia held that the site-neutral payment adjustment for clinic visits is a "price-setting tool" that is "manifestly inconsistent with the statutory scheme" of the OPSS. 410 F. Supp. 3d 142 (D.D.C. 2019). After reviewing the structure of the OPSS, the court concluded:

[I]f CMS wishes to reduce Outpatient Prospective Payment System payments for E&M services, it must make budget-neutral adjustments to either that service's relative payment weight or to other adjustments under paragraph (t)(9)(A). Alternatively, CMS may update the conversion factor to apply across-the-board cuts under paragraph (t)(9)(C). But nothing in the adjustment or payment scheme permits service-specific, non-budget-neutral cuts.

Id. The court thereafter properly dismissed the contention that subsection (t)(2)(F) permits CMS to "supersede Congress' carefully crafted relative payment system by severing the connection between a service's payment rate and its relative resource use." *Id.* at 158. Moreover, even if the payment reduction fell within CMS' (t)(2)(F) authority, it cannot be adopted in a non-budget neutral manner because "Congress did not intend CMS to use an untethered 'method' to directly alter expenditures independent of other processes" under the OPSS. *Id.* at 159. Ultimately, Congress "retains for itself the authority" to make these kinds of complicated payment decisions, and CMS cannot ignore and circumvent the multi-factored, complicated annual process required by statute by unilaterally setting service-specific rates without regard to their relative position or budget neutrality. *Id.* at 160.

On appeal, the United States Court of Appeals for the District of Columbia applied *Chevron* deference and reversed, concluding that "Congress did not 'unambiguously forbid' the agency" from implementing the non-budget neutral payment adjustment and that "the agency

¹¹ These concerns are detailed further in the FAH's September 24, 2018 letter commenting on the original proposed payment adjustment (Attachment A), which is incorporated here by reference.

reasonably read subparagraph (2)(F) to allow a service-specific, non-budget-neutral reimbursement cut” in these circumstances. 964 F.3d 1230, 1241 (D.C. Cir. 2020). Critically, the D.C. Circuit did not exercise independent judgment in determining the meaning of subsection (t)(2) and (t)(9) and did not purport to identify the best reading of the statute. Following the Supreme Court’s decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. ___, 144 S.Ct. 2244 (2024), however, *Chevron* is overturned and courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority without deferring to an agency’s interpretation of the law. Following *Loper Bright*, an agency can no longer rely on statutory ambiguity and reasonableness to defend its action. As can be seen from the district court’s evaluation of subsection (t)(2) and (t)(9), the “best reading” of the OPSS statute does not permit CMS to impose a non-budget neutral, site-neutral payment adjustment for clinic visits at excepted, off-campus provider-based departments. CMS should therefore reverse this payment adjustment or, at a minimum, budget neutralize its application consistent with statute.

VIII. Proposed Payment for Partial Hospitalization and Intensive Outpatient Services

The CY 2024 OPSS final rule included a number of changes related to mental and behavioral health services and reimbursement. Section 4124 of the *Consolidated Appropriations Act, 2023* (CAA), created a new benefit category for intensive outpatient services which was added to the scope of benefits that may be provided as an “incident to” service under section 1861(s)(2)(B) of the Social Security Act and also may be furnished by hospital outpatient departments, Community Mental Health Centers (CMHCs), federally qualified health centers (FQHCs), and rural health clinics (RHCs). These services are furnished under an intensive outpatient program (IOP). An IOP is similar to a partial hospitalization program (PHP); it is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, including depression, schizophrenia, or substance use disorders. However, it is considered to be less intensive than a PHP.

CMS established four separate PHP APC per diem payment rates and four separate IOP per diem payment rates for CY 2024, and proposes to continue these APCs for CY 2025 with the following proposed rates for CY 2025:

Provider Type	# of Services per Day	IOP APC	PHP APC	Payment Rate
CMHC	3	5851	5853	\$114.79
CMHC	4 or more	5852	5854	\$159.43
Hospital-based	3	5861	5863	\$279.97
Hospital-based	4 or more	5862	5864	\$428.39

For hospital-based PHPs, CMS again proposes to calculate payment rates using the broader hospital OPSS data set instead of hospital-based PHP data only. The broader OPSS data set allows the agency to capture data from claims not identified as PHP, but that include the service codes and intensity required for a PHP day. For CY 2024, CMS set a methodology and rates for IOPs at the PHP rate because IOPs furnish the same types of services as PHPs, but at a lower intensity and because the IOP was a newly established benefit, and CMS lacks definitive data on utilization. CMS proposes to continue to pay IOP and PHP services at the same rate for

CY 2025. The FAH supports CMS' proposed methodology to use broader OPPS claims to set CY 2025 payment rates for PHP services and to use the PHP rate for IOP services.

IX. Services That Will Be Paid Only as Inpatient Services

CMS did not find sufficient evidence to remove any services from the inpatient only (IPO) list for 2025. CMS does propose to add three new CPT codes for 2025 to the IPO list. These codes are:

- 0894T – Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion.
- 0895T – Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment).
- 0896T – Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure).

The FAH supports the addition of these three liver allograft codes to the IPO list.

X. Nonrecurring Policy Changes

X.A. Remote Services

1. Therapy, Diabetes Self-Management Training (DSMT), and Medical Nutrition Therapy (MNT)

2. Periodic In-Person Visits for Mental Health Visits Furnished by Hospital Staff to Beneficiaries in their Homes

CMS discusses that a number of telehealth waivers, that allow specific services to be furnished remotely by hospital employed staff to patients in their homes through the use of real-time interactive telecommunications technology and paid under the OPPS, will expire December 31, 2024. CMS further discusses that if telehealth waivers are extended by Congress, CMS will likewise extend these waivers regarding services furnished remotely by hospital staff to beneficiaries in their homes, including waivers for: outpatient therapy, diabetes self-management training (DSMT), and medical nutrition therapy (MNT); and delay of the periodic in-person visit requirement for mental health visits.

The FAH supports extending waivers for these remote services beyond December 31, 2024, and urges CMS to work with Congress to ensure enactment of legislation that extends these flexibilities into future years. FAH member hospitals have extensively provided these services to patients at home during the COVID-19 public health emergency (PHE or pandemic) and believe that these services are well-suited for remote delivery via communication technology, while providing important clinical benefits for patients, especially amid continued workforce shortage challenges. **We also support extending such waivers to partial hospitalization program and intensive outpatient program services.**

Specifically, with regard to mental health services, including PHP and IOP services, patients across the United States suffer from the serious shortage of qualified mental health providers in this country. This compromises the ability of patients to get timely access to care, and sometimes requires patients to travel long distances for necessary services. The delays associated with provider scarcity have significant negative consequences on health. For example, individuals are likely to develop more acute mental illness when they do not receive needed and timely interventions, ultimately leading to increased suffering for patients and their families, as well as higher burdens on the health care system. The use of communications technology offers an opportunity to interrupt a cascade of negative outcomes by ensuring that care is available promptly.

Multiple studies support the need for ongoing flexibility and expanded coverage of telehealth for mental health services. For example, previous epidemics have shown that the impact on mental health and substance use will continue for years to come.¹² Further studies demonstrate that telehealth is particularly effective in mental healthcare delivery.¹³ This is true for PHP services delivered via telehealth as well. A comparative effectiveness study demonstrated that the only significant differences between those who participated in PHPs via telehealth technologies and those who attended in person was that those who participated via telehealth had greater lengths of stay and were more likely to stay in treatment until completed.¹⁴

Other studies have shown that various types of mental health services (and often delivered through PHPs) can be provided effectively via telehealth including depression screening, follow up care after hospitalization, behavioral counseling for substance use disorders

¹² Hawryluck L, Gold WL, Susan, S: SARS Control and Psychological Effects of Quarantine, Toronto, Canada. *Emerg Infect Dis.* 10;7: 1206–1212 (July 2004); Reardon S: Ebola's mental-health wounds linger in Africa: healthcare workers struggle to help people who have been traumatized by the epidemic. *Nature*, 519; 7541:13 (2015); Goldmann E, Galea S: Mental health consequences of disasters. *Ann Rev Public Health*, 35:169–83 (2014). Available online at https://www.annualreviews.org/doi/full/10.1146/annurev-publhealth-032013-182435?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed.

¹³ Mace S, Boccanelli A, Dormond M: The Use of Telehealth within Behavioral Health Settings: Utilization, Opportunities, and Challenges. Behavioral Health Workforce Research Center, University of Michigan, (March 2018) Available at https://behavioralhealthworkforce.org/wp-content/uploads/2018/05/Telehealth-FullPaper_5.17.18-clean.pdf; Bashshur RL, Shannon GW, Bashshur N, Yellowlees PM: The empirical evidence for telemedicine interventions in mental disorders. *Telemed J E Health*, 22(2): 7-113 (Jan. 2016).

¹⁴ Zimmerman M, Terrill D, D'Avanzato C, et al.: Telehealth Treatment of Patients in an Intensive Acute Care Psychiatric Setting During the COVID-19 Pandemic: Comparative Safety and Effectiveness to In-Person Treatment. *J Clin Psychiatry*. 82(2) (2021). Available at <https://www.psychiatrist.com/jcp/covid-19/telehealth-treatmentpatients-intensive-acute-care-psychiatric-setting-during-covid-19/>

(SUD), medication management, and psychotherapy for mood disorders.¹⁵ Telehealth has been found to increase retention for SUD treatment, including medication treatment, especially when treatment is not otherwise available or requires lengthy travel.¹⁶ In addition, there is evidence of reduced utilization of higher-cost services associated with providing access to mental healthcare services via telehealth technologies.¹⁷

The experience of our members in delivering mental healthcare services during the PHE is consistent with these research studies. They were able to continue providing mental health and addiction treatment services during the PHE and experienced significantly reduced missed appointments by patients. In addition, telehealth enabled patients and family members who do not have PHPs in their communities to access these services remotely which significantly improved access to a level of care that is simply not otherwise available in most communities, especially in rural areas.

3. Proposed HOPD Payment for Telemedicine Evaluation and Management (E/M) Services

CMS is requesting comments on hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for HCPCS code G0463. The FAH urges CMS to recognize and provide payment for the unique resource costs that hospitals face in furnishing telehealth E/M services.

In providing telemedicine E/M services, it is critical that hospitals receive adequate payment so that patients can maintain widespread access to these important services and avoid a return to the pre-pandemic infrastructure where many patients had limited access to many services or had to take hours or even days to travel to a provider to receive these services in person.

Hospitals incur substantial upfront investment and ongoing costs to establish and annually maintain their virtual infrastructure, including secure platforms, licenses, information technology support, scheduling, patient education and clinician training. Typically, more preparation is required for hospital providers and staff to furnish a virtual visit than for an in-person visit, for example:

- Prior to the visit, the hospital must provide providers and hospital staff with the hardware they need, such as laptops and webcams, and acquire professional licenses for the virtual platform they choose to use, whether Zoom, Teams, WebEx, or another similar platform.

¹⁵ National Quality Forum and AHA Center for Health Innovation: Redesigning Care: a How-To Guide for Hospitals

and Health Systems Seeking to Implement, Strengthen and Sustain Telebehavioral Health. (2019). Available at <https://www.aha.org/system/files/media/file/2020/03/Telebehavioral-Health-Guide-FINAL-031919.pdf>.

¹⁶ Lin L, Casteel D, Shigekawa E, et al.: Telemedicine-delivered treatment interventions for substance use disorders: A systematic review. *Journal of Substance Abuse Treatment*, 101: 38-49 (June 2019).

¹⁷ Shigekawa E, Fix M, Corbett G, et al.: The current state of telehealth evidence: A rapid review. *Health Affairs*, 37(12): 1975-1982 (2018).

- If the hospital staff is at home, hospitals may also purchase additional software to protect the privacy of personal phone numbers and redirect staff to focus exclusively on helping providers and patients execute virtual visits.
- Other dedicated staff work to set patients up on the selected platform, communicate with patients prior to the visit to complete pre-registration, obtain patients' verbal consent to telehealth and then manually record that consent, and provide several pre-visit points of communication to ensure patients have the correct link for their telehealth visit. (For in-person care, these points of contact occur at the in-person visit when the patient interacts with registration staff while waiting for the provider.)
- To start the virtual visit, clinical staff admit a patient from a virtual waiting room or call the patient if they do not show up to, or have difficulties accessing, the waiting room.
- The clinical staff complete an intake process and notify the provider when to enter the virtual visit.
- Upon conclusion of the visit, instead of sending a patient to check-out to schedule any follow-up visits, the provider must conduct this follow-up as it is not possible to conduct a handoff to a staff person.
- Once the visit is finished, hospital staff must send patients their visit summaries via a patient portal or via mail for patients not on the portal; whereas if the patient is in person, staff would simply hand the patient their summary sheet.

CMS should study these infrastructure, practice, and labor resource costs, taking into account their intensity and complexity, to ensure payment for telehealth that accurately reflects the inputs for furnishing these critical services upon which Medicare beneficiaries have come to rely for purposes of increased access to healthcare.

X.B. Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) and Diagnostic Services Furnished to Hospital Outpatients

During COVID, CMS allowed direct supervision of CR, ICR, PR and diagnostic services to be furnished remotely (but not audio only). This flexibility was extended by CAA, 2023 through December 31, 2024. CMS now proposes to extend availability of virtual direct supervision of therapeutic and diagnostic services under the physician fee schedule (PFS) through December 31, 2025. Similarly, CMS is proposing to allow direct supervision of CR, ICR, PR services, and diagnostic services via audio-video real-time communications technology (excluding audio-only) under the OPSS through December 31, 2025.

The FAH appreciates and supports these CMS proposals as they would permit greater access to these services, especially amid ongoing workforce shortages. In addition, the FAH urges that the flexibility to provide direct supervision through real-time audio/video technology be made permanent. In the experience of our member hospitals, physicians and other professionals have been able to provide clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth. Further, requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits. The reality is that a physician office, clinic,

or hospital outpatient department typically has many other practitioners on site who can assist if a physical presence is required. Moreover, in an emergency, the most appropriate course of action is to transfer the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. A virtually available supervisor may even facilitate a faster transfer of the patient to the emergency department when necessary.

Moreover, under a permanent policy, there should not be a requirement for a service-level modifier to identify when direct supervision is provided via appropriate telehealth technology. Physicians and other supervising practitioners benefit from the flexibility to supervise in person, via telehealth, or through a combination of modalities depending on clinical need and circumstances. In some cases, services may even be supervised in part through an in-person presence and in part through a telehealth modality. Requiring practitioners to track whether and to what extent they supervised through telehealth would significantly increase administrative burdens associated with these flexibilities, undermining their ability to improve physician care delivery. Because there is no obvious benefit to collecting data on how supervision is facilitated, the burdens associated with a modifier requirement cannot be justified. **Thus, the FAH requests that the definition of direct supervision of CR, ICR, PR, and diagnostic services be permanently amended to allow supervision to be provided via audio-visual technology, and without the requirement for a new modifier.**

X.E. Coverage Changes for Colorectal Cancer (CRC) Screening Services

For 2025, CMS proposes to modify its policies on payment for colorectal cancer (CRC) screening services by removing coverage for the barium enema procedure, adding coverage for the computed tomography colonography (CTC) procedure, and expanding the existing definition of a “complete colorectal cancer screening” to include a follow-on screening colonoscopy after a positive Medicare covered blood-based biomarker CRC screening test.

The FAH supports these proposals. The removal of the coverage for the barium enema is appropriate given that the procedure fails to meet modern clinical standards of CRC screenings. The FAH believes coverage for the CTC procedure and inclusion of a blood-based biomarker with a follow-up colonoscopy with a positive test result offers patients increased flexibility for non-invasive CRC screening services. The FAH appreciates CMS for prioritizing patient experience and safety while modernizing CRC screening options.

X.F. Request for Comment on Payment Adjustments under the IPPS and OPSS for Domestic Personal Protective Equipment

The CY 2023 OPSS/ASC final rule implemented payment adjustments under the OPSS and IPPS to offset the marginal costs hospitals face in obtaining domestically made NIOSH approved and FDA-certified surgical N95 respirators. However, CMS acknowledges that the use of the payment adjustments has been very limited. Data suggests and experience from our members support that a majority of surgical N95 respirators purchased by hospitals are not wholly domestically made, largely due to the availability and production capability of domestically manufactured PPE and foreign material inputs.

Given domestic production capabilities and requirement for all materials to be sourced domestically, the payment adjustments for both surgical and non-surgical N95 masks may not be worth the increased costs, especially considering that the payment adjustments are reduced to exclude non-Medicare patients. Given the fact that domestic manufacturers can only produce a mere 0.05% of U.S. demand for materials for nitrile gloves, the FAH also finds that its addition would be minimally impactful. Domestic manufacturers must first be able to consistently produce PPE at the needed rates for such a payment adjustment to make sense, or CMS needs to consider some allowance for manufacturing these products in the United States while still having foreign raw material inputs. Unfortunately, the current available supply of domestically manufactured and sourced PPE, combined with the minimal financial incentives offered through the current add-on payments, are not enough to incentivize significant modifications in the market or the availability of domestically made products.

XV. Hospital Outpatient Quality Reporting (OQR) Program

Hospital Commitment to Health Equity (HCHE) measure for the Hospital OQR program

CMS proposes the adoption of the Hospital Commitment to Health Equity (HCHE) measure, beginning with the 2025 reporting period/2027 Payment Determination. The FAH is fully committed to achieving equity in the provision and quality of health services and we believe that many of the priorities included in this structural measure are currently addressed by hospitals and health systems. Many already have language and communication access plans woven into their frameworks for ongoing provision of culturally competent care to patients with limited English proficiency and hearing or vision disabilities. These plans typically form part of the curricula for onboarding and refresher training of patient-facing staff. Hospitals also maintain certified electronic health record technology (CEHRT) capabilities as required under the CMS Promoting Interoperability Program for hospitals. These activities also overlap with accreditation requirements of hospitals generally or of special hospital programs (e.g., accreditation of bariatric surgery programs that mandates culturally competent care of morbidly obese patients). Hospital associations already have underway a variety of programs addressing equity, including organizational focus and leadership.

The FAH urges CMS to first catalogue what hospitals are already doing before establishing new measures or requirements to preclude burden caused by overlap and redundancy. A complete environmental scan, listening sessions, focus groups, and/or a Technical Expert Panel would be helpful.

In addition, the FAH believes that CMS should address inequities in care through existing measurement efforts. For example, the collection of race/ethnicity, payer, and gender have always been included in the electronic clinical quality measure (eCQM) specifications as supplemental data elements. CMS could choose to make the collection and reporting of these data required. This change would allow hospitals to collect the data, use it for improvement purposes, and receive automatic credit through reporting of these data rather than require them to attest to it through a structural measure. Further specificity regarding what would satisfy each of the statements is also needed to ensure that every hospital interprets and attests to them consistently. For example, what constitutes most patients under question 2b and what are the

minimum requirements for participation in a local, regional, or national quality improvement activity under question 4a?

Because of the importance of this issue, the FAH regrets that we cannot support consideration of this measure for the Hospital OQR Program at this time due to the need for additional specificity and lack of clear linkages that each of the statements can improve outcomes in health equity. The FAH encourages CMS to explore other measures that are more directly linked to quality improvement and accountability while also minimizing reporting burden for hospitals.

Screening for Social Drivers of Health (SDOH) for the Hospital OQR program

CMS proposes the adoption of the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for 2025 reporting period followed by mandatory reporting for the 2026 reporting period/2028 payment determination.

The FAH supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, the FAH is unable to support the inclusion of this measure in the Hospital OQR Program for several reasons.

We continue to question why these specific social drivers of health were selected and what if any evidence demonstrates that process is linked to improvements in health outcomes. During several reviews, the Measures Application Partnership (MAP) placed conditions on this measure, which remain unanswered. Specifically, the MAP asked that the measure be tested for reliability and validity and subsequently submitted to a Consensus-Based Entity (CBE). None of the measures focused on social drivers of health have been submitted for endorsement consideration nor has any additional information around the feasibility, reliability, or validity of the measures been released, particularly for this setting. In addition, it remains unclear how CMS plans to address the additional conditions from the MAP around additional details on how potential resources, tools, and best practices map to the individual drivers.

Furthermore, the FAH questions the actionability of this measure. The measure assesses the rate of screens completed by a hospital in the absence of any information on the facility's access to resources and tools that would address the individual's needs. We continue to see these measures put forward for inclusion into additional CMS quality programs without any real-world assessments of their feasibility and scientific acceptability. These measures will require significant time for facilities to integrate the data collection and create clinical workflows to capture and improve patient care. Hospitals need at least two years to complete this work, particularly if they intend to integrate the measure into the HOPD's electronic health record system, which is often not the same vendor as what is used in the inpatient setting.

The FAH believes that these questions and concerns must be addressed and endorsement by the CBE should be achieved prior to implementation of this measure in the Hospital OQR Program.

Screen Positive Rate for Social Drivers of Health (SDOH)

CMS proposes the adoption of the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for 2025 reporting period followed by mandatory reporting for the 2026 reporting period/2028 payment determination. The FAH supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. However, regrettably **the FAH is unable to support the inclusion of this measure in this program for several reasons.**

We continue to question why these specific social drivers of health were selected and what if any evidence demonstrates that reporting the positivity rate for any one of these drivers is linked to improvements in health outcomes. During several reviews, the MAP placed conditions on this measure, which remain unanswered. Specifically, the MAP asked that the measure be tested for reliability and validity and subsequently submitted to a CBE. None of the measures focused on social drivers of health have been submitted for endorsement consideration nor has any additional information around the feasibility, reliability, or validity of the measures been released, particularly for this setting. In addition, it remains unclear how CMS plans to address the additional MAP condition around how the results of this measure will be shared and contextualized for public reporting.

Furthermore, the FAH continues to question whether this measure is actionable and whether the resulting performance score should be attributed to a hospital. This measure assesses the rate of positive screens but does not appear to address the degree to which a facility has been equipped with the necessary resources and tools to address the individual's needs. In the absence of this information, the FAH does not believe that a rate of positive screens will reflect the quality of care provided by a hospital.

We continue to see these measures put forward for additional CMS quality programs without any real-world assessments of their feasibility and scientific acceptability. These measures will require significant time for facilities to integrate the data collection and create clinical workflows to capture and improve patient care. Hospitals need at least two years to complete this work, particularly if they intend to integrate the measure into the HOPD's electronic health record system, which is often not the same vendor as what is used in the inpatient setting.

The FAH believes that these questions and concerns must be addressed and endorsement by the CBE should be achieved prior to implementation of this measure in the Hospital OQR Program.

Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)

CMS proposes the adoption of the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-

Based Performance Measure (Information Transfer PRO-PM), beginning with voluntary reporting for 2026 reporting period followed by mandatory reporting for the 2026 reporting period/2028 payment determination.

The FAH opposes the inclusion of this PRO-PM due to the ongoing concerns with the existing PRO-PM Following an Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) and based on the need for additional refinements to the measure. We expressed concerns on the existing THA/TKA PRO-PM in our comment letter on the FY 2025 IPPS proposed rule, including the extremely burdensome response rate of 50% and the rush to move toward mandatory reporting without adequate time for hospitals to gain experience with the measure. **We urge CMS to rescind the mandatory reporting of this measure in the Hospital Inpatient Quality Reporting (IQR) program to give hospitals more time to prevent the payment penalties that potentially hundreds of hospitals will incur. We also urge CMS to lower the 50% response rate requirement and include a minimum threshold.**

We believe that adding another PRO-PM to this program when hospitals are still attempting to address the data collection challenges of the existing measure is unreasonable and CMS must delay implementation of this new PRO-PM. Additional reviews of this PRO-PM are needed to address how facilities will be able to administer a survey and report on a denominator that is extremely broad, particularly since no other specifications are included in the measure other than a “code set” that includes six variables. This information is not sufficient for successful reporting of this PRO-PM and serves as one of the barriers to successfully implementation of the measure.

We also do not believe that CMS can be confident that this measure is feasible to collect and produce scores that are accurate and consistent since the survey was only tested in 26 facilities, none of which were rural or small. CMS proposes to require a minimum random sample size of 300 completed surveys, which is overly burdensome and contrary to the minimum responses outlined in the measure specifications that were endorsed by the CBE. That application only required 100 responses, which we still believe is excessive but is more reasonable than what is currently proposed. We also note that testing did not attempt to receive at least 300 completed surveys and the feasibility challenges identified in the application included an issue that some facilities were unable to achieve enough case volumes and/or survey administration rates. CMS has not demonstrated that HOPDs can reasonably collect this volume of responses, particularly small or rural hospitals, and we do not support CMS putting forward requirements that real-world implementation has not shown to be feasible.

CMS must also address how hospitals and others can avoid survey fatigue for patients when asked to complete multiple surveys and across various entities for different purposes, the potential impact that additional PRO-PMs may have on the reporting of well-established measures such as OAS CAHPs, and what level of data collection burden for an individual PRO-PM is acceptable for a hospital or other healthcare provider. It is also critical to understand what resources and staffing are truly needed to administer and then report these measures. For example, to what extent do these data impact clinical workflows and are additional staff

resources required? And, what additional costs might a facility encounter because of implementation of this PRO-PM?

The FAH is deeply concerned with the continued emphasis on increasing the number of PRO-PM measures even as hospitals report significant barriers in successfully reporting the THA/TKA PRO-PM. CMS must not move forward with implementing this measure in the Hospital OQR Program and first focus on addressing the challenges with the THA/TKA PRO-PM.

Proposed Measure Removals

CMS proposes to remove the MRI Lumbar Spine for Low Back Pain and the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measures, beginning with 2025 reporting period/2027 payment determination. **The FAH supports removal of these measures.**

Electronic Health Record (EHR) Certification Requirement

CMS proposes, beginning with the 2025 reporting period/2027 payment determination, that HOPDs using EHR technology certified to the ONC Health IT certification criteria would be required to have the technology certified to all eCQMs that are available for reporting in this program.

The FAH has significant concerns about the proposed time requirement, as it presents considerable challenges. Hospitals work with a wide range of EHR vendors, each with different capabilities and timelines for achieving certifications for all eCQMs. The required updates to EHR systems will involve complex coordination with vendors, testing, and staff training, all of which are time intensive. Given the substantial operational and technical efforts involved, we urge CMS to provide additional ramp-up time to ensure a smoother implementation process.

We respectfully request that CMS allow for an extended timeline to meet these new requirements, ensuring that hospitals and their EHR vendors have sufficient time to address any technical issues and fully comply with the certification standards. This additional time will help ensure that hospitals can effectively meet the program's goals without compromising care quality or introducing unintended administrative burdens.

Public Reporting of Measure Data

CMS proposes to make data for the psychiatric/mental health patients' stratification on the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure available on Care Compare beginning in 2025.

The FAH does not support stratifying this measure for these individuals. While we agree that transitioning all patients to another clinical setting or home as efficiently as possible is critically important, we are very concerned with reporting data on a population where there are known barriers to efficient transitions. Median times for those individuals with psychiatric or

mental health diagnoses may be more reflective of access or availability in the appropriate facility. In addition, adding this new stratification requires hospitals to collect these data and CMS will increase the reporting burden for HOPDs without adequate time to prepare. We urge CMS to delay this reporting and further investigate the implications of this stratification, particularly whether the data would truly be reflective of the quality of care provided.

XIX. Changes to Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

The *Advancing Interoperability and Improving Prior Authorization Processes* final rule¹⁸ shortens prior authorization timeframes for certain payers such as Medicare Advantage (MA), Children’s Health Insurance Program (CHIP), Medicaid managed care plans, and CHIP managed care entities to respond to prior authorization requests. Payors must send prior authorization decisions as expeditiously as the enrollee’s/beneficiary’s health condition requires, but no later than 72 hours for expedited (urgent) requests and 7 days for standard (non-urgent) requests.

The CY 2020 OPPS final rule established nationwide prior authorization processes and requirements for certain HOPD services, and HOPD providers must submit to the Medicare Administrative Contractor (MAC) a prior authorization request for any service on the list of HOPD services that require prior authorization. The MACs are then required to review and issue a decision within specific timeframes.

Medicare fee-for-service (FFS) is not an impacted payor under the *Advancing Interoperability and Improving Prior Authorization Processes* final rule, and CMS proposes to align its Medicare FFS prior authorization review timeframe for standard review requests for HOPD services with the timeframe in that final rule. Specifically, CMS proposes to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests for these services from 10 business days to 7 calendar days.

The FAH supports this CMS proposal. We continue to have significant concerns – as we commented on the *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule – that the timeframes, *i.e.*, 72 hours for expedited decisions and 7 days for standard decisions, are too long, creating unnecessary risks that patients will delay or forego necessary care or remain in the acute care environment long past the time when they are ready to transition to post-acute care. In lieu of these timeframes, we support timeframes of no more than 72 hours for standard decisions and no more than 24 hours for expedited decisions. **Nevertheless, we also believe that standardized and streamlined reporting timeframes eliminate confusion and reduce burden, thus we support and appreciate this CMS proposal.**

¹⁸ 89 *Fed. Reg.* 8,758 (Feb. 8, 2024).

XXI. Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

General Comments Opposing CMS' Proposal for New Conditions of Participation (CoPs)

In the FY 2025 IPPS proposed rule, CMS requested public comment on establishing CoPs specific to labor and delivery, prenatal and post-partum care for newborn infants and mothers (89 FR 36498). The public comment period on the IPPS proposed rule ended on June 10, 2024. One month later, on July 10, 2024, the CY 2025 OPSS proposed rule became publicly available. In the CY 2025 OPSS proposed rule, CMS proposed standards for hospitals that furnish labor and delivery services, prenatal and post-partum care for newborn infants and mothers.

While the FAH strongly supports efforts to improve labor and delivery, prenatal, and post-partum care for newborns and mothers, we have significant concerns about the potential unintended consequences of adding new CoPs. These additional requirements could be counterproductive to CMS' goal by increasing the regulatory burden on hospitals, particularly in rural areas where resources are limited. Hospitals unable to meet the new CoPs may face the loss of Medicare certification, while others may choose to stop offering obstetric services altogether. This outcome would exacerbate the growing issue of "OB deserts"—areas where no maternity care is available—especially in rural and underserved regions, further limiting access to essential obstetrical services and potentially increasing maternal morbidity and mortality.

According to the March of Dimes, the United States already faces significant maternity care gaps, particularly in rural areas, where over half of rural counties lack hospital-based obstetric services. This shortage has led to increased out-of-hospital births and higher rates of pre-term births, both of which contribute to poor maternal and infant health outcomes.¹⁹ Imposing additional CoPs could worsen the situation by prompting more hospitals to eliminate obstetric services, leaving many rural areas without access to necessary maternal healthcare and deepening the crisis of maternal health "deserts."

Under CMS' regulations, the new CoPs specific to labor and delivery, prenatal and post-partum care for newborn infants and mothers are optional, e.g., hospitals are not required to provide these services. However, if a hospital does provide labor and delivery services, prenatal and post-partum care services, the hospital must comply with the requirements of the CoP specific to these services. If a hospital delivers emergency services, CMS proposes to add CoPs specific to obstetrical emergencies. Immediate post-delivery care would always apply. The FAH believes that CMS should strongly consider whether hospitals would respond to these additional requirements by deciding to no longer furnish labor and delivery, prenatal and post-partum care.

The costs of additional regulatory compliance serves to increase the risk that hospitals will eliminate labor and delivery, prenatal and post-partum care for newborns. Following each new CoP, CMS provides compliance costs for the new regulations. CMS' estimates that hospital

¹⁹ GAO, *Maternal Health, Availability of Hospital-based Obstetric Care in Rural Areas*, GAO-23-105515, (Washington, DC., October 2022).

compliance costs associated with these new CoPs could reach \$180,000 per hospital per year—certainly a factor that hospitals will consider, in addition to the severe penalties for non-compliance when deciding whether to continue providing labor and delivery, prenatal and post-partum care for newborns.

The FAH recommends that CMS work with hospitals to adopt voluntary guidelines for labor and delivery, prenatal and post-partum care for newborn infants and mothers instead of establishing new CoPs for these services. However, if CMS decides to finalize its policy, hospitals will need more time for compliance than is provided for in the proposed rule. The proposed rule does not provide a specific date as to when any of the new CoP requirements are effective suggesting that default effective date is January 1, 2025 or 60 days following the November 1, 2024 deadline for CMS to make the CY 2025 OPPTS final rule publicly available. The FAH requests that CMS make any new rules effective no earlier than January 1, 2026 or allow for discretionary enforcement while hospitals undertake efforts to be in compliance with these new regulations.

Alternative to CMS' Proposal

The FAH believes the best alternative is for CMS to work with stakeholders on voluntary compliance with existing standards for furnishing high quality labor and delivery, prenatal and post-partum care for newborn infants and mothers including through the following resources:

- Departments of Health and Human Services (HHS) [Office of Women's Health](#) (OWH) through the [Maternal Morbidity and Mortality Data and Analysis Initiative](#) has initiated an \$8 million nationwide contract with Premier, Inc. to improve maternal health data and create a network of at least 200 hospitals to deploy clinical, evidence-based best practices in maternity care.
- A related initiative through OWH is the HHS Perinatal Improvement Collaborative; a multi-year collaborative comprised of more than 220 hospitals from all 50 states and the District of Columbia to standardize data and improve performance through identification of the root causes of maternal-infant mortality and morbidity.²⁰
- Obstetric Care Consensus: Levels of Maternal Care: a consensus document defining the levels of maternal care was released in August of 2019 with the goal of reducing maternal morbidity and mortality, and disparities, by standardizing and defining risk-appropriate care.²¹
- The Association of Women's Health, Obstetrical and Neonatal Nurses (AWHONN), published standards for registered nurse staffing for perinatal units in 2022 that also includes guidance on credentialing.²²
- Guidelines for Perinatal Care, 8th Edition. These guidelines are a joint project by the American College of Obstetrics and Gynecology (ACOG) and the American Academy of Pediatrics. This edition maintains the focus on reproductive awareness and regionally based perinatal care services with an added focus on patient safety and quality

²⁰ [Maternal Morbidity and Mortality Data and Analysis Initiative | Office on Women's Health \(womenshealth.gov\)](#)

²¹ Obstetric Care Consensus: levels of Maternal Care, Number 9, Vol 134, No.2, August 2019. Obstetrics and Gynecology

²² AWHONN *Standards for Professional Registered Nurse Staffing for Perinatal Units*, 2022.

improvement. This edition provides updated information on maternal transport, definitions of levels of neonatal care, immunizations, nutrition in addition to capabilities and equipment recommendations.²³

- The Alliance for Innovation on Maternal Health’s (AIM; a partnership between the Health Resources and Services Administration (HRSA), ACOG and other stakeholders) has developed resources which include example protocols and training resources for responding to obstetrical hemorrhage, severe hypertension, perinatal mental health conditions, sepsis, substance use disorder, and cardiac conditions, among others.²⁴
- ACOG has also developed resources for Obstetric Emergencies in Non-Obstetric Settings.²⁵
- Similarly, the HRSA-supported Emergency Medical Services for Children Innovation and Improvement Center has resources for emergency departments seeking to improve ‘‘pediatric readiness.’’²⁶

These efforts are designed to drive clinical quality improvement and make obstetrical and maternity care safer without imposing new costs or punitive measures on hospitals. The FAH encourages public dissemination of these and other resources on obstetrical, maternity and neonatal care to improve the delivery of these services nationwide.

In addition, the FAH notes that the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey does not include any questions specifically designed to measure prenatal and childbirth care from the patient's perspective in ambulatory and inpatient care settings. The FAH recommends that the Agency for Healthcare Research and Quality (AHRQ) create a dedicated survey tool designed to measure prenatal and childbirth care from the patient’s perspective to be included in the CAHPS survey.

XXII. Modification to the Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide All-Cause risk Standardized Mortality (HWM) Measures in the Hospital Inpatient Quality Reporting Program

CMS is proposing to continue voluntary reporting of the CCDEs and linking variables for both the Hybrid HWR and Hybrid HWM measures, for the performance period of July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program. **The FAH strongly supports CMS' proposal to keep the submission of Core Clinical Data Elements (CCDEs) and linking variables voluntary for the FY 2026 payment determination under the Hybrid HWR and Hybrid HWM Measures in the Hospital Inpatient Quality Reporting (IQR) Program.** This approach allows hospitals the necessary flexibility they need as they continue to work through the challenges associated with collecting and reporting these data elements.

Since the inclusion of hybrid measures into the IQR program, hospitals have faced significant hurdles in adhering to the data submission and reporting requirements. FAH

²³ [Guidelines for Perinatal Care, 8th Edition](#)

²⁴ [AIM | Alliance For Innovation On Maternal Health \(saferbirth.org\)](#)

²⁵ [Obstetric Emergencies in Nonobstetric Settings | ACOG](#)

²⁶ [National Pediatric Readiness Project • EIIC \(emscimprovement.center\)](#)

members, for example, have encountered issues related to the timing and capture of specific data, such as vital signs, patient body weight, and laboratory tests, within the precise time frames required by the measures. These challenges are particularly evident in certain patient populations, such as surgical patients, patients transferred between facilities, and those in observation status prior to inpatient admission.

For instance, the timing of vital signs and lab tests for surgical patients often does not align with the measure specifications due to the nature of surgical procedures and the care provided by anesthesia teams. Similarly, data inconsistencies arise for patients transferring between facilities, as clinicians rely on clinical judgment when deciding when to capture the next set of vital signs, making it difficult to meet rigid data submission criteria.

Moreover, there is industry-wide concern regarding the lack of transparency around the calculation and output of results, as well as confusion about the percentage thresholds for submission compliance. Other healthcare organizations have voiced similar issues through ONC's JIRA CMS Hybrid Measure issue tickets, suggesting these challenges are widespread and not unique to a single institution.

Given these complexities, we strongly encourage CMS to finalize its proposed approach and maintain the voluntary nature of submissions for FY 2026. This will allow hospitals time to adapt and improve their processes, as well as ensure the data collected is accurate and reflective of clinical care practices. We support the proposal to transition to mandatory submission for the FY 2027 payment determination and beyond, as this timeline should provide sufficient lead time for hospitals to adjust their systems and workflows.

Additionally, we urge CMS to reconsider the timing requirements for data submission and to review the expected percentage thresholds, especially given the widespread challenges reported. Ensuring these thresholds are realistic and attainable will be critical for the long-term success of the hybrid measures in the IQR program.

XXIV. Hospital Quality Star Rating – Request for Information

CMS is considering potential adjustments to the Overall Hospital Quality Star Ratings methodology that would place more emphasis on the measures within the Safety of Care measure group. CMS requested feedback on three options for modifying the methodology, including reweighting the Safety of Care measure group, policy-based 1-start reduction for poor performance on Safety of Care, or a combination of the first two options.

The FAH opposes any adjustment of the Overall Hospital Quality Star Ratings methodology due to concerns over the unintended consequences of this change to hospitals such as those that are small and/or rural. CMS' analyses showed that smaller hospitals are more likely to be at the extremes of the performance distribution with the current approach and it is very likely that they will be further negatively impacted with any of the three options. Our members report that frequently these hospitals can achieve sufficient case minimums for only one or two of the measures within this measure group and they are penalized if only one instance of a hospital-acquired infection occurs.

In addition, hospitals are subject to significant changes to their star ratings year-over-year that are not directly related to changes in performance scores but rather reflect some of the flaws in the star ratings methodology. These issues would be further exacerbated for smaller and/or rural hospitals if any of the proposed options are pursued. CMS must avoid any changes that increase the potential for misperceptions of the quality of care delivered by these hospitals within their community. We believe that if CMS examined the impact that any of these options would have on the star ratings for these hospitals, these concerns would be validated.

We urge CMS to reconsider these options and explore alternative approaches that do not penalize small and rural hospitals.

The FAH appreciates the opportunity to submit comments on these important issues in the proposed rule. If you have any questions, please contact me or a member of my staff at (202) 624-1534.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. Kuntz". The signature is fluid and cursive, with a large, sweeping flourish at the end.

ATTACHMENT A



Charles N. Kahn III
President and CEO

September 24, 2018

The Honorable Seema Verma
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

SUBJECT: CMS-1695-P. Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching full-service community hospitals in urban and rural parts of America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on the above Notice of Proposed Rulemaking ("Proposed Rule") published in the Federal Register (83 Fed. Reg. 37046) on July 31, 2018.

Proposal and Comment Solicitation on Method to Control Unnecessary Increases in the Volume of Outpatient Services

The Proposed Rule would reduce the payment rate for clinic visit services (Healthcare Common Procedure Coding System (HCPCS) Code G0463), when provided at an excepted, off-campus provider-based department (*i.e.*, a Provide Based Department (PBD) that bills with the

modifier “PO”) by 60%.¹ CMS asserts that it has the authority to implement this significant negative adjustment in a non-budget neutral manner under 42 U.S.C. § 1395l(t)(2)(F), which requires CMS to “develop a method for controlling unnecessary increases in the volume of covered [outpatient department (OPD)] services.” ***The FAH strongly opposes this proposed adjustment because it is not a method for controlling unnecessary increases in volume, it addresses a purported volume increase that Congress has already addressed under section 603 of the Bipartisan Budget Act of 2015 (“Section 603”), it fails to provide any deference to physician’s judgment as to the clinical necessity of the hospital outpatient setting, and the payment reduction may have unintended and counterproductive effects, including volume increases and decreased beneficiary access.*** For these reasons, the FAH strongly urges CMS not to implement the proposed payment adjustment. ***Furthermore, the FAH maintains that the proposed policy constitutes an “adjustment” that is subject to the budget neutrality requirements set forth in 42 U.S.C. § 1395l(t)(9)(B).***

1. The proposed adjustment is not a permissible “method for controlling unnecessary increases in the volume of covered OPD services.”

CMS’s proposal to reduce the payment rate for clinic visit services (HCPCS Code G0463) billed with the “PO” modifier is not a “method” as it is not targeted to control a growth in volume and does not distinguish between necessary and unnecessary volume increases. The proposal, therefore, does not satisfy the statutory requirements of 42 U.S.C. § 1395l(t)(2)(F), which requires CMS to “develop a method for controlling unnecessary increases in the volume of covered OPD services.”

As proposed, the Outpatient Prospective Payment System (OPPS) rate cut would apply only to clinic visits furnished in an off-campus PBD that is excepted under Section 603. There is no evidence, however, of unnecessary growth in the volume of clinic visits furnished in excepted off-campus PBDs or that the proposed adjustment is properly targeted to control any such unnecessary volume increases. ***In fact, because full implementation of Section 603 (42 U.S.C. §1395l(t)(21)) (as amended to address mid-build departments) did not occur until CY 2018, there are no claims data that can support any conclusion concerning volume trends—let alone unnecessary volume growth—in excepted off-campus PBDs.*** Accordingly, the FAH urges CMS to forego the proposed payment adjustment for excepted, off-campus PBDs because it is not targeted to any “unnecessary increase[] in the volume of covered OPD services.”

Prior to CY 2017, the “PO” modifier was used for all off-campus PBDs, so it was impossible to distinguish between volume increases related to the acquisition of physician practices, the establishment of wholly new off-campus PBDs, and volume increases in existing, off-campus PBDs. Starting in CY 2017, the PN modifier was introduced and used for non-excepted, off-campus PBDs (namely PBDs that were newly acquired or established after November 2, 2015), and only excepted, off-campus PBDs continued using the “PO” modifier. Moreover, from CY 2017 to CY 2018, a number of “mid-build” PBDs transitioned from using the PN modifier to the “PO” modifier pursuant to 42 U.S.C. §1395l(t)(21)(B)(iv), likely

¹ The amount of the proposed reduction is based on the Physician Fee Schedule (“PFS”) Relativity Adjuster. For CY 2018, the PFS Relativity Adjuster is 40%, and CMS has proposed maintaining it at 40% for CY 2019. 83 Fed. Reg. at 35,740.

producing a one-time increase in the volume of services billed with the “PO” modifier. In light of this timeline, there simply are no claims data from which to assess whether there is an ongoing increase in the volume of clinic visits furnished in excepted off-campus PBDs. Without this data, CMS cannot assess whether there is any unnecessary increase in the volume of clinic services furnished in excepted, off-campus PBDs, and the proposed policy therefore exceeds CMS’s lawful authority under 42 U.S.C. §1395l(t)(2)(F).

Along these same lines, the data cited by CMS in the Proposed Rule do not demonstrate a growing volume of unnecessary clinic visits in off-campus, provider based departments. CMS references various statistics from the Medicare Payment Advisory Commission (MedPAC), 83 Fed. Reg. at 37,140, but all of this data predates adoption of Section 603. In fact, as CMS notes, MedPAC attributed some of the pre-2015 growth in evaluation and management visits furnished in hospital outpatient departments to the acquisition of freestanding physician practices, *id.*, a trend that CMS has stated Congress intended to “curb” with the passage of Section 603. 81 Fed. Reg. 45,684. Therefore, this data cannot properly inform the question of whether the volume of clinic visits furnished in PBDs has continued to grow post-Section 603. The only other data that CMS presents concerning clinic visits consist of two statistics that predate full implementation of Section 603 and show no trends. First, CMS restates its November 2016 observation that “the most frequently billed service with the ‘PO’ modifier was described by HCPCS code G0463,” 83 Fed. Reg. at 37,142; *see* 81 Fed. Reg., at 79,723. Next, CMS states that “the total number of CY 2017 claim lines for [clinic visits] was approximately 10.7 million as of May 2017. 83 Fed. Reg. at 37,142. As this data is one-year only data for a single code, it does not show an increase in volume or allow for any judgment as to whether any portion of this volume is unnecessary. ***Thus, there is no evidentiary basis for CMS’s assertion that there is an unnecessary increase in the volume of outpatient clinic visits that the proposed payment adjustment would target.***

Moreover, the general data that CMS presents concerning trends across all covered OPD services (*see* Tables 30 and 31) do not distinguish between necessary and unnecessary increases in the volume of covered OPD services. Rather, CMS appears to implicitly assume that any growth in OPSS expenditures or OPD volume and intensity that exceeds the pace of growth for other payment systems under Medicare Parts A and B could only be explained by the differential between the OPSS and the Physician Fee Schedule (PFS) payment rates. *See* 83 Fed. Reg. at 37,139. This approach fails to account for changes in medical technology and the delivery system that might disproportionately fuel necessary OPSS growth. For example, medical advancements have allowed a number of procedures to now be performed in the outpatient setting in lieu of the inpatient setting. Most recently, in the CY 2018 OPSS Final Rule, CMS removed total knee arthroplasty from the inpatient-only list. 82 Fed. Reg. at 52,525. This shift from the inpatient to the outpatient setting fuels the growth of covered OPD services in a way that is not only necessary, but also desirable. Disproportionate growth in the volume of covered OPD services may also be explained by changes in the acuity of Medicare beneficiaries or a general reduction in the number of physician practices as physicians sell or retire from their practices, citing stagnating reimbursement rates that fail to offset growing practice expenses and regulatory burdens.

In addition to addressing a volume growth problem that cannot be substantiated (and may have already been solved by Congress with the adoption of Section 603), the proposed payment cut for clinic visits in excepted, off-campus PBDs is not designed to control unnecessary volume

increases, and therefore cannot be implemented under 42 U.S.C. § 1395l(t)(2)(F). CMS has not identified a rate by which volume should necessarily increase for clinic visits in off-campus PBDs and, therefore, has no benchmark against which to measure volume trends with the payment cut in place. ***In the absence of such a benchmark or any effort to distinguish between necessary and unnecessary volume increases, the proposed policy operates as a plain, negative payment adjustment rather than a method to control volume under subsection (t)(2)(F).*** Moreover, the FAH believes that the exclusion of year-to-year monitoring of volume from the proposed policy confirms that the proposal is not designed to operate as a volume-control measure.

Assessing the potential effects of the proposed payment cut reveals a further misalignment between the proposed policy and the requirements of subsection (t)(2)(F) using CMS's own logic. CMS has previously acknowledged the risk that payment cuts could unintentionally increase volume. For example, in the CY 2008 final rule, CMS declined to adopt a sustainable growth rate (SGR)-like methodology for the OPDS, explaining:

implementing such a system could have the potentially undesirable effect of escalating service volume as payment rates stagnate and hospital costs rise, thus actually resulting in a growth in volume rather than providing an incentive to control volume. Therefore, this approach to addressing the volume growth under the OPDS could inadvertently result in the exact opposite of our desired outcome. 72 Fed. Reg. 66,579, 66,613.

The FAH notes that subsection (t)(2)(F) only authorizes a method for controlling unnecessary increases in volume, so following CMS's own logic, a policy that increases volume through price reductions would not be a permissible volume-control method.

2. CMS's proposed adjustment makes no allowance for the physician's professional judgment concerning the most appropriate site of service for the patient, ignores the significant costs borne by hospital outpatient departments, and jeopardizes patient access to needed services

The FHA also maintains that the proposed payment cut is flawed as a matter of policy. Much of the Proposed Rule's discussion of the proposed payment reduction for clinic visits furnished in excepted, off-campus PBDs turns on the purported equivalence between outpatient services furnished in physicians' offices and those furnished in hospital outpatient departments. 83 Fed. Reg. 37,046, 37,142. Along these lines, the proposed policy would treat an outpatient department and a physician's office as virtually interchangeable, applying the payment cut regardless of patient acuity and the physician's professional judgment.

This approach fails to acknowledge the real difference in the resources and level of care offered by hospital outpatient departments. There are certain services which simply cannot be furnished in a physician's office, as demonstrated by the fact that there is no nonfacility payment rate under the PFS for those services, and there are instances where a physician, in his or her judgment, would determine that a hospital outpatient department, not a physician's office, is the appropriate setting for a particular patient. This decision may be based on the patient's needs, the presence of comorbidities, or a desire for the resources available in an outpatient

department.² As a result, these departments typically care for higher acuity patients and can provide more complex care as compared to a physician's office.

The selection of the appropriate site of service for a particular patient's needs should be left to the discretion of the treating physician, and CMS's decision to cut reimbursement to all clinic visits furnished in excepted off-campus outpatient departments fails to give proper deference to physicians' judgments. Even more, the proposal's uniform treatment of all clinic visits furnished in excepted off-campus outpatient department underscores the fact that the proposal is not targeted at services that are actually "unnecessary," a logical prerequisite to invoking paragraph (t)(2)(F)'s authority.

Moreover, though the proposed rule is aimed at outpatient departments, it is *physicians* that largely make the decisions that drive the volume of outpatient services. As CMS acknowledged in its OPSS proposed rule for CY 1999, "to the extent that hospital outpatient volume is physician driven, an outpatient [sustainable growth rate (SGR)] could arguably be viewed as unnecessarily and unfairly penalizing facilities." 63 Fed. Reg. 47,552, 47,586. This disconnect is particularly clear in the context of clinic visits, the service that is the subject of this proposal, since physicians actually order these visits and outpatient departments are limited in their ability to control the volume of clinic visits.

The proposed payment cut for clinic visits furnished in excepted off-campus outpatient PBD threatens real harm to providers, some of which may be forced to choose between maintaining the off-campus PBD at a loss, reducing their scope of services, or shutting their doors entirely. The impact would be felt most by rural providers, which already operate at narrow margins and play a critical role in ensuring access to care in underserved communities, where there may be no reasonably available alternative providers or clinics. CMS's proposal contains no safeguards to ensure necessary services would continue to be offered by off-campus PBDs in the communities where they are most needed. The proposal is simply too blunt a tool for the problem CMS claims to have identified, and the FAH urges CMS to leave in place the careful distinction between reimbursement rates for excepted and non-excepted services selected by Congress and set out in Section 603.

Finally, the FAH objects to the use of the PFS relativity adjuster as a volume-control measure because the PFS relativity adjuster does not account in any way for the very real differences between the costs and value of services furnished in a hospital outpatient setting as compared to a physician office setting. CMS designated the Medicare PFS as the applicable payment system for nonexcepted, off-campus PBDs, and the PFS relativity adjuster is intended to adjust the OPSS rate to a Medicare PFS rate. In contrast, reimbursement under the OPSS is based on the relative resources expended in the hospital outpatient setting when furnishing various services or packages of services to Medicare beneficiaries. Congress has rightly designated the OPSS—not the PFS—as the applicable payment system for covered OPD services furnished in an excepted, off-campus PBD, and the PFS relativity adjuster is not an appropriate or useful tool for addressing any issues with the volume of covered OPD services. Moreover, as

² A hospital-based outpatient department must be clinically integrated with the hospital, and when the outpatient department's patients require further care, they must have "full access" to the hospital's services. 42 C.F.R. § 413.65(d)(2)

explained in the FAH's September 10, 2018 comment letter on the CY 2019 Medicare PFS proposed rule (CMS-1693-P), which is incorporated herein by reference, the PFS relativity adjuster also produces payment levels that fall below an approximated PFS rate because the methodology CMS used to establish the PFS relativity adjuster does not adequately incorporate the full practice expense portion under the PFS or account for packaging differences between the PFS and the OPPS.

3. CMS's proposed payment cut for excepted, off-campus PBDs is at odds with Congress' express determination in Section 603 that excepted, off-campus PBDs are entitled to full OPPS reimbursement.

Section 603 represents Congress's thoughtful consideration of MedPAC's recommendation to eliminate the difference in payment between hospital outpatient departments and physician's offices in certain circumstances, and CMS's proposal undermines the balance struck by Congress. Though the legislative history of Section 603 is scant, as noted in the proposed rule (83 Fed. Reg. 37046, 37148), the statute clearly reflects an understanding that under certain circumstances, the services provided in outpatient departments typically involve higher acuity patients and more complex episodes of care as compared to services provided in a physician's office, such that the higher reimbursement rate under the OPPS is appropriate. The statute, as amended by the 21st Century Cures Act, also recognizes that hospitals had lawfully made significant investments in existing PBDs and mid-build PBDs based on existing law. To this end, Congress expressly excepted PBDs located on the hospital campus or within 250 yards of a remote location as well as PBDs that provided covered OPD services on or before November 2, 2015 or met the mid-build requirements.

CMS's proposal, however, would essentially reimburse services described by HCPCS code G0463 and billed with the "PO" modifier as if they were billed by a non-excepted PBD. The proposal would thus improperly erode the express choices that Congress made in passing Section 603. Providing context for its proposal, CMS observes, "While the changes required by the section 603 amendments . . . address some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting, the majority of hospital off-campus departments continue to receive full OPPS payment . . . which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting." 83 Fed. Reg. 37,046, 37,141. But this is not a problem to be solved by rulemaking; this simply describes the policy choice Congress made in Section 603. Congress clearly could have chosen to cut reimbursement rates for excepted services, too, but opted not to do so, and an effort to reverse this decision through rulemaking is in direct conflict with the statute and in excess of CMS's statutory authority.

4. Regardless of whether this proposal is a "method to control volume" within the meaning of 42 U.S.C., section 1395l(t)(2)(F), it is an "adjustment" that is subject to the statute's budget neutrality requirement.

The FAH believes that, in addition to being deeply flawed and unlawful, the proposed payment cut for services described by HCPCS code G0463 and billed with the "PO" modifier is an adjustment under section 42 U.S.C. § 1395l(t)(2) that could only be implemented in a budget neutral manner in accordance with the strict requirements of subsection (t)(9)(B). *Therefore, if*

CMS implements any variation on the proposed payment cut despite the foregoing concerns, the FAH strongly urges CMS to do so in a budget neutral manner, as required by statute.

As CMS has previously observed, the “OPPS is a budget neutral payment system.” 82 Fed. Reg. 59,216, 59,484. Accordingly, CMS “has maintained budget neutrality through offsetting estimated payment decreases/increases within the OPPS, such as by increasing/decreasing the conversion factor by an equal offsetting amount.” *Id.*; *see also* 67 Fed. Reg. 66718, 66754 (“With respect to budget neutrality, [42 U.S.C. § 1395l(t)(9)(B)] makes clear that any adjustments to the OPPS made by the Secretary may not cause estimated expenditures to increase or decrease.”); *e.g.*, 71 Fed. Reg. 49506, 49533 (42 U.S.C. § 1395l(t)(9)(B) “requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a manner that assures that aggregate payments under the OPPS for [the coming calendar year] are neither greater than nor less than the aggregate payments that would have been made without the changes.”); 72 Fed. Reg. 42628, 42647 (same); 72 Fed. Reg. 66580, 66610 (same); 73 Fed. Reg. 41416, 41452 (same).

The requirement of budget neutrality derives largely from 42 U.S.C. § 1395l(t)(9)(B), which requires that “adjustments” under § 1395l(t)(9)(A) “not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made.” The referenced adjustments described in § 1395l(t)(9)(A) expressly include “other adjustments described in paragraph (2)” (*i.e.*, § 1395l(t)(2)). Notably, the referenced adjustments are not restricted to adjustments under § 1395l(t)(2)(D) and (E); instead, any “adjustment” under subsection (t)(2) constitutes an adjustment under subsection (t)(9)(A). Thus, if CMS develops “a method for controlling unnecessary increases in the volume” of covered outpatient department services and that particular method constitutes an “adjustment,” then the provisions of subsection (t)(9)(B) are plainly applicable to that method.

In the Proposed Rule, however, CMS appears to advance the radical argument that a payment cut is only an “adjustment” for purposes of § 1395l(t)(9)(A) if the statutory authority for that payment cut in subparagraph (t)(2) uses the word “adjustment.” Thus, CMS contends that “section [§ 1395l(t)(2)(F)] is not an ‘adjustment’ . . . [because it] refers to a ‘method’ for controlling unnecessary increases in the volume of covered [outpatient department] services, not an adjustment.” 83 Fed. Reg. at 37,142. In advancing this position, CMS essentially argues that the applicability of the budget neutrality provision is determined by whether the statutory provision under which a policy is implemented uses the word “adjustment” instead of whether the policy under review actually constitutes an adjustment. Had Congress intended to limit the budget neutrality provision based on the underlying legal authority for a policy rather than the nature of the policy itself, it would have done so by referencing “other adjustments described in paragraph (2)(D) or (E).” Instead, however, the statute broadly references any “other adjustments described in paragraph (2),” thereby including a method to control volume described in paragraph (2)(F) insofar as the particular method at issue constitutes an adjustment.

Based on the statutory language, it is the FAH’s position that, although there are some volume-control methods that are not “adjustments,” a particular volume-control “method” may qualify as an “adjustment” and therefore be subject to budget neutrality requirements. ***A payment cut like the one at issue here is unequivocally an adjustment as it reduces (adjusts)***

the OPPS payment rate for covered outpatient department services described by HCPCS code G0463 and billed with the “PO” modifier. Indeed, CMS itself identifies the payment change as an adjustment because the payment rate was determined by multiplying the PFS relativity adjuster by the full OPPS payment for a clinic visit. CMS states “[f]or a discussion of the PFS relativity adjuster that will now also be used to pay for all outpatient clinic visits provided at all off-campus PBD...” 83 Fed Reg 37,142. The product of the PFS adjuster and the full OPPS payment constitutes the “adjusted payment amount” while the reduction to the full OPPS payment is the amount of the “adjustment.”

On the other hand, there are other types of methods for controlling unnecessary increases in volume that would not constitute adjustments, some of which are briefly broached in the Proposed Rule. Because of the range of “methods” that could be employed to control unnecessary increases in volume, it is entirely sensible that Congress used the term “method” in subsection (t)(2)(F), but nonetheless required that any “adjustment” under (t)(2) be subject to budget neutrality requirements under subsection (t)(9)(B).

The language of § 1395l(t)(9)(C) does not alter the foregoing analysis. Subsection (t)(9)(C) authorizes CMS to “appropriately adjust the update to the conversion factor” if it “determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies.” This language does not speak to whether a method authorized solely under subsection (t)(2)(F) must be budget neutral; rather, it establishes separate authority for adjusting the update to the conversion factor if the volume of services increases beyond the amounts established under subsection (t)(2)(F). If, as CMS asserts, subsection (t)(2)(F) itself authorizes implementation of a non-budget neutral adjustment, Congress would have had no need to adopt subsection (t)(9)(C) because it would be redundant with subsection (t)(2)(F).

CMS’s past proposals to control volume confirm that subsections (t)(2)(F) and (t)(9)(C) serve different purposes and that subsection (t)(2)(F) does not provide statutory authority to control volume through a non-budget neutral adjustment. In 1998, CMS proposed expanding the sustainable growth rate (SGR) system for physician services to the hospital outpatient setting. Under this proposal, CMS would have set target volume and intensity growth allowances under the OPPS in accordance with subsection (t)(2)(F) and then, if volume increases cause expenditures to exceed the target amount, lower the annual update to the conversion factor accordingly, consistent with subsection (t)(9)(C) (at that time found at subsection (t)(6)(C)). 63 Fed. Reg. at 47,586 – 87 (Sep. 8, 1998). This proposal was rightly rejected because of its likely undesirable effects. 72 Fed. Reg. 66,580, 66,613. Nonetheless, this rejected SGR proposal reflects the potential interplay between subsections (t)(2)(F) and (t)(9)(C) where subsection (t)(2)(F) is used to set volume targets and subsection (t)(9)(C) is used to implement a non-budget neutral adjustment. In contrast, the instant proposal is a payment adjustment that does not fit within the parameters of subsection (t)(9)(C) and is therefore subject to the budget neutrality requirements of subsection (t)(9)(B).

Lastly, CMS’s contention that a budget neutral adjustment under subsection (t)(2)(F) “would not appropriately reduce the overall unnecessary volume of covered OPD services,” 83 Fed. Reg. at 37,143, is not the relevant point. Subsection (t)(2)(F) does not authorize CMS to “reduce the overall unnecessary volume of covered OPD services.” Instead, it authorizes CMS

to develop a method for “controlling unnecessary increases in the volume of covered OPD services” (emphasis added). It is section 1833(t)(9)(C) that authorizes a change to payment but only when volume of services paid increases beyond those established by the Secretary using the method established under 1833(t)(2)(F). ***Because CMS’s proposal exceeds the scope of its statutory authority and risks significant harms, the FAH strongly urges CMS to not finalize the proposed rate cut for services described by HCPCS code G0463 and billed with the “PO” modifier. Moreover, any future adjustments that are proposed to be adopted as volume-control methods under subsection (t)(2)(F) must be implemented in a budget neutral manner.***

Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

The FHA strongly opposes CMS’s renewed proposal to restrict the expansion of clinical families of services at excepted PBDs, reiterating our prior objections to the proposal and noting the absence of any information indicating that this burdensome policy is now warranted or appropriate. Previously, CMS agreed that this proposed policy “could be operationally complex and could pose an administrative burden to hospitals, CMS, and [CMS] contractors to identify, track, and monitor billing for clinical services.” 81 Fed. Reg. 79,707. Accordingly, CMS rejected the proposed clinical families of services policy for CY 2017 and declined to advance a similar policy for CY 2018, noting that “[a]ny future proposal on service expansion would need to be practicable and take into consideration the administrative burden on providers and the Federal Government,” 82 Fed. Reg. at 33,647. Moreover, CMS indicated that it would “monitor service line growth” before proposing any future limits on the expansion of clinical families of services at excepted PBDs. 81 Fed. Reg. at 79,707; see also 82 Fed. Reg. at 33,647; 82 Fed. Reg. at 59,367. In the Proposed Rule, however, CMS presents no data indicating that there has been service line growth among excepted, off-campus PBDs that warrants any policy response. In addition, CMS provides no explanation—let alone a reasoned explanation—as to why a previously unworkable and unduly burdensome policy would now be appropriate and practicable.

The CY 2019 clinical families proposal only differs from the rejected CY 2017 proposal in that (1) it uses a shorter baseline period (one year) and (2) it provides for an alternative baseline period for excepted PBDs (including mid-build PBDs) to cover the first year of claims data. As noted above, the FAH objects to this proposal outright and asks that CMS not finalize it. If CMS were to finalize the proposal, the FAH believes the accommodation for PBDs that were relatively new at the time Section 603 was enacted or that were mid-build on the date of enactment are insufficient. The FAH continues to urge CMS to adopt a robust exceptions process that would be available where the baseline period does not appropriately capture the range of services furnished in an excepted PBD. For example, a hospital with a large, off-campus PBD might have been mid-build on a physical renovation of the PBD to accommodate the addition of a new service line (e.g., major imaging services) as of November 2, 2015. Under CMS’s proposal, the new imaging services would be billed with the “PN” modifier because the PBD was generally in operation during the year prior to November 2, 2015 and no major imaging services were provided. This result would be inequitable and in tension with Congress’ specific allowance for mid-build PBDs. The FAH, therefore, strongly urges CMS to, at a

minimum, adopt a robust exceptions process to address situations where service types furnished during the baseline period are inconsistent with the excepted PBD's actual range of services.

Even with the addition of a robust exceptions process, however, CMS's clinical families proposal is unworkable. The differences between the CY 2017 and CY 2019 clinical families proposals are relatively minor and do not address the significant administrative burdens of the policy or make it sufficiently practicable. For example, as the FAH has previously noted, CMS periodically rennumbers and revises APCs, the American Medical Association modifies HCPCS codes on a regular basis, and CMS reassigns HCPCS codes to different Ambulatory Payment Classifications (APC) and/or status indicators from time to time. As a result, crosswalking claims data for services furnished during a baseline period to the proposed listing of clinical families is a burdensome process.

Based on the fact that the APCs used in the proposed rule to define clinical families did not exist in the baseline period and that there have now been 4 to 5 years of coding changes since the baseline period, the FAH believes it will be virtually impossible for hospitals to correctly determine what services are considered service line expansions. There is simply no meaningful comparison between the 2019 APC codes and the baseline period. A simple comparison of the HCPCS codes in the 2015 and 2019 addendum B files indicates that 495 codes in the 2015 file are no longer active in the 2019 file and 1361 codes in the 2019 file were not active in the 2015 file. For example, the proposed clinical family for Minor Imaging includes four 2019 APCs (5521, 5522, 5591, 5592) which include 297 HCPCS codes of which 28 were not effective in 2015. The HCPCS codes which were active in 2015 map to 31 different APCs. There are 470 HCPCS included in those 31 APCs for 2015 of which 445 are still active in 2019 and correspond to 19 APCs and 6 different clinical families. Likewise, it will be difficult to keep the list of APCs and clinical families dynamic, appropriate, and predictable on a prospective basis.

In short, the clinical families process remains operationally complex and administratively burdensome. Moreover, a provider that offers services in both new and old clinical families in an individual, off-campus PBD would have the operationally difficult and burdensome responsibility to identify and append the correct modifier to each applicable claim line. Implementation of the proposal is further complicated by apparent gaps among the APCs identified with the various, proposed clinical families. For example, APC 5401, which includes certain dialysis services, does not fall within any of the listed clinical families, and therefore, under the Proposed Rule, would always be billed with the "PN" modifier. Thus, an excepted outpatient PBD that had provided dialysis services before November 2, 2015 and continued to do so today would be required to bill dialysis as a nonexcepted service despite Congress' explicit instruction that such facility be excepted and eligible for OPSS payment.

Last, the FAH continues to maintain that service line limitations on OPSS-reimbursable services furnished in excepted PBDs are not permissible under 42 U.S.C. § 1395l(t)(21)(B). As the FAH has emphasized in past comments, the statute excepts the entirety of a PBD, not individual service lines within a PBD. In the Proposed Rule, CMS states that it does "not believe that Congress intended to allow for new service lines to be paid OPSS rates because providing for such payment would allow for excepted off-campus PBDs to be paid higher rates for types of

services that they were not performing prior to enactment of the Bipartisan Budget Act of 2015 that would be paid at lower rates if performed in a nonexcepted PBD.” 83 Fed. Reg. at 37,148. This belief, however, has no foundation in the text, which only restricts OPSS payment for an applicable item or service based on the *location* where that service is furnished. *See* 42 U.S.C. § 1395l(t)(1)(B)(v) (covered OPD services “does not include applicable items and services . . . that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider”). Along the same lines, the statute excepts the entirety of a department under subsection (t)(21)(B)(ii) if “the department . . . was billing under [the OPSS] with respect to covered OPD services furnished prior to” November 2, 2015. Congress simply did not bar OPSS payment for new service types furnished in excepted, off-campus PBDs. Although CMS has repeatedly asserted its authority to bar OPSS payment for particular services furnished in an excepted, off-campus PBD, this position is not supported by the statutory text, and CMS’s belief that Congress must have intended something different from what Congress did is simply unavailing.

In the end, the FAH strongly urges CMS to continue monitoring provider behavior with respect to off-campus PBDs over the coming years in ways that do not unreasonably burden hospitals or patients and, in the interim, to forego the clinical families proposal or any other policy that would impose additional restrictions on excepted PBDs. ***The FAH reiterates its concerns that limiting the types of services furnished by excepted PBDs and reimbursable under OPSS would run contrary to Congress’ direction, is unworkable, and would be administratively burdensome.*** These issues are explained further in the FAH’s September 6, 2016 comment letter on the CY 2017 OPSS proposed rule (CMS-1656-P), January 3, 2017 comment letter on the CY 2017 OPSS final rule with comment period (CMS-1656-FC), and September 11, 2017 comment letter on the CY 2018 OPSS proposed rule (CMS-1656-P) each of which are incorporated herein by reference. ***Based on the foregoing, the FAH respectfully urges CMS to decline to implement any service line limitations for excepted PBDs, recognizing that Congress’ intended to curtail the creation of new PBDs rather than limit the operation of existing or mid-build PBDs.***

Proposed Payment for Partial Hospitalization Services

The FAH urges CMS to adopt a clear policy that the provisions of Section 603 of the Bipartisan Budget Act of 2015, 42 U.S.C. § 1395l(t)(21), and the implementing regulation do not apply to Partial Hospitalization Programs (PHP). We are in the midst of well-recognized opioid and suicide crises, with drug overdoses rates at an all-time high and suicides rates at a 30-year high. Partial hospitalization is a critical and cost-effective level of care for Medicare beneficiaries living with mental illnesses and substance use disorders, and there is no comparable “physician office” service. Failure to implement an exception will effectively place a moratorium on new PHPs, compromising access to needed treatment in the midst of these epidemics. These issues are explained further in the FAH’s September 6, 2016 comment letter on the CY 2017 OPSS proposed rule (CMS-1656-P), which is incorporated herein by reference.

The FAH further notes that CMS’s proposal to limit the expansion of clinical families of services at excepted off-campus PBDs would intensify rather than moderate the impact of

Section 603 on PHPs, limiting access to these critical mental health services. CMS has proposed that OPSS reimbursement would be unavailable for any service that does not fall within a clinical family of services that was being furnished in an excepted off-campus PBD prior to November 2, 2015. This proposal would essentially eliminate OPSS reimbursement for all PHPs in the community because the APCs used by PHPs are wholly omitted from the listing of clinical families proposed in Table 32 of the Proposed Rule. PHPs in the community (*i.e.*, off-campus PHPs) would thus be universally reimbursed as nonexcepted services and paid at the inadequate and inappropriate rate for Community Mental Health Centers (CMHCs). We continue to be very concerned that application of the CMHC rate to provider-based PHPs will unreasonably cut the reimbursement rate for PHP services. (As the FAH has previously noted, the CMHC rate is based on an analysis of the 44 CMHCs in the PHP claims data file, meaning that a few outlier CMHCs can skew the rate. By comparison, hospital-based PHP rates are based on claims from nearly 400 programs.)

An effective response to the opioid epidemic requires payment for the full continuum of care and partial hospitalization is included in the American Society of Addiction Medicine’s (ASAM) treatment continuum. But, CMS’s current approach puts the continued viability of this level of care, a statutory benefit for Medicare beneficiaries, at risk. The FAH is concerned that if this level of care is eliminated, individuals with substance use disorder will no longer be able to enter treatment at their clinically appropriate level of care. The scientific literature on substance use disorder (SUD) treatment is clear that different levels of care are not clinically interchangeable. If patients do not receive the level of care they need, they will likely drop out of services, relapse, overdose, or even die. There is little room for error in this high-stakes opioid epidemic.

Proposed Adjustment for Rural Sole Community Hospitals and Essential Access Community Hospitals

FAH supports CMS’s proposal to provide this important payment adjustment. These hospitals are typically the chief, if not sole, source of community outpatient care for rural residents and this adjustment is vital to ensuring continued access to the care they need.

Proposed OPSS Payment for Devices: Device-Intensive Procedures

While the FAH generally supports the modifications to the device-intensive procedure criteria that CMS has proposed for CY 2019, we believe that CMS has included several Current Procedural Technology (CPT)/HCPCS codes that do not always involve implantable/insertable single-use devices. Many CPT/HCPCS code descriptions include language such as “when performed” or “with or without” that indicate that the CPT/HCPCS code is used for varying procedures. Other CPT/HCPCS codes include the term “revision” in the description and many of these codes involve procedures where a previously implanted device is removed and reinserted and therefore do not involve a charge for a new device. We believe that CMS has inappropriately included several of these types of codes in the proposed expansion of CPT/HCPCS codes subject to device-intensive policies. Many of the procedures with this language allow use of the CPT/HCPCS code when a device is not required for the procedure. Below is an illustrative list of

20 such codes from Addendum P that can be performed without use of a single-use device during the procedure. Since CMS applies device edits that require reporting of a device HCPCS “C” code on the claim when a device-intensive procedure HCPCS/CPT is present, this will create claims processing issues for procedures that do not involve use of a device.

To prevent these issues and ensure hospitals are appropriately paid for these procedures when devices are not used, CMS must modify its proposal. The FAH believes the following options should be considered:

- Exclude these procedures (and other HCPCS/CPT codes that do not always require use of a device) from the device-intensive policies, or
- Include these procedures (and other HCPCS/CPT codes that do not always require use of a device) in all of the device-intensive policies **except** the device edit requirements, or
- Implement a new HCPCS code for providers to report without a charge (or with a token charge) that indicates an applicable device was not used for the procedure.

In addition, we believe that CMS has erroneously included some CPT/HCPCS codes such as CPT code 86891 for autologous blood collection that will not involve insertion or implantation of a device. It is important that CMS consider the codes clinically rather than making decisions solely based on cost data. The FAH urges CMS to thoughtfully consider its proposed list of device-intensive CPT/HCPCS codes and make appropriate modifications to its proposal before implementing the proposed changes to ensure that hospitals continue to be able to submit and receive payment for procedures that do not involve the insertion or implantation of a device.

HCPCS	Long Descriptor
23585	Open treatment of scapular fracture (body, glenoid or acromion) includes internal fixation, when performed
24685	Open treatment of ulnar fracture, proximal end (eg, olecranon or coronoid process[es]), includes internal fixation, when performed
27784	Open treatment of proximal fibula or shaft fracture, includes internal fixation, when performed
28485	Open treatment of metatarsal fracture, includes internal fixation, when performed, each
27792	Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed
28555	Open treatment of tarsal bone dislocation, includes internal fixation, when performed
24575	Open treatment of humeral epicondylar fracture, medial or lateral, includes internal fixation, when performed
27814	Open treatment of bimalleolar ankle fracture (eg, lateral and medial malleoli, or lateral and posterior malleoli, or medial and posterior malleoli), includes internal fixation, when performed

28300	Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation
25525	Open treatment of radial shaft fracture, includes internal fixation, when performed, and closed treatment of distal radioulnar joint dislocation (Galeazzi fracture/ dislocation), includes percutaneous skeletal fixation, when performed
27822	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; without fixation of posterior lip
25515	Open treatment of radial shaft fracture, includes internal fixation, when performed
28465	Open treatment of tarsal bone fracture (except talus and calcaneus), includes internal fixation, when performed, each
24579	Open treatment of humeral condylar fracture, medial or lateral, includes internal fixation, when performed
28615	Open treatment of tarsometatarsal joint dislocation, includes internal fixation, when performed
28445	Open treatment of talus fracture, includes internal fixation, when performed
23515	Open treatment of clavicular fracture, includes internal fixation, when performed
23680	Open treatment of shoulder dislocation, with surgical or anatomical neck fracture, includes internal fixation, when performed
27832	Open treatment of proximal tibiofibular joint dislocation, includes internal fixation, when performed, or with excision of proximal fibula
62350	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy

Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

Payment for Drugs Acquired Through the 340B Program

In the CY 2019 Proposed Rule, CMS proposes to largely keep in place the 340B Program policies it finalized and implemented in CY 2018. Under that policy CMS adjusted the rate for separately payable drugs and biologicals (other than drugs on pass-through status and vaccines) acquired by a hospital outpatient department under the 340B program to ASP minus 22.5 percent. To ensure budget neutrality within the OPPS payment system, CMS then applied to the OPPS conversion factor savings resulting from the policy. CMS further excepted rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals from the 340B payment adjustment. In addition, CMS paid for drugs that were not purchased through a 340B discount at ASP+6 percent.

The FAH fully supports CMS's proposed 340B payment policy and agrees that it is an appropriate action by the Secretary. In addition, the FAH appreciates the decision in the CY 2018 Final Rule, and again proposed for 2019, to maintain budget neutrality under OPSS, which we believe the statute requires, and to increase the conversion factor by an amount commensurate with the savings generated by the 340B payment adjustment. Finally, FAH supports CMS's proposal to continue to pay for drugs or biologicals that were not purchased with a 340B discount at ASP+6 percent.

CMS notes various beneficiary and Medicare program benefits arising from its policy including reduced copayments, especially for cancer patients, and a more efficient program that better aligns payment and cost. Our preliminary analysis also indicates a widespread benefit across a vast majority of hospitals paid under the OPSS. For example, some 2800 hospitals - 80 percent of all hospitals paid under the OPSS - would experience a net increase in payment in 2019 under CMS's 340B payment policy, compared to only 578 hospitals that would experience a net reduction in payments. 89 percent of rural hospitals would have higher payments. This is especially important as rural hospitals serve as a vital lifeline for outpatient care in the communities they serve, and struggle with Medicare OPSS payments that fall well below the cost of care.

Payments increase for 74 percent of government hospitals, and almost half of 340B hospitals - 43 percent - would have higher payments from CMS's decision to apply to the conversion factor the savings from the 340B payment adjustment. Accordingly, the FAH urges CMS to finalize its proposed policies regarding drugs purchased under the 340B program as well as drugs not purchased under the program.

Wholesale Acquisition Cost (WAC)-based Payments

CMS proposes to reduce payment for certain Part B drugs when average sales price (ASP) data is unavailable and when WAC data is used for reimbursement, per the statute, until ASP data becomes available. Under current regulation, for drugs when ASP price data is unavailable during the first quarter of sales, the Part B payment is determined as the WAC plus an add-on percentage of 6 percent. CMS proposes to reduce the add-on payment for these drugs to 3 percent. **The FAH opposes CMS's proposal to reduce reimbursement for these drugs.**

The current formula for reimbursing this special set of Part B drugs at WAC plus 6 percent is appropriate and is working and there is little to no evidence that physicians are making prescribing decisions to maximize reimbursement. The current formula accounts for both provider acquisition costs and the additional costs associated with the complexity of Part B drugs including shipping fees, administration, and complicated storage and handling requirements.

In addition, the proposed reduction of the add-on payment to 3 percent is arbitrary and based on data analysis from third-party sources and not a review conducted by CMS.

Proposed CY 2019 Packaging Policy for Non-Opioid Pain Management Treatments

We agree with CMS's desire to support the use of non-opioid pain management drugs. To further that shared goal, we encourage CMS to adopt the policy it proposes of providing

separate payment for non-opioid pain management drugs that function as a supply when used in surgical procedures when the procedure is performed in an ASC to those same surgical procedures performed in the hospital outpatient setting. While the use of non-opioid pain management drugs in the outpatient setting may have modestly increased, these drugs are only used in a very small percentage of all surgical procedures. Applying to hospital outpatient departments the same separate payment policy it proposed for ASCs will spur broader use of non-opioid pain management drugs and help hospitals achieve even greater success.

Chimeric Antigen Receptor T-Cell (CAR-T) Therapy Category III CPT Code Status Indicators and APC Assignments

The FAH supports the Hospital Outpatient Panel's (HOP) recommendation to change the status indicators for the four new Category III CAR-T CPT codes from "B" to "S". In order to do this, we recognize that CAR-T cell collection and cell processing and preparation services will need to be removed from the CAR-T product Q-codes (Q2040 and Q2041), which we understand is under the purview of the HCPCS Workgroup. Therefore, we urge the HCPCS Workgroup to make the necessary changes as outlined further below.

We understand that in the absence of specific service CPT codes, CMS and the CAR-T manufacturers may have thought it appropriate to embed patient cell collection and preparation and processing services into the product Q-codes. Now that the American Medical Association's (AMA's) CPT Editorial Panel has released specific codes for CAR-T cell collection and cell processing and preparation procedures for implementation beginning January 1, 2019, we believe the HCPCS Coding Committee has a new, clear rationale for removing these patient clinical services from HCPCS codes Q2040 and Q2041. In so doing, these codes will represent the CAR-T living drug product only and will enable providers to code, bill, and be paid for the drug separately from the patient clinical services provided in support of CAR-T therapy.

Therefore, the FAH requests the HCPCS Workgroup adopt the recommendations presented by the public at the May 2018 HCPCS meeting which specifically requested the removal of patient clinical services from the existing CAR-T Q-codes, Q2040 and Q2041. The FAH further requests that CMS make the complementary and consistent decision to assign status indicator "S" instead of "B" to 05X1T, 05X2T, and 05X3T.

Separate from the issues outlined for the three new CAR-T CPT codes described above, we do not understand why CMS assigned status indicator "B" to the new CAR-T infusion code 05X4T since infusion is not included in the description of the product Q-codes. We believe this may have been an oversight since correct CPT coding guidelines require coding to the highest level of specificity, which, starting on January 1, 2019, would mean that this code be reported for outpatient CAR-T infusion rather than an unlisted code or some other approximate code. Therefore, since a specific CAR-T infusion administration code (05X4T) will be available starting January 1, 2019, we urge CMS assign it status indicator "S" and, in addition, work with its Medicare Administrative Contractors to ensure this code and the other CAR-T Category III CPT codes are recognized in local contractor policies.

While CAR-T therapy is different from stem cell transplants, we believe that until coded claims data are available, this recommended process presents the best mapping of the new CAR-T services and codes based on clinical and resource homogeneity. Accordingly, we recommend CMS cross-walk the new Category III CAR-T CPT codes to stem cell transplant services in the manner recommended by the Hospital Outpatient Payment (HOP) Panel. Assigning payable status indicators to these services will enable CMS to pay hospitals appropriately for services provided during each step of the CAR-T process. It will also enable the agency to collect data on this important new service both for tracking purposes and for future rate-setting.

In summary, now that the AMA has finalized new Category III CPT codes for CAR-T services, we urge CMS to do the following:

- Change the descriptions of the HCPCS CAR-T product Q-codes (Q2040 and Q2041) so that these codes only represent the CAR-T drug and no longer include the collection of cells or processing and preparation services
- Assign status indicator “S” to the four new Category III CAR-T CPT codes released by the AMA for implementation starting January 1, 2019

Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

The FAH commends CMS for its proposed application of the Meaningful Measures initiative to the hospital outpatient quality reporting program. Prioritizing and reducing the number of quality measures addresses our previously expressed concerns about the burden of managing many measures. The FAH supports a focus on measures designed specifically for improving patient care and working towards meaningful patient outcomes.

CMS is proposing to adopt an eighth removal factor to consider when evaluating measures for removal from the Hospital OQR measure set. Factor 8 would serve to remove measures where “the costs associated with a measure outweigh the benefit of its continued use in the program” as has been done for the Inpatient Quality Reporting (IQR) Program, Inpatient Rehabilitation Facility (IRF) Quality Reporting Program, and Skilled Nursing Facility Quality Reporting Program (SNF QRP). The FAH supports the proposal to add an eighth factor to the lists of factors used for considering removal of measures from the Hospital OQR Program. This proposed new factor is appropriate for moving toward measure sets that meet the goal of streamlining measures with a focus on those that will work toward the best outcomes for patients.

The FAH has long advocated for recognition of the costs associated with data collection and submission and appreciates that CMS has identified them as costs for consideration when undertaking an overall review of a measure. In addition, the FAH strongly recommends that CMS also consider the costs associated with tracking performance and investing resources for quality improvement. It would be useful for CMS to clarify in the Final Rule the nature of the burden that the removal of a measure relieves, and methods or criteria used to assess when the measure cost or burden outweighs the benefits of retaining it such as investment variation by measure or burden of measure tracking.

In addition, the FAH would like to propose that for next year's rulemaking, CMS consider the addition of a ninth removal factor that considers the loss of NQF endorsement. A measure that loses National Quality Forum (NQF) endorsement should be summarily considered for removal regardless of whether any of the other removal factors apply. FAH believes that the NQF provides a rigorous and thorough review of measures against the measure evaluation criteria as it involves a comprehensive assessment of the measure to ensure its currency with the evidence, ability to drive improvements in patient outcomes, feasibility, reliability, validity and current use. Decisions made by this endorsement body should be considered and prioritized by CMS. The FAH also requests that CMS include in any announcement of the removal of a measure for a CMS program, the reason the measure lost the NQF's endorsement.

Hospital OQR Program Quality Measures

CMS is proposing to remove 10 measures from the OQR program; one beginning with the 2020 payment determination, and the others beginning with the 2021 payment year. The FAH supports the proposed removal of the identified ten measures from the OQR Program.

OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

The FAH supports removal of this measure beginning with the 2020 payment determination given that the burden of collecting and reporting for this measure outweighs its benefits. This measure is also reported for the IQR Program, capturing most of the hospital personnel and as noted in the proposed rule, many hospital outpatient departments (HOPD) only participate in the Centers for Disease Control and Prevention National Healthcare Safety Network (NHSN) in order to report this measure.

OP-5: Median Time to ECG (NQF #0289)

The FAH supports removal of this measure beginning with the 2021 payment determination due to its loss of NQF endorsement and that the burden of collecting data for this chart-abstraction measure far exceeds the value provided with its reporting. NQF removed endorsement due to the lack of a demonstrated link that measuring median times to ECGs can positive impact patient outcomes. The FAH strongly encourages CMS to continue to evaluate all of the measures in the OQR and other federal programs to ensure that only those measures that demonstrate this ability to drive improvements be included in the future.

OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)

The FAH supports removal of this measure beginning with the 2021 payment determination period. The measure allows for providers to utilize different surveys, limiting its validity. In addition, the burden and cost of collecting this measure far exceeds the limited value provided with its reporting. FAH would note that this measure was developed for physician and group use and testing was not provided to NQF to demonstrate the reliability and validity of reporting at the facility level. This lack of alignment between the intended and actual use may have contributed to these data collection challenges. The FAH strongly encourages CMS to only

consider those measures for which the specifications and testing demonstrate that the results are reliable and valid and is appropriate for its intended use.

OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)

OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps -Avoidance of Inappropriate Use (NQF #0659)

The FAH supports removing both these measures beginning with the 2021 payment determination period as the cost of collecting this data through chart abstractions exceeds the value derived from reporting on them. FAH would note that these measures were developed for physician and group use and testing was not provided to NQF to demonstrate the reliability and validity of reporting at the facility level. This lack of alignment between the intended and actual use may have contributed to these data collection challenges. FAH strongly encourages CMS to only consider those measures for which the specifications and testing demonstrate that the results are reliable and valid and is appropriate for its intended use.

OP-9: Mammography Follow-up Rates

The FAH supports removing this measure beginning with the 2021 payment determination period on the basis of its mis-alignment with current clinical guidelines and research.

OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513)

OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT

The FAH supports the removal of this measure beginning with the 2021 payment determination period on the basis of the measure achieving overall high performance. This removal will enable facilities to focus data collection and quality improvement efforts on other important processes and outcomes.

OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data

OP-17: Tracking Clinical Results between Visits

The FAH supports the removal of these measures beginning with the 2021 payment determination period due to the loss of NQF endorsement and lack of correlation with better patient outcomes. NQF removed endorsement due to the lack of sufficient testing for reliability and validity. FAH strongly encourages CMS to continue to evaluate all of the measures in the OQR and other federal programs to ensure that only those measures that can drive improvements in patient outcomes and demonstrate reliable and valid results are included in the future.

Impact to Hospital Overall Star Ratings

The removal of some measures from the OQR program raises the question of the impact to the Hospital Overall Star Ratings. The five measures that are currently proposed for removal from OQR that would impact the Hospital Overall Star Ratings are:

- OP-5, Median Time to electrocardiogram
- OP-14, Simultaneous use of brain CT and Sinus CT
- OP-27, Influenza Vaccination Coverage among Healthcare Personnel
- OP-29, Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
- OP-30, Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

The FAH requests that, in the final rule, CMS discuss the impact of the removals on the Hospital Overall Star Ratings. If the intent is to remove the measures from the star ratings, the FAH requests that CMS conduct and release an analysis of the impact to star ratings as a result of the removal of these measures prior to the implementation of the removal proposal. The industry needs to have an understanding of the impact on Star Ratings prior to it going into effect and being publicly posted.

Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

CMS is proposing to update the frequency with which they would release the Hospital OQR Program Specifications Manual to occur every 6 to 12 months beginning with CY 2019 and for subsequent years. Currently CMS releases the Hospital Outpatient Quality Reporting Specifications Manual every six months, releasing addenda as necessary.

While the FAH supports the release of the Specifications Manuals only when there are substantive changes to publish, the FAH is concerned that making manual releases less predictable will cause confusion for Hospital OQR participants as to whether a Specifications Manual was or was not updated during a given 6-month period. For this reason, the FAH requests that CMS continue to be held periodically accountable and retain the 6-month schedule, with specified dates, of either releasing an updated Specifications Manual or notifying hospitals and vendors if no update to the Specifications Manual occurred during that period.

Extension of Reporting Period for OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

CMS proposes to extend the reporting period the claims-based measure OP-32 from 1-year to 3-years. The FAH concurs that changing from 1 to 3 years provides for a small increase of the included facilities to have scores measured with higher reliability. However, the five percent increase in the number of HOPDs with eligible cases is not substantial enough given that a three--year reporting period makes the data impractical and meaningless to inform quality improvement efforts. Any data older than nine to twelve months from its date of service, in this context, creates a challenge for quality improvement. Clinicians are commonly unpersuaded by

data that is not timely as they do not believe it reflects improvements that have been implemented in the interim and thus does not demonstrate current performance. It is substantially more difficult to influence meaningful change in a hospital using data that is three to five years old.

Finally, the FAH members suggest that the resources spent on trying to evaluate this longer time period would be better spent on evaluating how to increase the reporting frequency to quarterly from the current annual schedule. More time reporting will allow hospitals to evaluate if actions taken are improving the quality of care provided to patients and the outcome of that care.

Proposed Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

CMS is proposing the removal of the three Communication About Pain questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measures beginning with 2022 discharges.

The FAH understands that there is reason for concern with regards to the pain questions. Firstly, the current pain questions never received NQF endorsement. Secondly, although the current pain questions positively correlate with overall patient satisfaction as CMS indicated in the FY18 IPPS/LTCH Proposed Rule (81 FR 20037), our members have found these values to be so low as to not substantially influence the overall measures.

The FAH strongly believes that these changes to the HCAHPS Survey warrant overall impact modeling and review by NQF to evaluate the impacts on the overall performance of the composite. The FAH urges CMS that regardless of their final rule, whether they decide to remove the pain questions or retain them, that they submit the HCAHPS and the Pain Communication Questions respectively for NQF endorsement. The FAH would like to see a model of the impact of the removal of these measures on the overall HCAHPS scores and Hospital Star Ratings. Removal or changes in the HCAHPS measures without this consideration undermines the validity and reliability of the original instrument.

The FAH further believes that it is vitally important that CMS take this opportunity to develop an updated HCAHPS system rather than to continually edit the existing one. The data on which the HCAHPS survey was built is now dated and the patient experience and healthcare landscapes have vastly changed. Consideration of the opioid epidemic is only one of the necessary changes. It is time for CMS to re-evaluate all the domains and questions currently in the HCAHPS. In addition, the HCAHPS survey is dated due to the absence of an electronic mode of survey deployment and the time-lag between patient response and measure reporting (between nine and twenty-one months) is too long to be actionable.

The data collecting and reporting modes also need to be updated. Our members encounter difficulties in obtaining completed surveys due to the survey length and the limitations of a telephone or paper interview. Allowing beneficiaries to choose to reply to the survey electronically via the web or a phone application would increase survey participation. In addition, the FAH believes that greater participation would result from a shorter survey, which

could be accomplished by randomly rotating questions. CMS has been stating that they are actively investigating these modes as possible options for the future since 2016. The FAH requests that CMS provide a timeline for CMS expects to conclude their evaluation of potential bias and feasibility. In addition, electronic survey deployment will be less costly to hospitals than the current modes of deployment. CMS is inadvertently shifting the burden of the cost of not implementing an electronic survey mode on hospitals who have to pay survey vendors for paper and phone modes. The FAH would like to remind CMS that all modes of survey administration have biases and that the current modes available are biased against younger inpatients. To continue an indefinite process of evaluation now calls into question the reliability of this instrument.

The FAH applauds CMS for requesting suggestions for other measures that would capture facets of pain management and related patient education and believes there is a need for the promotion of funding or other incentives to increase the research 1) to support evidence-based practices that meet patient need for effective assessment and intervention about their pain and 2) for the development of operational guidelines that support organizations upholding good leadership and clinical practice standards in this space. This would help inform suggestions for appropriate measures.

Although the FAH supports removal of the pain questions due to their limited value as currently asked, the FAH also has serious concerns about removing questions about pain altogether from the assessment of patient experience. Pain management is a fundamental issue central to a patient's ability to feel good about their care. The FAH urges CMS to carefully balance the need to remove pain questions that have potential unintended consequences with the need to retain an important component of the patient experience.

The FAH strongly discourages CMS from issuing guidance suggesting that hospitals not administer any surveys with pain-related questions. The topic of pain remains one of the most important in a patient's hospital experience as well as an important clinical indicator for hospitals that cannot be gleaned from other clinical parameters. Hospitals rely on this information for research and evaluation on its impact on quality and efficacy of care and must not be blocked from asking questions related to pain that help assess and improve their efficacy in this area.

Requests for Information (RFIs)

Request for Information on Promoting Interoperability and Electronic Health Care Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare-Participating and Medicaid-Participating Providers and Supplies

CMS is seeking feedback in the Proposed Rule on how it could advance the electronic exchange of information in support of care transitions among providers using: Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care Facilities. Specifically, CMS is considering revising these to require providers to electronically perform a variety of activities, including: transfer of medically necessary information from a hospital to another facility upon a patient transfer or discharge; transfer of discharge information from a hospital to a community provider, if possible; and

providing patients access to certain information via electronic means, if requested, including directing that information to a third-party application.

The FAH has long supported efforts to achieve comprehensive interoperability and data liquidity – the free flow of meaningful, actionable information that supports and enhances patient care within and across settings. As the largest purchasers and consumers of HIT, hospitals and health systems – and their employed and affiliated clinicians – have a vested interest in data flow to improve patient care, workflow efficiencies and clinician satisfaction, population health and payment models, and research. **However, the FAH does not support the proposed revision of the CoPs, CfCs, and RfPs related to interoperability and the exchange of health information.** The current ecosystem is simply not mature enough to facilitate the movement of this information, as evidenced by the obstacles that currently prevent seamless information exchange and would make it exceedingly difficult for hospitals and other providers to comply with the requirements. The FAH appreciates CMS’s acknowledgement of this in the Proposed Rule, noting that, “While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.”³

These obstacles are amplified in the patient discharge and transfer arenas because post-acute providers and behavioral health providers were ineligible for the EHR Incentive Programs under the *Health Information Technology for Economic and Clinical Health (HITECH) Act*, which have been instrumental in enabling acute care hospitals to achieve so much of the potential that EHRs specifically and HIT generally offer. As such, post-acute providers and behavioral health providers have not been able to adopt HIT to the extent of hospitals and CAHs. Thus, were CMS to move forward with revisions to the CoPs, CfCs, and RfPs, hospitals and CAHs would be unable to meet these requirements because of the lack of providers available to accept that information electronically. And, for post-acute care and behavioral health providers, it would be unfair, and tantamount to an unfunded mandate, to require that these providers adopt and maintain expensive EHRs and other HIT through CoPs, CfCs, and RfPs when they receive no corresponding financial assistance to do so.

The lack of providers in a position to accept this information electronically raises questions regarding how providers would be deemed in compliance with such requirements. How would providers prove during a survey process that they are “interoperable?” Would they need to send information to other providers electronically? Ensure those providers ultimately received the information? Receive information from other providers? And/or receive information and incorporate it into an actionable format in the EHR? These are just a sampling of the multitude of questions that would arise in determining compliance – and many of them would hinge not on the individual provider’s action, but the actions of HIT vendors and other providers over whom the hospital and clinicians have virtually no control. For example, a hospital may be able to send the information electronically, but the receiving hospital or post-acute care provider is unable to accept it. Or, a provider may be unable to incorporate the information it receives into its EHR in a format acceptable to the surveyors due to the limitations of the EHR itself, for

³ 83 Fed. Reg. 36006-36007 (July 27, 2018).

example, the misaligned standards, semantics, and specifications that currently hinder data flow and useable data across vendor platforms. Additionally, the CoPs, CfCs, and RfPs are infrequently updated relative to the annual Medicare payment rules and rules related to the Promoting Interoperability Programs. As such, it is possible that the proposed revisions to these requirements could quickly become outdated and hinder future HIT-related innovation, in many cases even before they are finalized.

Failure to comply with CoPs, CfCs, or RfPs, carries serious penalties for health care providers, including the potential inability to treat Medicare and Medicaid beneficiaries. Such penalties also have profound consequences for patients as well, as they may lose the ability to receive treatment in their communities. **Imposing these penalties on providers and patients in the face of an immature health information ecosystem – and the significant implementation issues raised above – would only restrict rather than facilitate patients’ access to care and information exchange.**

The FAH appreciates CMS’s focus on interoperability and shares CMS’s frustrations regarding the lack of actionable, accessible electronic information, as well as the desire to accelerate an interoperable health system that improves the safety and quality of care, enables innovations, and achieves the best possible outcomes for patients. **To continue to address these concerns, the FAH recommends that CMS permit the numerous public and private initiatives in this area, some of which are nascent, time to mature and advance our shared goals. CMS and ONC should also continue to work to improve the capabilities of EHRs and other HIT, including: simplifying information exchange across HIT vendor platforms; identifying patients across vendor platforms; and simplifying clinician workflow related to sending, receiving, incorporating, and utilizing information.** As CMS states in the Proposed Rule, there are “several important initiatives that will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information.”⁴ These initiatives include the Trusted Exchange Framework and Common Agreement (TEFCA), which is still in draft form; the revamped and refocused Promoting Interoperability Program, which was recently proposed; the Prevention of Information Blocking Attestation;⁵ and the MyHealthEData initiative, which was announced earlier this year, among others. There are also private-sector led efforts underway to advance other components of the interoperability puzzle, such as plug-and-play interoperability among devices and systems.⁶ The FAH provided feedback on these and other initiatives and looks forward to continuing to work with CMS, ONC, and other private-sector partners to realize the promise of HIT to improve our nation’s health care system.

⁴ *Id.* at 36007.

⁵ Eligible hospitals, eligible professionals, and CAHs participating in the Promoting Interoperability Programs must attest to the Prevention of Information Blocking Attestation. *The Medicare and Medicaid EHR Incentive Programs Prevention of Information Blocking Attestation Fact Sheet*, October 2017, available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHR_InformationBlockingFact-Sheet20171106.pdf.

⁶ Center for Medical Interoperability, *Fact Sheet*, available at: <http://medicalinteroperability.org/wp-content/uploads/2017/01/CMI-Overview-Jan2017.pdf>.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

The FAH is supportive of efforts to ensure that consumers have clear, accessible, and actionable information concerning their cost-sharing obligations, but is concerned that CMS is considering avenues for providing this information that focus exclusively on hospitals when payers—insurers, group health plans, Medicare, Medicare Advantage organizations, and others—are best suited to provide actionable coverage and cost-sharing information for all providers and suppliers involved in an episode of care.

CMS should give careful consideration to the best method and data needed to provide patients with the information required to understand potential cost-sharing obligations. Requiring hospitals to disclose competitively sensitive information, including average or median contracted rates or discounts, would not enable patients to better understand their potential financial liability for services or to accurately compare their likely cost-sharing exposure between hospitals. A patient's cost-sharing obligation is determined based on benefits and coverage under her plan, the plan's provider network and cost-sharing structure, and the plan's specific negotiated rates with each provider and supplier involved in an episode of care. As a result, average or median contracted rates or discounts do not help patients to accurately compare their potential financial liability for an episode of care. In fact, by consulting with her plan, a patient might discover that her actual projected financial liability for an episode of care would be lower at a hospital with "higher" average or median contracted rates. Meanwhile, disclosing information concerning contracted rates or discounts would ultimately be counterproductive to a competitive marketplace. Economists and antitrust enforcers have recognized that the disclosure of negotiated provider network rates could lead to inflation of prices by discouraging private negotiations that can result in lower prices for some buyers. In fact, the Department of Justice and Federal Trade Commission's antitrust safety zone for pricing surveys requires that the source data be at least three months old. Department of Justice and Federal Trade Commission, Statement on Provider Participation in Exchanges of Price and Cost Information (Aug. 1996).

Payers, on the other hand, can provide clear, accurate and actionable cost-sharing information to members and beneficiaries without jeopardizing price-based competition among providers. Payers are uniquely qualified to provide patients with precise information concerning any limitations on their coverage, the scope of patient cost-sharing obligations (including out-of-pocket spending limits, deductibles, coinsurances, and any reference-based pricing strategies used by the plan), any network tiering used by the plan, and the applicable allowed amount for each provider or supplier involved in an episode of care. CMS's Office of the Actuary estimates that approximately 90 percent of individuals will have health coverage in 2019 (an uninsured rate of 9.6 percent). 83 Fed. Reg. at 20,392. Thus, for the vast majority of patients, payers are in the best position to provide the most relevant information. Payers understand the full range of benefits under a patient's applicable health coverage and cost-sharing obligations and, because an episode of care typically involves multiple providers and suppliers, the payer is the only entity that is capable of providing a patient with an accurate and actionable estimate of their potential financial exposure for the entire episode of care.⁷ Seeking this information from each provider

⁷ This is also true with regard to Medigap coverage. CMS asked who is best situated to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care. 88 Fed. Reg. at 20549.

and supplier involved in an episode of care is not only inefficient, but it is also error-prone because the cost-sharing picture is fragmented among the providers and suppliers and may not accurately reflect the details of the patient's coverage.

With regard to the small minority of patients that are uninsured, hospitals and other providers may be the preferred source of pricing information, but it is the FAH's belief that uninsured patients are best served by receiving individualized information through a provider's financial counselors. Most uninsured patients receive substantially discounted or even free care under a hospital's charity care policy or receive other generous discounts that limit their financial obligations. Moreover, a sizeable number of uninsured patients are actually eligible for free or subsidized health coverage. By meeting with a hospital's financial counselor, these individuals can access individualized and actionable pricing information and make informed choices concerning their medical care. Overemphasizing a hospital's typical or average rates, discounts, or charges, on the other hand, may dissuade individuals that may be entitled to free or low-cost care from speaking with a financial counselor and, in some circumstances, may cause an individual to forego needed care.

For these reasons, the FAH believes requiring hospitals to publish median contracted rates or discounts or to provide an estimate of the patient's out-of-pocket costs before furnishing a service is not an appropriate avenue to address concerns about transparency. Hospitals will always provide patients with assistance in understanding their obligations and with available programs and policies such as eligibility for charity care and discounts. But as stated earlier, it is far more appropriate for covered individuals to receive cost-sharing estimates from the applicable payer, whereas uninsured individuals should consult with the provider's financial counselor to obtain an individualized assessment of her eligibility for charity care, discounts, or free or subsidized health coverage. Along similar lines, the FAH believes that information concerning "what Medicare pays" for a service is not a useful reference point and does not help patients to understand their potential financial liability. Medicare rates are not negotiated in arm's-length transactions and provide little to no information about the rates negotiated with or established by other payers, let alone the cost-sharing obligation borne by the patient. In addition, the provision of Medicare-specific pricing information by providers would likely create confusion among patients who are either not enrolled in Medicare or who receive their Medicare benefits through a Medicare Advantage plan that pays a different, negotiated rate. However, should CMS desire for patients to have that information, it is in the best position to provide it.

The FAH also opposes any effort to expand section 2718(e) of the Public Health Service Act (PHSA) to require disclosure of median rates, discounts, or competitively sensitive information. Section 2718(e) requires each hospital to establish, update, and make public "a list of the hospital's standard *charges* for items and services provided by the hospital" (emphasis added). Critically, Congress chose to use the word "charges" in lieu of "price," "rate," "cost," or any other similar term. CMS should not ignore Congress' clear intent to address dissemination of charge information by redefining "standard charges" as rate information, discounts, or other pricing information that is simply unrelated to charges.

Responsibility to provide this information should fall on the Medigap plan itself, which is the entity in a position to provide enrollees with accurate and actionable information regarding their cost-sharing obligations for an entire episode of care.

Finally, the FAH opposes the creation of a federal enforcement mechanism for section 2718(e) of the Public Health Service Act. Based on the plain text of the Public Health Service Act, Congress declined to provide *any* penalties or enforcement authority with regard to section 2718(e). In addition, the enforcement provisions for Part A of title XXVII of the Public Health Service Act, which apply only to health insurers, emphasize the overriding importance of state-level enforcement of insurance market requirements. States are far better suited than CMS to experiment with price transparency measures and to enforce these measures as appropriate under their general police powers. Meanwhile, Congress specifically did not grant CMS statutory authority to enforce the requirement that hospitals publish their standard charges.

The FAH supports CMS’s goal of ensuring that patients have access to clear, accurate, and actionable cost-sharing information, and urges CMS to pursue this goal through payer-side regulations. Hospitals are simply not the appropriate entity to be tasked with interpreting and explaining a patient’s cost-sharing obligations under a particular plan. Payers, on the other hand, are in a position to offer this important information. As such, the publication of average or median hospital rates or discounts as some sort of proxy for an individual’s cost-sharing obligations would be misleading to individual consumers, contrary to Congress’s express direction that hospitals publish information on standard “charges,” and counterproductive to a competitive marketplace for hospital services.

Related to ensuring patients have access to clear, accurate, and actionable cost-sharing information is the opportunity for CMS to take action to negate negative outcomes from instances where consumers are subject to a “surprise bill” when they receive services in an in-network hospital, but some of those services are delivered by an out-of-network physician. This is another example of how consumers may not have accurate information from their insurance plan about in-network providers and are not adequately protected against unexpected out-of-pocket costs. CMS finalized a policy in the Final Notice of Benefit and Payment Parameters for 2017 to address surprise bills to consumers. Under this policy, beginning in 2018, Qualified Health Plans (QHP) sold on the Marketplace must count the cost-sharing amount associated with an essential health benefit provided by an out-of-network provider in an in-network facility (e.g., hospital) toward an enrollee’s annual cost-sharing limit. This requirement does not apply if the QHP provides written notice to the beneficiary (a non-customized form letter would suffice) that the provider might be out-of-network and the beneficiary could be subject to additional cost-sharing obligations. The QHP has the longer of 48 hours prior to the service or the time in which the plan would typically respond to a prior authorization request to provide the notice.

Unfortunately, the CMS policy falls short of the mark as it provides more protection for plans than it does for consumers. It is reasonable to assume that QHPs will routinely issue the form letter, in which case the consumer remains exposed to the additional cost-sharing, while the plan keeps the consumer that much further away from reaching the annual cost-sharing limit, the point at which the plan becomes fully responsible for the cost of care. **Instead, the FAH continues to recommend that CMS adopt the surprise billing section of the National Association of Insurance Commissioners’ (NAIC) Health Benefit Plan Network Access and Adequacy Model Act (Model Act) as a more robust way to address the issue of surprise billing.** The FAH believes this policy provides real protection for patients by providing an

important measure of transparency combined with reasonable protections of patients' financial interests. In addition, the NAIC provision strikes the right balance between the roles and responsibilities of hospitals, providers, and plans in situations in which a patient seeks care at an in-network hospital and may be treated by a provider who is not covered by the patient's plan.

Under the NAIC's Model Act, if a patient receives emergency treatment from an out-of-network provider (e.g., anesthesiologist, pathologist, radiologist) at an in-network facility, the patient's out-of-pocket costs would be limited to those of an in-network provider. If the billed amount from the out-of-network provider is at least \$500 more than the allowed amount under the patient's plan, the proposal offers a mediation process between the out-of-network physician and the insurance company when they cannot agree on a payment amount – essentially holding the patient harmless. Additionally, before any non-emergency treatment is scheduled, the Model Act would require the in-network hospital to provide the patient a written notice stating, among other items, that the patient might be treated by a provider who the patient's plan determines is out-of-network, as well as a range of what the charges could be for such treatment. The notice also would include a statement telling the patient that she can obtain from her plan a list of providers who are covered by her plan, and request treatment from one.

Finally, for information to be meaningful, accessible, and actionable, it must be readily available for all types of consumers. Health plans should use effective and innovative communication methods and convey the information as simply and directly as possible. Insurers should continually communicate price and other information in multiple ways using a variety of methods to be most effective and have the broadest reach.

Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

As large purchasers of drugs for our patients – in both the outpatient and inpatient settings – hospitals have a great deal of experience with the drug supply chain and how to best acquire the drugs our patients need. Should CMS pursue testing a restarted Competitive Acquisition Program (CAP) or some derivation of CAP for certain Part B drug acquisitions, we believe it would be best tested as a voluntary option for free-standing physician practices. Given the mature and sophisticated acquisition tools hospitals currently use to acquire drugs, hospitals are unlikely to benefit from the program. As such we encourage CMS to evaluate a future model in the physician context only.

The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or Steve Speil, Executive Vice President, at 202-624-1529.

Sincerely,

