Charles N. Kahn III
President and CEO

September 13, 2022

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-1772-P, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating, July 26, 2022.

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 comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Proposed Rule and provide our comments on specific proposals below.

V.B.6. CY 2023 OPPS Payment Methodology for 340B Purchased Drugs

The FAH regrets that CMS has indicated it intends in the final rule to abandon the current prospective budget-neutral 340B payment policy that pays Average Sales Price (ASP) minus 22.5 percent for 340B-acquired drugs and increases the conversion factor by an amount commensurate with the savings generated by the 340B payment adjustment.

In 2018, CMS took an important step to directly benefit seniors and improve the accuracy of Medicare's payment for outpatient hospital services across all hospitals treating Medicare beneficiaries. The agency said it was implementing this change to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur" while also ensuring that Medicare beneficiaries "share in the savings on drugs acquired through the 340B Program." We believe the policy has achieved this important goal and advanced Congressional intent underlying the OPPS statute to promote efficiency, equity, and patient-centered care through, for example, reduced copayments for Medicare beneficiaries, especially for cancer patients.

That action, to better align Medicare payment with 340B hospital acquisition costs, had two immediate benefits. First, seniors who get their drugs at a 340B hospital pay less because the lower Medicare OPPS payment to the hospital means a lower copayment for the Medicare beneficiary. This is due to the Medicare copayment structure, which requires seniors to pay 20% of the amount Medicare reimburses the hospital, not 20% of what it costs the hospital to buy the drugs. The prior payment policy resulted in a significant, negative impact on beneficiaries. Because Medicare payment rates far exceeded 340B hospitals' acquisition costs, beneficiaries were making disproportionately large coinsurance payments compared to 340B hospitals' costs of acquiring the drugs. A study issued by Avalere Health[1] in 2021 noted that reversing the CMS 340B payment policy in 2021 would have increased beneficiaries' drug co-payments by an estimated 37% on average, or $472.8 million, at 340B hospitals.

Second, all hospitals, including 340B hospitals, have been getting a much-needed 3.2 percent bump in Medicare payment for primary and emergency care, as well as outpatient procedures and other non-drug services – a welcome increase in a chronically underfunded system. The inefficiencies of the pre-2018 drug payment policies had tangible impacts on non-340B hospitals and the communities they serve. Because of the OPPS prospective payment budget neutrality requirement, the gains realized by 340B hospitals as a result of the mismatch between acquisition costs and payment rates came at the expense of non-340B hospitals, who received lower OPPS payments to account for the comparatively inflated payments relative to costs to 340B hospitals. The pre-2018 OPPS payment rates to non-340B hospitals increased the financial burden of providing outpatient services, by requiring non-340B hospitals to effectively subsidize the provision of similar services to 340B hospitals serving comparable patient populations. Along those lines, an examination of the latest cost reports as contained in the CMS Healthcare Provider Cost Reporting Information System file dated June 30, 2022, reveals that non-340B hospitals had marginally higher uncompensated care cost rates than 340B hospitals – 3.7 percent of total operating costs compared to 3.5 percent. FAH member hospitals had an even

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[1] Avalere Health, Report: OPPS Medicare Part B Payment Impact Analysis, page 11 (https://www.fah.org/wp-content/uploads/2021/04/20210326_OPPS_Analysis_for_FAH.pdf).

higher uncompensated care cost rate of 5.7 per cent. Charity care cost rates were comparable at 340B and non-340B hospitals at 2.5 percent, and higher, 4.4 percent, at FAH hospitals.

CMS' actions have leveled the playing field across all OPPS hospitals, reinforcing the purpose of the Medicare OPPS to incentivize efficient and equitable behavior. Yet reversing CMS' current 340B payment policy for separately payable drugs and removing the proposed 4.04 percent increase to the base rate for all non-drug OPPS services to all OPPS hospitals as CMS indicated in the Proposed Rule it plans to do in the final rule would result in a stunning negative hospital impact: 80% of all hospitals paid under the OPPS – including 86% of rural hospitals, and even 52% of all 340B hospitals – would experience a net payment decrease in 2023 based on CMS's published data. The negative impact to rural hospitals, struggling to survive and closing at an alarming rate, would be particularly damaging.

The policy foundation supporting CMS' current policy is clearly compelling, and the FAH strongly urges CMS to maintain that policy consistent with the limited decision rendered by the Supreme Court for CYs 2018 and 2019.

Budget Neutral Reversal of the 340B Purchased Drug Policy for CY 2023

In the OPPS Proposed Rule, CMS proposes to continue to pay ASP minus 22.5 percent for 340B-acquired drugs in CY 2023, but indicates that, in light of the Supreme Court's decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (June 15, 2022), it anticipates reverting to its prior policy of paying ASP plus 6 percent. The Proposed Rule indicates that this alternative proposal would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor (a 4.04% payment reduction for non-drug items and services). This proposed negative budget neutrality adjustment exceeds the currently effective budget neutrality adjustment associated with the policy (3.2 percent) such that the reversal of the 340B drug payment policy would produce a net permanent reduction to the OPPS conversion factor of 0.84 percent. ***The FAH strongly opposes the imposition of any payment reduction for CY 2023 that does more than make the offsetting budget neutrality adjustment associated with the abandonment of the 340B drug payment policy.*** Simply stated, it would be inappropriate for CMS's unravelling of its payment methodology for 340B purchased drugs to produce a *net permanent reduction* to the OPPS conversion factor.

CMS determined the budget neutrality factor associated with the 340B drug payment policy when it first adopted the policy for CY 2018 and left it unchanged through CY 2022. CMS should not now recalculate the budgetary impact of the policy after steadfastly refusing to do so over the past four years. In comments on the CY 2022 OPPS Proposed Rule, stakeholders argued that the 340B drug payment policy was not actually operating in a budget neutral manner and that the 3.2 percent increase to the conversion factor was insufficient to fully offset the reduction in payments for 340B-acquired drugs. In the Final Rule, however, CMS declined to update the budget neutrality adjustment, emphasizing the prospective nature of budget neutrality adjustments and that the "broader budget neutrality adjustments" adopted annually adequately address changes in drug utilization and payment such that the existing budget neutrality adjustment remained appropriate as long as the 340B drug payment policy remained in place. 86 Fed. Reg. 63,458, 63,648 (Nov. 16, 2021). Given CMS's assurance that a continued positive 3.2 percent budget neutrality adjustment would be appropriate in connection with a continuation of

the 340B drug payment policy, it likewise stands to reason that a simple reversal of that budget neutrality adjustment is appropriate in connection with the termination of that policy. Moreover, the alternative approach would result in the inappropriate erosion of OPPS payment rates, to the ultimate detriment of program beneficiaries.

Remedies for CYs 2018-2022

CMS also seeks public comment on how to structure any potential remedy for CYs 2018-2022, given that the Supreme Court did not specify a remedy in its ruling in *American Hospital Association v. Becerra*, 142 S. Ct. 1896. 87 Fed. Reg. 44,649. In the course of litigation, the American Hospital Association ("AHA") correctly stated that the Secretary may make 340B hospitals whole for past shortfalls without offsetting budget neutrality reductions. The Supreme Court noted the AHA's position, and, although the Court did not specify a remedy, it explicitly rejected the Secretary's argument that judicial review was unavailable based on budget neutrality concerns. ***As the FAH has explained in prior OPPS rulemaking comments, the Medicare Act does not permit CMS to make any offsets to achieve actual or retrospective budget neutrality, and, to the extent that CMS ultimately provides relief to 340B hospitals through payments designed to compensate such hospitals for past underpayments, those payments may not be adopted in a budget neutral fashion because any offsetting payment reduction would unlawfully recoup past payments that were properly made for non-drug OPPS items and services.***

The Medicare Act requires that CMS *prospectively* adjust payment rates within OPPS in a budget neutral manner to account for the decreased payments for 340B drugs *in advance of* the commencement of each OPPS fiscal year. *See* 42 U.S.C. § 1395*l*(t)(9)(B). Importantly, while Congress very clearly intended that budget neutrality be reached within this *prospective* payment system, Congress only permits that the Secretary make adjustments to achieve a *prospective estimate* of budget neutrality. To conceive of budget neutrality as a retrospective requirement would be inconsistent with the text and structure of the statute and wreak havoc on Medicare's payment systems and the reliance interest of stakeholders throughout the health care system.

The text of the Medicare Act plainly conveys the prospective-only nature of the budget neutrality requirement:

> If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may 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.

42 U.S.C. § 1395*l*(t)(9)(B) (emphases added).[2] Paragraph (9) is entitled "Periodic review and adjustments components of prospective payment system," and subparagraph (A), which triggers the budget neutrality provision, requires the Secretary to review and revise "the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)"

[2] 42 U.S.C.§ 1395*l*(t)(14)(H) does not add to this requirement; instead, it simply refers back to subsection (t)(9)(B) in providing that expenditures resulting from paragraph (14) are taken into account under paragraph (9) only starting in 2006.

not less than annually to take into account various factors and information. 42 U.S.C. § 1395*l*(t)(9)(A). These statutory provisions describe the OPPS prospective rulemakings CMS undertakes prior to the start of each calendar year. The budget neutrality provision cited above addresses only *estimated* costs for the *following* calendar year. The estimates are just one of the inputs into the OPPS formula subject to the agency's notice-and-comment rulemaking each year—and, critically, after a rule is finalized for a particular year, the estimates do not change as a result of unanticipated increases or decreases in spending, and the budget neutrality provision, by its plain terms, has no further application. CMS itself has long-recognized the prospective nature of this budget neutrality requirement. *See, e.g.*, CY 2003 Final Rule, 67 Fed. Reg. 66,718, 66,754 (Nov. 1, 2002) ("With respect to budget neutrality, section 1833(t)(9)(B) of the Act [42 U.S.C.§ 1395*l*(t)(9)(B)] makes clear that any adjustments to the OPPS made by the Secretary may not cause *estimated* expenditures to increase or decrease.") (emphasis added). While budget neutrality remains a rate-setting requirement guiding adjustments *prospectively*, the law does not permit *post-hoc* reconciliation or recoupment to achieve budget neutrality *after* actual payments are made to providers.

Likewise, in setting OPPS rates for future years, it would be improper for the Secretary to attempt to indirectly recoup payments that resulted from CMS' lawfully applied and unchallenged 3.2% budget neutrality adjustment, which the agency adopted in CY 2018 and maintained without further adjustment through CY 2022, or to otherwise attempt to offset any relief to 340B hospitals. ***Put simply, the Secretary did not err in applying a positive adjustment to non-340B claims in order to achieve budget neutrality based on his estimates in the CY 2018 OPPS Final Rule. And any future adjustment, under the plain terms of the budget neutrality provision, must concern estimated savings and costs in the following year, not any prior year. Thus, any remedy should not and may not either directly or indirectly seek to recoup non-drug payments, which were properly made under the OPPS Final Rules in CYs 2018-2022.***

Critically, the Medicare Act does not permit after-the-fact reconciliation to achieve *actual* budget neutrality in a given payment year under any prospective payment system (except in very narrow circumstances explicitly prescribed by Congress). Thus, where, for *any* reason, a prospective payment system ultimately produces "excessive payments" (*i.e.*, payments beyond those anticipated), such excessive payments may not be recouped absent specific statutory authorization. By way of example, the provisions of the Medicare Act establishing the inpatient prospective payment system ("IPPS") and those establishing the OPPS each contain language authorizing the Secretary to adopt prospective adjustments to the IPPS or OPPS payment amounts to eliminate estimated *future* (but not past) changes in aggregate payments that are due to changes in the coding or classification of inpatient discharges or covered outpatient department services that do not reflect real changes in case mix or service mix. 42 U.S.C. §§ 1395ww(d)(3)(A)(vi), 1395*l*(t)(3)(C)(iii).[3]

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[3] In relevant part, the statutory language provides as follows: "Insofar as the Secretary determines that [certain IPPS or OPPS] adjustments . . . for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the . . . year that are a result of changes in the coding or classification of [discharges or covered outpatient department services] that do not reflect real changes in [case mix or service mix], the Secretary may adjust [the average standardized amounts or the conversion factor] computed under this [paragraph or

Although the Medicare Act permits CMS to implement *prospective* adjustments to eliminate anticipated excessive payments in future years (42 U.S.C. § 1395ww(d)(3)(A)(vi)), the statute includes no general authority for CMS to recoup excessive payments in prior years. A narrow exception proves this general rule: In 2007, Congress passed the TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–87 (2007) ("TMA"), to specifically authorize additional adjustments during specified fiscal years to recoup certain excessive payments related to inpatient discharges in FY 2008 and FY 2009. And in 2013, Congress amended the TMA to authorize additional adjustments during specified fiscal years to recoup $11 billion in purported excessive payments between FY 2008 through 2013. American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013) ("ATRA"). Tellingly, Congressional action was required to specifically authorize such after-the-fact reconciliation. *See, e.g.*, Hospital IPPS and Fiscal Year 2014 Rates, 78 Fed. Reg. 50,496, 50,514 (Aug. 19, 2013) (acknowledging that any FY 2010 through 2012 "overpayments could not be recovered by CMS [prior to the passage of ATRA] as section 7(b)(1)(B) of Public Law 110–90 [TMA] limited recoupments to overpayments made in FY 2008 and FY 2009"). No comparable specific statutory authorization for recoupment of amounts properly paid at the prospectively set CYs 2018-2022 OPPS rates exists here.

Bolstering this plain understanding of the statute, as CMS routinely has opined and various courts have agreed, the idea that payment will be made at a predetermined, specified rate serves as the foundation of the Medicare prospective payment systems, of which the OPPS is one. *See, e.g.*, *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1232 (D.C. Cir. 1994); *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1169 (D.C. Cir. 2015); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996). The D.C. Circuit has recognized these core principles of predictability and finality, finding that "the Secretary's emphasis on finality protects Medicare providers as well as the Secretary from unexpected shifts in basic reimbursement rates" and permits hospitals to rely on the predetermined rates and resulting payments made thereunder. *Methodist Hosp.*, 38 F.3d at 1232. Any attempt at after-the-fact rebalancing would be contrary to such principles and therefore fundamentally at odds with Congress's intent that rates be established *prospectively* under the OPPS.

In line with the finality and predictability principles underlying the OPPS, the FAH's members relied on and already have received reimbursement at the prospectively set payment rates for the outpatient non-drug items and services they provided to Medicare beneficiaries over the five-year period the 340B drug payment policy has been in place. The government recognized in H. Lee Moffitt Cancer Center that "retroactively recalculating payments under the OPPS" could "adversely impact[] the reliance interests of hospitals operating under the OPPS." Gov't MSJ (ECF No. 17), H. Lee Moffitt Cancer Ctr. v. Azar, 324 F. Supp. 3d 1 (D.D.C. No. 1:16-cv-02337-CKK). The same fundamental fairness concern exists here. In line with the finality and predictability principles underlying the OPPS, the FAH's member hospitals relied on, received reimbursement under, and have long-since used or obligated funds from amounts paid at the prospectively-set payment rates for 2018 through 2022 to deliver services to Medicare patients. And, as discussed above, the Secretary may not attempt to remedy any underpayments

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subparagraph] for subsequent fiscal years so as to eliminate the effect of such coding or classification changes."

to 340B hospitals in CYs 2018-2022 by increasing payments for 340B drugs in a future payment year in a budget neutral manner (i.e., by reducing payments for non-340B items and services) because this would amount to an unlawful retroactive recoupment of past payments that were properly made for non-drug items and services under the OPPS Final Rules for CYs 2018-2022, and would represent an impermissible application of the forward-looking-only budget neutrality provision. Moreover, such an approach would be inherently inequitable and arbitrary because, among other things, it would artificially depress OPPS payments for non-drug items and services, unevenly distribute additional payments among 340B hospitals, and inflate beneficiary cost sharing for 340B-acquired drugs.

What is more, there is clear precedent for CMS providing non-budget neutral remedies for the agency's violations of the law, which do not disrupt the interests of finality and predictability by directly or indirectly recouping payments from a prior year. In fact, CMS has retroactively corrected underpayments in a non-budget neutral fashion under 42 U.S.C. § 1395*l*(t), without "suggest[ing] any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr.,* 324 F. Supp. 3d 1, 15 (D.D.C. 2018). For example, in 2006, CMS made a "retroactive payment adjustment" under 42 U.S.C. § 1395*l*(t)(2)(E) that applied to a group of rural hospitals the agency said it had mistakenly excluded from that year's prospective adjustment. Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates, 71 Fed. Reg. 67,960, 68,010 (Nov. 24, 2006). In later litigation involving OPPS payments to cancer hospitals, the court noted that CMS did not offset this 2006 retroactive payment adjustment with any recoupment and "did not suggest any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr.,* 324 F. Supp. 3d at 15. CMS should (and must) do no differently here.

Any direct recoupment or prospective reduction in OPPS payments for non-drug items and services to offset relief provided to 340B hospitals would be not just unlawful—it would also risk harm to Medicare beneficiaries by placing unnecessary and unfair additional financial strain on hospitals already grappling with the destabilizing effects of the COVID-19 pandemic, record inflation, and acute labor shortages. For more than two years, hospitals have been on the front lines of the COVID-19 pandemic, which has significantly strained an already-fragile healthcare workforce with over 80 million cases, over 4.6 million hospitalizations, and nearly 1 million deaths. *Massive Growth in Expenses & Rising Inflation Fuel Continued Financial Challenges for America's Hospitals & Health Systems,* Am. Hosp. Ass'n, https://www.aha.org/guidesreports/2022-04-22-massive-growth-expenses-and-rising-inflation-fuel-continued-financial (last visited Aug. 12, 2022).

The pandemic also coincided with a range of other financial and operational challenges like historic volume and revenue losses and skyrocketing expenses. Record inflation has made increases in expenses "severely detrimental to hospital finances, leading to billions in losses and over 33% of hospitals operating on negative margins." *Id.* "[H]ospital margins are still in the red" more than halfway through 2022. Erik Swanson, *National Hospital Flash Report: July 2022,* Kaufman Hall (Aug. 1, 2022), https://www.kaufmanhall.com/insights/research-report/national-hospital- flash-report-july-2022. Hospital "expenses remain at historic highs, leaving hospitals with cumulatively negative margins" that "remain significantly lower than pre-pandemic levels." *Id.* This instability necessarily creates risks for beneficiaries who depend on

their community hospitals for care and provides all the more reason that CMS should not seek to retroactively recoup OPPS reimbursements or to prospectively offset relief to 340B hospitals with payment reductions.

In sum, the FAH's members relied on and were properly paid under an OPPS payment rate properly designed to be budget neutral based on CMS estimates. That the CY 2018-2022 OPPS payment rates may not ultimately result in *actual* budget neutrality, whether due to the Supreme Court's decision, fluctuations in service volumes, or any host of other factors, should not (and lawfully cannot) directly or indirectly jeopardize the payments that were made under the prospectively set payment rates. ***Therefore, the FAH strongly opposes any effort to offset any relief to 340B hospitals or to otherwise provide relief to such hospitals on a budget-neutral basis.*** Instead, the FAH urges CMS to take the most pragmatic and equitable approach to swiftly remedying the 340B payment reduction: Make each 340B hospital whole with a lump sum payment based on its actual claims for 340B-acquired drugs in CY 2018 through CY 2022 without waiting for the CY 2024 OPPS rulemaking (*e.g.*, through a CMS Ruling). This approach would avoid the legal and policy concerns set forth above and would provide finality after five years of litigation. Critically, the simple payment of make-whole relief to 340B hospitals holds non-340B hospitals harmless for the five years they rightfully relied on OPPS payment rates for non-drug items and services.

II.B. Proposed CY 2023 Outpatient Hospital Conversion Factor Update

The Projected Inflation Undergirding CMS' Proposed Market Basket Fails to Capture Hospitals' Actual Experience of Record Inflation

The FAH is concerned that the historical data upon which both the proposed CY 2023 forecast of the market basket increase and the FY 2023 final rule IPPS market basket are based falls far short of reflecting the real rate of increase that hospitals are experiencing. CMS' recent September 2, 2022, data release is instructive. While the data remains incomplete for CY 2022, CMS projections show that the market basket update is less than half of the current estimates for 2022 inflation -- 5.5 percent compared to the 2.7 percent market basket update adopted by CMS. That means hospitals are arguably being underpaid today by 2.8 percent for services they are providing in CY 2022. We are concerned that CMS' estimates for CY 2023 (expected at 4.1 percent) will also result in structural underpayments, and we urge CMS to use its authority to further increase the update for hospitals, which are struggling with COVID and inflationary pressures that are unprecedented in the history of the outpatient prospective system.

Recent data released by Kaufman Hall reflect the continued pressure on total hospital expenses, with year-over-year cost growth of 7.6 percent from July 2021 to July 2022. Total labor expenses were up 8.9 percent year-over-year and labor expenses per adjusted discharge were up a staggering 13.5 percent. Unfortunately, the pressure on hospital expenses shows no sign of abating.

One reason that CMS' market basket data may be reflecting lower increases in staffing costs compared to what hospitals are experiencing relates to the use of contract labor. Hospitals have confronted worrying 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 that 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.[4] **We understand that the BLS' 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.**

Accounting for Understatement of Market Baskets

Given the unprecedented nature of the pandemic and its extraordinary impact on hospital costs alongside record inflation, the FAH urges CMS to consider a one-time adjustment to ensure that the CY 2023 rate increase is applied to a base rate that more accurately accounts for actual inflation during CY 2022. Without such an adjustment, OPPS rates will fail to keep pace with rising hospital costs, compounding the instability already produced by the COVID-19 pandemic. As noted above, the projected market basket used to update OPPS rates for CY 2022 is now 2.8 percentage points below the actual rate of hospital cost inflation. The unique and unprecedented circumstances confronted by hospitals today highlight the challenges of inadequate payment and accelerating costs and we urge CMS to exercise its full authority to remedy this situation.

Total Factor Productivity

Pursuant to section 1833(t)(3)(F)(i) of the Act, the Secretary reduces the OPPS market basket increase 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 offsets for economy wide total productivity is that the hospital sector should be able to realize the same productivity gains as the general economy. Even before the pandemic, however, OACT questioned the wisdom underlying this assumption. An OACT analysis from 2016 indicated:

> The most recent 10-year moving average growth of hospital MFP, ending in 2013, ranges from 0.1 percent to 0.5 percent, compared to 0.8 percent growth in private nonfarm business MFP. In addition, more recently published estimates of hospital productivity by other researchers seem to indicate that hospitals are unable to

4 Massive Growth in Expenses and Rising Inflation Fuel Continued Financial Challenges for America's Hospitals and Health Systems, American Hospital Association, April 2022.

achieve the productivity gains of the general economy over the long run. In the 2015 Trustees Report, it was assumed that hospitals could achieve productivity gains of 0.4 percent per year over the long range; this growth rate is relative to the assumed growth in private nonfarm business MFP of 1.1 percent.[5]

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.

Another factor to consider during recent years is instability in the level of productivity improvements both economy-wide and specifically for hospitals resulting from the COVID-19 pandemic. While use of a 10-year moving average may be designed to improve predictability of the offset when there are year-to-year swings in productivity, it also has the effect of minimizing the impact of lower productivity growth during a once-in-a-century pandemic. Two recent periods of decreased productivity occurred during the COVID-19 pandemic – a 0.4 percent decline in July 2021 and a 0.6 percent decline in January 2022.[6] Yet these substantial declines that disproportionately impact hospitals are significantly discounted in a 10-year moving average. The FAH believes that the highly unusual circumstances of the COVID-19 pandemic are sufficient reason for the Secretary to provide a one-time adjustment that offsets application of the otherwise applicable productivity adjustment for CY 2023.

II.C. Proposed Wage Index Changes

The FAH commends CMS' continued commitment to supporting rural hospitals by mitigating the negative feedback loop created by the wage index through an increase to the wage index values of low wage index hospitals. Rural hospitals are imperative in ensuring access to care for the more than 60 million Americans living in rural areas across the United States, including close to one quarter of all Medicare beneficiaries. Because Medicare beneficiaries disproportionately rely upon rural hospitals for care, Medicare reimbursement tends to impact rural hospitals' revenue more than non-rural hospitals. As CMS has previously noted in the FY 2020 IPPS rulemaking, the wage index has created a "downward spiral" whereby low wage index hospitals receive lower reimbursement, thereby weakening their capacity to invest in recruitment or employee retention, and further depressing reimbursement exacerbating the workforce shortage challenge that is especially acute in rural America. The FAH, however,

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[5] ***Paul Spitalnic, Steve Heffler, Bridget Dickensheets and Mollie Knight, Hospital Multifactor Productivity, An Updated Presentation of Two Methodologies, page 2 (Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies (cms.gov))***

[6] FTI Consulting, Report: Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, page 8.

strongly recommends that CMS reverse its budget neutrality adjustment associated with the low wage index hospital policy and instead apply the policy in a non-budget neutral fashion. Non-budget neutral implementation of this policy would avoid unnecessarily reducing already low OPPS reimbursement, particularly in the midst of the ongoing COVID-19 pandemic as well as record inflation pressures.

The FAH also strongly supports the proposal to permanently cap wage index decreases at 5 percent but urges CMS also to apply the permanent cap in a non-budget neutral manner. A policy that ensures each hospital's wage index will not be less than 95 percent of its final wage index for the prior fiscal year appropriately promotes predictability for hospitals as they budget and plan their operations and mitigates instability in OPPS payments that might otherwise result from significant wage index decreases.

II.E. Proposed Adjustment for Rural Sole Community Hospitals

The FAH supports CMS' 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.

II. G. Proposed Hospital Outpatient Outlier Payments

CMS proposes to adopt an outpatient outlier threshold for CY 2023 of $8,350—a 35 percent increase from the CY 2022 amount of $6,175. The FAH is concerned about the large increase in the proposed 2023 outpatient outlier threshold.

The FAH notes that we had similar concerns about the inpatient fixed loss threshold that CMS proposed to adopt. For the FY 2023 IPPS Proposed Rule, CMS proposed an outlier threshold for FY 2023 of $43,214, an increase of 39.5 percent and $12,266 from the FY 2022 amount. In the final rule, CMS adopted an outlier threshold of $38,859, an increase of 25.4 percent and $7,871 from the FY 2022 amount—still a large increase but far less than what had CMS proposed.

CMS made a number of special interventions to keep the FY 2023 inpatient outlier threshold from increasing even more than it did. For instance, CMS used the one-year charge inflation factor between FY 2018 and FY 2019 to inflate FY 2021 charges to determine the FY 2023 outlier threshold. Normally, CMS would compute the charge inflation factor using data for FYs 2020 and 2021. However, CMS' analysis indicates that the one-year increase in charges between FY 2020 and FY 2021 is 10 percent compared to 6 percent between FY 2018 and FY 2019. Similarly, CMS used the changes in cost-to-charge ratios (CCRs) between the March 2019 and March 2020 updates to the provider-specific file to adjust the CCRs to determine the proposed 2023 outlier threshold.

Both of these special interventions lowered the FY 2023 inpatient fixed loss threshold in the proposed and final IPPS rules. In addition, CMS calculated two fixed-loss thresholds for the final rule – one including COVID-19 cases and one excluding COVID-19 cases – and then

averaging these two fixed-loss thresholds to determine the final fixed-loss threshold for FY 2023. This last special intervention was the most effective in ensuring the FY 2023 IPPS fixed loss outlier threshold did not increase inappropriately due to the special circumstances surrounding the COVID-19 pandemic.

For the 2023 OPPS Proposed Rule, CMS proposed to use the same charge inflation and CCR adjustment factors that were used in the FY 2023 IPPS Proposed Rule. However, CMS did not propose to calculate two thresholds—one including COVID cases and one excluding COVID cases—as it did in the FY 2023 IPPS final rule. The FAH understands that adopting the same policy for COVID cases in the OPPS will not appreciably impact the outpatient outlier threshold as outlier COVID cases in hospital outpatient departments are not as prevalent as they were in 2021 in hospital inpatient units. Nevertheless, we appreciate and support the other special interventions CMS has taken to lower the outpatient outlier threshold and request CMS continue to consider any options it that it could adopt to make the 2023 final rule outlier threshold less than the one it proposed.

V. C. Proposal in Physician Fee Schedule Proposed Rule To Require HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Refundable Single-Dose Container or Single-Use Package Drug

Per Section 90004 of the *Infrastructure Investment and Jobs Act* (the Act), CMS is implementing a requirement that manufacturers provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund is the amount of discarded drug that exceeds 10 percent of total charges for the drug in a calendar quarter. CMS is implementing this provision through the 2023 physician fee schedule rule. The OPPS Proposed Rule advises interested parties to direct their comments on this issue to the 2023 physician fee schedule (PFS) Proposed Rule. While the FAH submitted our comments on this issue under the PFS Proposed Rule, as directed, we reiterate our comments here.

The impact of this new requirement is unclear and could potentially increase the cost of health care delivery – including drug acquisition costs as well as overhead and labor costs. It also could increase operational burden due to decreased package sizes. For example, many drugs are dosed in a variable manner and are based on the patient's body weight. These weight-based dose products may need larger than single use package sizes to provide the appropriate volume of a drug depending on the patient's weight. If package sizes decrease as a result of this new requirement, there could be a cascading effect on providers by increasing the time and resources needed to prepare the proper dose. Thus, CMS should actively monitor potential downstream outcomes and mitigate any adverse impacts, as necessary.

Discarded Amounts

Under current policy, CMS requires hospitals and physicians to apply the JW modifier to identify the amount of discarded drug being billed from a single use vial. To implement the Act, which is effective on January 1, 2023, CMS proposes that the JW modifier would be required on claims for all single-dose container or packages for which any amount is discarded (as reflected

in current policy), and a separate new JZ modifier would be required on claims for these drugs when there are no discarded amounts. Currently, no modifier is required when there are no discarded amounts from a single use vial or single use package drug – and the absence of a modifier speaks for itself.

The new proposed JZ modifier would apply to over 450 different separately payable HCPCS coded items and would present an extensive, burdensome, and wholly unnecessary provider mandate, as compared to the current system. Implementing the modifier, as proposed, by January 1, 2023, is unrealistic as providers will have very little time to work with vendors to build the new modifier into their clinical and billing systems and integrate the new system into their clinician and staff workflow. Further, as CMS notes in the proposed rule, the JW modifier is often omitted on claims forms, which CMS acknowledges could be due to provider burden. The addition of the new modifier would only increase provider burden and is unlikely to improve data integrity.

Since the JW modifier already is current policy and provides CMS with the data needed to indicate discarded amounts, we urge CMS to reconsider use of the new modifier. We believe the best way to improve compliance is not with the creation of a new modifier but instead using provider education. CMS must educate providers that accurate use of the JW modifier is needed to ensure compliance with section 90004. If CMS does implement the modifier, we urge the agency to delay its implementation date well beyond January 1, 2023.

X. Nonrecurring Policy Changes

X.A. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

Medicare Coverage of Mental Health Services Via Remote Technologies

CMS proposes to designate certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by clinical staff of a hospital using communications technology to beneficiaries in their homes as hospital outpatient services for which payment can be made under the OPPS. CMS also is proposing to delay the requirement of an in-person visit within six months prior to the initial mental health telehealth service for 151 days after the end of the PHE.

As the FAH has previously commented, we support permitting the provision of mental health services furnished remotely by hospital staff to beneficiaries in their homes beyond the COVID-19 public health emergency (PHE). The FAH also supports extending this policy to partial hospitalization program (PHP) services. In addition, we support delaying the requirement of an in-person visit within 6 months prior to the initial mental health telehealth service for 151 days after the end of the PHE.

FAH member hospitals have extensively provided these services to patients at home during the PHE and believe that mental health services are well-suited for remote delivery via

communication technology, while providing important clinical benefits for patients. In addition, 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.[7] Further studies demonstrate that telehealth is particularly effective in mental healthcare delivery.[8] 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.[9]

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 (SUD), medication management, and psychotherapy for mood disorders.[10] Telehealth has been

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[7] 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.

[8] 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).

[9] 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/

[10] 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.

found to increase retention for SUD treatment, including medication treatment, especially when treatment is not otherwise available or requires lengthy travel.[11] In addition, there is evidence of reduced utilization of higher-cost services associated with providing access to mental healthcare services via telehealth technologies.[12]

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

Medicare Coverage of Mental Health Services Via Audio-Only Telehealth

CMS also proposes that hospital clinical staff must have the capability to furnish two-way, audio/video services but may use audio-only communications technology given an individual patient's technological limitations, abilities, or preferences.

To further promote access to mental health services, especially in light of the persistent shortage of mental health care professionals, the FAH also supports making permanent the ability to furnish audio-only mental health services (including PHP services). Our members are concerned that many of their more vulnerable patients are unemployed, under-employed, homeless, or reside in geographic areas and populations without widespread access to broadband. Further, there may be circumstances in which a patient is unable or does not wish to use two-way, audio/video technology, or when furnishing services via audio-only technology is necessary in the physician or practitioner's clinical judgment. Coverage of audio-only telehealth services can help fill gaps in care by enabling underserved and vulnerable populations to access mental health services. Importantly, beneficiaries and providers have become more familiar with and better equipped to use telehealth, including audio-only telehealth.

X.C. Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology

Cardiac (CR), intensive cardiac (ICR) and pulmonary rehabilitation (PR) services can be provided via telehealth under the PFS until December 31, 2023. Under current OPPS policy, CR, ICR and PR may be provided in the hospital with the physician direct supervision being provided to a patient via a virtual presence. The virtual supervision policy will end with the conclusion the

[11] 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).

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

COVID-19 PHE. CMS is seeking comments on whether to extend the virtual direct supervision requirement through the end of 2023 comparable to the PFS. The FAH supports such an extension.

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, 12 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 be permanently amended to allow for telehealth supervision, without the requirement for a new modifier.

X.E. Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients

Supervision by physicians or NPP regulations apply to services paid under the physician fee schedule. However, parallel supervision requirements for both diagnostic and therapeutic services applicable to the outpatient department services of hospitals and CAHs reference these regulations. CMS proposes to modify these regulations, at 42 CFR §§ 410.27 and 410.28, to include NPPs as supervising practitioners in addition to physicians for diagnostic and therapeutic services furnished under personal or direct supervision to the extent that they are authorized to do so under their scope of practice and applicable state law. The FAH supports this proposal as all applicable regulations should permit physicians and NPPs to supervise these services.

X.G. OPPS Payment for Software as a Service

We commend CMS' recognition in the proposed rule that Software as a Service (SaaS) can be a separate and distinct service to be paid separately and not considered as an ancillary packaged service that is part of a primary service. For 2023, CMS proposes not to recognize the CPT add-on codes that describe SaaS procedures under the OPPS and instead establish C-codes to describe the add-on codes as standalone services. The new C-codes would be billed with the associated imaging service and paid the same rate as the initial CPT code that provides data analysis using an existing image, as both codes use the same technology. The FAH supports these proposals. We also urge CMS to continue consideration of coverage and payment for SaaS for services beyond radiology services, and as it does so, to review data resulting from these initial SaaS policies to guide CMS in developing consistent and standardized policies that can easily be adapted down the road to other potentially eligible services linked to SaaS.

H. Proposed IPPS and OPPS Payment Adjustments for Domestic NIOSH-Approved Surgical N95 Respirators

CMS proposes to make a payment adjustment under the OPPS and IPPS for the additional costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. The FAH appreciates CMS' recognition of the significant and costly supply challenges for hospitals and health systems have faced throughout the course of the pandemic. We also appreciate the agency's novel approach to incentivizing domestic manufacturing of N95 respirator masks, but have several concerns over the proposed payment adjustment.

CMS proposes to base the payment adjustment on the estimated difference in the reasonable costs of purchasing domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators, provided as a biweekly interim lump-sum payment. The agency recognizes that hospitals cannot independently determine if respirators are manufactured domestically, and therefore, proposes that they rely on written statement from the manufacturer that the respirator is domestically made. In order to determine the payment adjustment, CMS proposes that a hospital would need to separately report on its cost report the aggregate cost and total quantity of domestic and non-domestic respirators.

We are concerned that these proposals would increase reporting burden on hospital staff and frontline workers, and that this would come at a time when workforce shortages have already created challenges to hospitals and health systems. First, hospitals must differentiate domestically made respirators from non-domestically made. As such, hospitals must obtain a written statement as to manufacturing origin, as proposed by CMS, which has been certified by the manufacturer's Chief Executive Officer (CEO); the manufacturer's Chief Operating Officer (COO); or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. It is unclear how hospitals would be able to obtain such a document or if the manufacturer would provide one for the

purposes of Medicare reimbursement. Certainly, requiring manufacturers to meet new labeling and reporting requirements (potentially in the bar code) would be more efficient and less burdensome.

Additionally, hospitals and health systems would be required to separately report on a new supplemental cost report form the aggregate cost and quantity of domestically made and non-domestically made respirators. To do this, hospitals must devote critical staff to track, report and maintain these requirements and cost report records. For example, if a hospital were to obtain a manufacturer's written statement attesting to domestically made status, hospitals would also be required to maintain these records to be included on the supplemental cost reporting form, presumably until cost reports have been settled. The FAH urges CMS to work with stakeholders to determine a less burdensome method of attestation and reporting for these payment adjustments.

Furthermore, the agency proposes to make the payment adjustment budget neutral under the OPPS but not budget neutral under the IPPS. CMS estimates that OPPS payments would total $8.3M for CY 2023, which would entail a budget neutrality adjustment. While we support CMS' proposal to increase Medicare reimbursement for those hospitals that purchase domestically manufactured N95 respirators, we urge CMS to make any additional payments non-budget neutral. Redistributing payments from an already underfunded system will not be of benefit to providers or to patients and we oppose the new payment approach for the OPPS if it is done on a budget neutral basis.

Finally, we also continue to have concerns over several potential unintended consequence of the proposal related to equity, as we have previously written. These include, but not limited whether CMS has considered the disadvantages this proposal may pose for hospitals and health systems that serve a significant number of Medicaid patients, as this proposal only would apply to Medicare fee-for-service beneficiaries. We also urge CMS to consider that Medicare fee-for-service utilization varies state-by-state across the country, which could put providers at a disadvantage depending on the state(s) in which they operate.

X.I. Exempting Rural SCHs from Clinic Visit Office-Campus Payment Limitation

Since 2019, CMS has been paying a physician fee schedule (PFS) equivalent rate for a clinic visit provided in an off-campus provider-based department (PBD). The PFS equivalent rate was implemented over a 2-year transition period at 70 percent of the full OPPS rate in 2019 and 40 percent of the full OPPS rate in 2020. The reduction in payment applies to a clinic visit irrespective of whether the off-campus PBD is new after November 2, 2015 and subject to a PFS-equivalent rate for all of their services (a non-excepted off-campus PBD) or excepted from the reduction as a result of being in operation as November 2, 2015 (an excepted off-campus PBD).

CMS previously sought public comment on whether there should be exceptions from this policy for rural providers, such as those providers that are at risk of hospital closure or those

providers that are rural SCHs. While the FAH and others supported an exception for rural providers, CMS felt that the two-year phase in of the policy would help mitigate the financial concerns for these types of hospitals.

Since this policy was implemented, CMS has continued to assess how this policy has been implemented, and how it affects both the Medicare program itself and the beneficiaries it serves. This policy was designed to address an increase in total utilization as CMS observed a shift in utilization of clinic visits from physician offices to off-campus provider-based departments because of higher payments under the OPPS. Nonetheless, CMS recognizes that the volume of clinic visits furnished in off-campus PBDs of certain hospital types may primarily be driven by factors other than higher payment, such as service shifts from the inpatient hospital to outpatient hospital setting and access issues.

The proposed rule indicates that many rural providers, and rural SCHs in particular, are often the only source of care in their communities, which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas further drives utilization to off-campus PBDs in areas where rural SCHs are located. For these and other reasons, CMS believes that exempting rural SCHs from being paid a PFS-equivalent rate for a clinic visit in an off-campus PBD would help to maintain access to care in rural areas.

Accordingly, beginning in 2023, CMS proposes that rural SCHs be excepted from being paid the PFS-equivalent rate in an excepted off-campus PBD. CMS is further soliciting comments on whether it would be appropriate to exempt other rural hospitals, such as those with under 100 beds from this policy. **The FAH fully supports CMS' proposal to except rural SCHs from being paid the PFS-equivalent rate in an excepted off-campus PBD. Further we urge CMS to expand this exception to all rural hospitals with fewer than 100 beds and all rural SCHs.**

XIV.B. Hospital OQR Program Measures and Topics for Future Considerations

B. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information (RFI)

General Considerations

CMS requests input into key principles and approaches to be considered as the agency further develops its strategy for advancing health equity across its quality reporting and value-based programs.[13] This RFI focuses on consistent measurement of disparities and routine reporting of stratified measure results as strategic tools to closing equity gaps in its programs. CMS plans to employ these tools to provide actionable information about disparities to providers across the continuum of care through applications of the tools tailored to accommodate the contextual and structural variations across its quality enterprise. In this RFI, CMS defines health equity as *the attainment of the highest level of health for all people, where everyone has a fair*

[13] Described at https://www.cms.gov/cms-strategic-plan.

and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. CMS also adopts a definition of measure stratification as the calculation of measure results for specific groups or subpopulations of patients.

The FAH welcomes the opportunity to respond to this Equity Measurement RFI on behalf of our hospital and health system members and their associated clinicians. Our members are diverse in size, location, and mix of services provided but are united in their commitment to achieving the best possible outcomes for all of their patients through holistic care without regard to demographic or social risk factors. We support the agency's definition of health equity and fully concur with CMS that approaches to identifying and addressing disparities in its programs must balance the goals of establishing consistency across programs with program-specific flexibility.

Key Considerations For Cross-Setting Use Of Quality Measures And Results Stratification

The FAH agrees with CMS that stratified results from the Within-Provider and Across-Provider Disparity Methods can support meaningful self-directed analysis by a hospital of its care for patients with and without specific sociodemographic risk factors associated with outcomes disparities. We also agree that care must be taken to avoid the inadvertent introduction of measurement and selection biases during stratification. We recommend that results be routinely examined for internal inconsistences (e.g., highly improbable results) and for consistent directional trends for interrelated stratification variables (e.g., low income and full Medicaid eligibility). The introduction of disparity methods and stratified reporting into a specific quality program must be fully transparent to providers and should begin on a small scale (e.g., a well-established measure and a single social risk variable). Interactions of stratification with a measure's risk adjustment methodology must be proactively sought and their impacts on accuracy, validity, and reliability assessed by CMS before stratified results are reported to providers. Privacy safeguards must be embedded into every step of the measurement, stratification, and reporting processes.

Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

The FAH agrees with CMS that decisions about how to identify and prioritize measures for possible stratified reporting should be made at the individual quality program level. In some programs, decision making should even occur at the domain or other subgroup level. Principles listed by CMS as being under consideration include the use of measures that are: existing, validated, and reliable clinical measures; outcome measures for which some evidence of disparities exists among Medicare beneficiaries; measures for which adequate sample sizes are available; measures broadly representative of providers and outcomes; and measures of appropriate access and care. The FAH believes that all of these principles have merit. We also agree with CMS that modifications may be needed based on the demographic or social risk variable being examined, each quality program's structure, and the intended use of a given

measure. Decisions should incorporate stakeholder input and decision making should be done transparently.

The FAH recommends that CMS also consider the following as guiding principles for selecting and prioritizing measures for disparities reporting: (1) measures for which CMS already has data sources containing potentially relevant demographic or social risk factors (e.g., zip code or dual-eligibility status); (2) measures for which self-reporting of data are inherent in the measure, such as experience-of-care surveys and patient-reported outcome performance measures (PRO-PM); (3) measures for which CMS can calculate performance results timely and provide feedback promptly to providers, as aging data quickly become irrelevant; (4) expansion beyond clinical measures to resource use measures, as providing appropriate and equitable care to at-risk patients may necessitate increased resource use (e.g., unplanned readmissions) that could cause what otherwise appears to be poor resource use performance; and (5) measures that are likely to align with collection and reporting requirements of states and other third-party payers as a means of minimizing provider burden that also will strengthen the validity and reliability of measure results. We also suggest that CMS explore mining of potentially relevant qualitative data already being generated in many of its programs as an adjunct to identifying disparities and drivers of disparities. These data include observations made by accrediting agencies and state surveyors, resident and family/caregiver complaints, ombudsmen reports, and insights gleaned during QIO interactions with facilities.

Principles for Social Risk Factor and Demographic Data Selection and Use

CMS notes the challenges of selecting from the myriad factors for which associations with disparities have been suggested and the limited availability of high-quality (i.e., self-reported) data sources for certain variables. CMS describes proxy variables (e.g., neighborhood indices) and tools (imputation for missing data) for possible use when self-reported data are scarce.

The FAH strongly recommends that CMS begin disparity analyses and stratified reporting with demographic and social risk variables for which CMS already has large data sets (e.g., Medicare enrollment and claims data) containing potentially relevant information (e.g., diagnoses, dual-eligibility status). We note that small variations may be smoothed out when data are collected and stratified for large groups and subgroups but will continue to impact reliability and utility of results for smaller populations and low-frequency variables. We further recommend strongly that all variables to be analyzed for disparities be required to have clear, standardized definitions that are used consistently across CMS quality programs. Practical barriers to the number of variables to be studied also must be taken into account, including reporting burden created for providers and optimal allocation of finite provider and CMS resources.

The FAH recognizes that patients may be reluctant to share sensitive personal information, contributing to the challenge of missing data points for the gold standard, self-reported data. When self-reported data availability is particularly limited, we support the judicious use of some of the substitute variables being considered by CMS, such as

neighborhood-based variables (e.g., Area Deprivation Index, Census Bureau's Community Resilience Estimates). The FAH does not support the use of imputed data techniques to replace missing demographic data, at least until considerably more data are made publicly available by CMS about data imputation efficacy and accuracy when used in its quality programs. The assumptions of the imputation technique may introduce unanticipated biases into the original data set. We firmly believe that CMS resources are better invested into enhanced efforts for collection of self-reported data than into expanding techniques for data imputation. We also suggest CMS carefully consider the translation of such indexes into composite measures. Composite scores can be useful, but they must be carefully considered, as underlying variables may or may not be predictive of performance for a given quality program.

The FAH encourages CMS to seek out alternative sources of social risk factor data in other HHS initiatives and other federal programs. Work underway by the Medicare Payment Advisory Commission could inform considerations of new sociodemographic variables (e.g., the expanded low-income category discussed at recent Commission meetings)14, as might the work of the Health Level 7 (HL7® Gravity Project. Finally, the FAH suggests that CMS explore establishing a needs assessment process through which variables with high face validity for potential disparities -- but lacking standardized definitions, credible self-reported sources within CMS data sets, and/or suitable proxy variables -- could be identified, analyzed, and refined in a transparent manner for future use (e.g., sexual orientation/gender identity).

Identification of Meaningful Performance Differences for Use in Stratified Results Reporting

CMS briefly describes multiple potentially useful methods for identifying meaningful performance differences (i.e., disparities) and sharing them with providers through stratified results reports: confidence intervals, standard deviation-based cut points, clustering algorithm use, rank ordering, categorization using thresholds or fixed intervals, benchmarking, and peer grouping. Comments are solicited about preferred methods.

The FAH believes that the preferred method(s) will vary with the quality measure and the program in which it is being used, the sociodemographic variable being studied, the disparity method being used, provider type, care setting, and intended audience for the results. Decision making should most often rest at the program level though domain, subgroup, and measure level decisions could be appropriate in select circumstances. We advise CMS to consider first if stratified results calculation and reporting of a given measure-sociodemographic variable combination is appropriate and the likelihood that the ensuing results when presented to providers will incent them to conduct self-directed analyses that could lead to effective interventions to reduce disparities. We also note that when multiple comparisons are performed, some statistically significant associations inevitably will emerge. Not all will be causal relationships and not all will be worthy of time and resource investment by providers to explore, particularly when exploration would depend heavily on scarce or costly health IT resources and

[14] Medicare Payment Advisory Commission. Medicare payment policies to support safety-net providers. Leveraging Medicare policies to address social determinants of health. Meeting Presentations March 2022 and April 2022.

capabilities. Establishing a CMS-sponsored technical assistance program for resource-limited providers should be considered.

The FAH recommends that categorization using thresholds or fixed intervals and rank ordering methods be used with particular care. Application of these methods carries relatively high risk for creating subgroups that could be inappropriately characterized as practicing discrimination. Labeling of providers as discriminatory, even though unintentional, when based on poorly chosen statistical methods and/or inappropriate application of stratified reporting results could cause long-term and nearly irreparable harm to beneficiaries, providers, and the Medicare program. The same risk appears even higher for the method of regression decomposition, not included in this RFI but described in some detail by CMS in recent rulemaking for other Medicare sectors (e.g., Inpatient Rehabilitation Facility Prospective Payment System FY 2023 Proposed Rule).

The FAH opposes the use of decompensation techniques in Medicare quality reporting and value-based programs at this time. Should CMS wish to adopt this analytic tool for use across its quality enterprise as something other than a research tool for internal agency use only, the FAH believes that CMS must first come to stakeholders with a body of evidence that credibly, transparently, and explicitly addresses the application of Blinder-Oaxaca decomposition to Medicare disparities data analysis. The evidence must include readily understood – but not oversimplified -- simulation and modeling examples and results using actual deidentified Medicare data from several quality programs. A plan that details how results would be used internally by CMS and perhaps someday shared publicly must also be presented with special attention to how misrepresentation of providers as discriminatory would be avoided.

Guiding Principles for Reporting Disparity Results

CMS observes that the agency typically begins with confidential reports to providers before transitioning to public reporting of results from its quality reporting and value-based programs. CMS believes that initial confidential reporting is especially beneficial when new programs, measures and/or measurement methodologies are being introduced. The agency also believes that public results reporting enables market forces to incent improvement by providers in order to remain competitive. CMS states that statute requires public reporting of results from all its quality programs and strongly implies that stratified results would be similarly subject to mandatory public reporting.

The FAH strongly believes that confidential reporting to providers is entirely appropriate for measures and initiatives involving stratification for demographic and social risk factors. Results reporting should be accompanied by a review and correction process and be subject to data validation. Properly structured provider-only reporting should create an environment that facilitates the detection of unintended consequences or confusing results before any public reporting of these sensitive data is considered. Transition to public reporting should be planned and implemented in a deliberate and unhurried manner, and only after the data collected have demonstrated a high degree of reproducibility and after a period of confidential reporting that is

sufficient to identify unintended consequences. We note that statute provides the Secretary with considerable discretion and flexibility regarding public reporting.

The FAH believes it to be essential for CMS to structure any public reporting of disparities comparison results in a way that avoids the risk of further disadvantaging providers who serve populations and areas with limited resources (e.g., located in low-income and rural communities). Also prior to public reporting, we strongly encourage CMS to undertake focus groups to test messaging and understanding of disparities data, so that the results reported are clear for patients, families, and caregivers. Finally, the FAH recommends that privacy protection be the foundational principle on which CMS bases decisions about disparities reporting. The importance of privacy safeguards for patients and facilities cannot be overemphasized.

Conclusion

The FAH remains supportive of the essential work being done by CMS related to healthcare disparities and inequities as represented by this Equity Measurement RFI. Application of methods for identifying and reporting disparities within CMS programs remains a worthy goal to which the FAH recommends a deliberative, consistent, coordinated approach be taken by the agency. Some of the tools and methods described in this RFI appear promising for use in CMS programs. The FAH remains fully committed to working with CMS, HHS, and others on additional principles, tools, and methods for disparities reporting that seem likely to be feasible, practicable, and lead to improved health outcomes.

XVII. Organ Acquisition Payment Policy

In this year's OPPS Proposed Rule, CMS proposes additional revisions and policies related to Medicare's organ acquisition payment policies. Specifically, the agency proposed to change how organs procured for research are counted for the purposes of calculating Medicare's share, requiring that Transferring Hospitals (THs) and Organ Procurement Organizations (OPOs) exclude organs used for research. The agency also clarified that organ acquisition costs would include certain hospital costs incurred for services provided to deceased donors

B. Research Organs to Calculate Medicare Share of Organ Acquisition Costs

The FAH supports the CMS proposal to (1) exclude organs used for research from the numerator (Medicare usable organs) and the denominator (total usable organs) of the calculation used to determine Medicare's share of organ acquisition cost on the Medicare cost report and (2) for THs and OPOs to deduct the cost of incurred in procuring an organ for research from their total acquisition costs. This policy allows for a more accurate reporting of Medicare usable organs while still ensuring the Medicare Trust Fund is not inappropriately paying for research costs.

C. Cost of Certain Services Furnished to Potential Deceased Donors

The FAH supports the CMS proposal to allow a donor community hospital or TH to incur costs for hospital services attributable to a deceased donor or a donor whose death is

imminent. This policy will result in incremental reimbursement that appropriately supports clinical situations where failure to provide hospital services to the potential donor may compromise the viability of organs and limit organ donation.

D. Clarification of Allocation of Administrative and General Costs

CMS' clarification that the "purchase cost" of organs acquired from an OPO by a TH must exclude these costs from the accumulated cost statistic on worksheet B-1. CMS references 42 CFR 424.24 (d)(6) which states in part:

"In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Where a provider has purchased services for a provider-based entity or for a provider department, like general service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department."

In the proposed rule, CMS' clarification to exclude the OPO "purchase cost" from the cost allocation statistic on the TH Medicare cost report to avoid the duplication of administrative & general (A&G) costs already incurred by the TH. The FAH believes this clarification inappropriately assumes that 100% of the OPO purchase costs and TH A&G costs are "like costs". The OPO and THs each have separate and distinct administrative overhead structures where "like costs" would be non-existent or de minimis and if this policy is implemented would result in the underreporting and under reimbursement of valid A&G reasonable costs incurred by a TH acting as a prudent buyer of goods and services. An analogous situation might be where a hospital acquires a high-cost medical device for implantation into a patient. The device company has its own overhead cost structure for its line of business that differs from the hospital's overhead costs. In the situation, there's no instruction to remove the cost of the device from the accumulated cost statistic. The FAH believes the same concept should apply to OPO purchase costs.

The FAH urges CMS to withdraw its clarification. However, if CMS believes some additional clarification on this cost reimbursement principle is required, we recommend that the CMS guidance should read:

"CMS reminds THs that OPO purchase costs included in the Medicare cost report accumulated cost statistic should be consistent with 413.24(d)(g) and where "like" A&G cost definitively exists and are able to be documented, those duplicative costs should be removed from the accumulated cost statistic."

XVIII. Rural Emergency Hospitals

Section 125 of the Consolidated Appropriations Act (CAA), 2021 establishes REHs as a new Medicare provider type that will furnish emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week. In addition, an REH may elect to furnish other medical and health services on an outpatient basis as the Secretary may specify through rulemaking. REHs may not provide acute inpatient services, with the exception of skilled nursing facility (SNF) services that are furnished in a distinct part unit.

An REH must have a transfer agreement in effect with a level I or level II trauma center and meet other conditions, including licensure, emergency department staffing, staff training and certification, and CoPs applicable to hospital emergency departments and CAHs for emergency services. REHs must have an annual per patient average length of stay of 24 hours or less.

Providers that are CAHs and small rural hospitals (50 or fewer beds) as of December 27, 2020, may convert to REHs. To be considered rural as of December 27, 2020, the hospital or CAH must have been either located in an area designated as rural by the Office of Management and Budget (OMB) or be treated as rural under the IPPS—e.g., located in an urban area but reclassified to a rural area for all IPPS purposes.

CMS solicited public comments through the 2022 OPPS rulemaking cycle on its implementation of the REH program and has taken all comments into consideration while drafting this proposed rule. The REH program will be very important to maintaining access to emergency services, observation services and other outpatient services in rural areas of the country where there are not enough patients to support an acute inpatient presence.

The FAH appreciates CMS deliberative process in implementing the REH provision including considering public comments provided on its implementation of the provision in 2021. Below are comments on specific proposals:

Number of Beds. FAH has reviewed the REH Conditions of Participation (CoP) Proposed Rule published on July 6, 2022, in the *Federal Register* (87 FR 40350). The CoP Proposed Rule preamble and proposed 42 CFR §485.506 restate the statutory requirement that to be eligible to convert to an REH, a hospital located in a rural area or treated as rural under the IPPS must have 50 beds or fewer. However, the Proposed Rule does not indicate how beds will be counted—e.g., whether CMS will used licensed beds to make the determination or beds actually in use.

Licensed beds means the number of beds licensed by the agency having licensing jurisdiction over the facility. This number could be greater than the number of beds that the hospital actually has in use. If a rural hospital has more than 50 licensed beds but 50 beds or fewer in use, the hospital would be precluded converting to REH status even though it otherwise meets the criteria for being an REH.

The FAH recommends CMS use the definition of beds from 42 CFR §412.105 to determine whether the 50-bed limit is met for a rural hospital to convert to REH status. This definition is used for purposes of Medicare's indirect medical education and

disproportionate share adjustments. More directly, it is also used for determining whether a hospital is eligible for Medicare Dependent Hospital status—also, a provision that is intended to facilitate access to services in rural areas (although expiring on September 30, 2022, the provision has been set to or actually expired previously but has later been extended a number of times in its 32-year history).

This definition relies on the number of bed days available during the cost reporting period divided by the number of days in the cost reporting period—e.g., it is a measure of available beds or beds in use and not licensed beds. Excluded from the count are non-acute care beds not used for care that is paid under the IPPS.

Defining "REH Services." Section 1861(kkk)(1)(A) of the Act defines "REH services" as emergency department and observation services as well as, at the election of the REH, other medical and health services furnished on an outpatient basis as specified by the Secretary through rulemaking. CMS is proposing to define "REH services," as all covered outpatient department services that would be paid under the OPPS.

This definition does not include services that may be provided in outpatient departments that are not paid under the OPPS such as laboratory services and outpatient rehabilitation therapy services. However, REHs may provide these services (and are actually required to provide laboratory services under the REH conditions of participation) even though they do not meet the definition of "REH" services. (The relevance of the distinction of a service as an "REH service" will be discussed in the next section).

The FAH supports CMS' proposal to allow REHs to be paid for providing all services that may be provided in hospital outpatient departments including those services that are not paid under the OPPS.

Monthly REH Facility Payment As part of its reimbursement, REHs will receive a monthly facility payment. By statute, the additional facility payment for 2023 is calculated as the excess of the *actual* total amount paid to all critical access hospitals (CAHs) in 2019 that exceeds what would have been paid had payments been made under the applicable prospective payment systems (i.e. the *projected* Medicare payment), divided by the total number of such hospitals in 2019. For 2024 and subsequent years, the facility payment would be increased by the hospital market basket percentage.

CMS is proposing to use 100% Medicare FFS claims data to calculate the additional facility payment. We appreciate that the agency has taken this approach and agree with CMS' assessment that CAH claims are the best available resource to determine the amount of Medicare payments to all CAHs in CY 2019. We also agree with the agency's proposal to include amounts paid to CAHs from Medicare and beneficiary copayments and to calculate amounts using calendar year 2019 claims and not fiscal year 2019 claims. Under this proposed methodology, CMS is estimating that the actual amount of Medicare spending for CAHs in CY 2019 was $12.08 billion and that the projected amount of Medicare spending is $7.68 billion, resulting in a monthly facility payment of $268,294. **We support the agency's use of Medicare claims data to determine the facility payment. Going forward, we ask that CMS continue to carefully**

consider the ongoing financial challenges for rural hospitals and monitor the adequacy of the facility payment given rising costs in labor and supply.

With that said, we urge CMS to publish a more detailed methodology of its facility payment calculations. Without this information, stakeholders are not fully able to replicate and evaluate the agency's methodology. Finally, REHs are required by statute to maintain information on how they have used their additional facility payments. CMS is proposing that this requirement be met using existing cost report requirements on outpatient services. We agree with this proposal and believe that REHs should not be required to report new data and information to meet this requirement.

Payment for REH Services. Section 1834(x)(1) of the Act states that payment for REH services "…shall be equal to the amount of payment that [would be paid under the OPPS] increased by 5 percent…". CMS proposes that payments for REH services will equal the applicable OPPS payment for the same service plus an additional 5 percent. CMS will update the OPPS claims processing logic to include an REH-specific payment flag to pay the OPPS payment rate plus 5 percent. Beneficiary coinsurance will be 20 percent of the OPPS payment without the additional 5 percent consistent with section 1834(x)(1) of the Act.

The relevance of being defined as an "REH service" will be to application of the payment increase of 5 percent. The additional 5 percent payment will only apply to services that meet the definition of "REH services"—or those services that are paid under section 1833(t) of the Act as OPPS services. As laboratory services and rehabilitation therapy services may be provided by an REH, they are not REH services and will be paid at clinical laboratory fee schedule rate or physician fee schedule rate respectively and are not eligible for the 5 percent additional payment made under the OPPS.

The FAH supports CMS' proposed policy as we recognize the statute limits CMS from applying the 5 percent increase to services that are not paid under section 1833(t). That said, beginning in 2014, CMS packaged most laboratory tests into its OPPS payments on the basis that laboratory tests are integral, ancillary, supportive, dependent or adjunctive to a primary service or services when provided on the same day and ordered by the same physician for a hospital outpatient. We ask CMS to clarify that its packaging policy for laboratory services will continue to apply to the adjusted OPPS payment made to an REH. If so, this means that most laboratory services when part of a packaged payment will be considered to be an REH service in this context and eligible for the 5 percent increase in payment.

Prohibition of Inpatient Psychiatric and Rehabilitation Units. REHs may not provide acute inpatient services, with the exception of skilled nursing facility (SNF) services that are furnished in a distinct part unit. This requirement is statutory although it is unclear what policy purpose is served by precluding REHs from having inpatient psychiatric and rehabilitation units that could be paid under the respective prospective payment systems for each type of service. The inability of an REH to provide inpatient psychiatric services is of particular concern given the strong need for mental health services in all areas but particularly rural of areas of the nation.

The FAH recognizes that CMS' authority here is limited by statute, but **we ask CMS to support us in advocating for legislative change that would allow REHs to have distinct part inpatient psychiatric and rehabilitation units that are paid under their respective prospective payment systems.**

Payment for an Off-Campus Provider-Based Department of an REH. Under section 1833(t)(21) of the Act, services provided by a new off-campus provider-based department of a hospital—new generally meaning that the department first began providing outpatient services on or after November 2, 2015—is paid 40 percent of the OPPS rate. CMS includes a complex legal explanation for its proposal that basically concludes that Congress did not intend to expand the application of section 1833(t)(21) to REHs.

CMS makes this conclusion because of a provision that indicates "nothing" in the REH statute should be construed as affecting application of the statutory provisions in section 1833(t)(21) that results in a new off-campus provider-based department of a hospital being subject to a limit based on 40 percent of the OPPS payment. Further, CMS notes that CAHs are not subject to the same or an analogous payment limit when providing services in a new off-campus provider-based department. CMS believes it would be inconsistent with the statutory goal of maintaining access to services in rural areas by applying a payment limit to an REH that did not apply to the facility when it was a CAH. **The FAH agrees with CMS' proposal.**

Requirement for Transfer Agreement with a Level I or II Trauma Center. By law, REHs must have a transfer agreement with a level I or level II trauma center. CMS is proposing to require that REHs must have in effect an agreement with at least one Medicare-certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. While CMS expects REHs to have a transfer agreement in place with a level I or II trauma center, REHs may also have a transfer agreement with a hospital that is not designated as a level I or II trauma center. As the law subjects REHs to the Emergency Treatment and Labor Act (EMTALA) requirements under section 1867 of the Act, CMS is modifying the EMTALA regulations to include their application to REHs.

The FAH recognizes that the requirement for a transfer agreement with a level I or II trauma center is a provision of the statute. However, it is possible that in a given circumstance, the REH may need to transfer a patient consistent with EMTALA to another type of hospital that is not a level I or II trauma center but has the specialized capabilities to treat a patient that cannot be treated by the REH. The FAH requests that CMS clarify that only the transfer agreement is required but that the REH would not be in violation of the CoPs or EMTALA if it made a transfer of a patient needing emergency care to a hospital capable of treating the patient even though it is not a level or level II trauma center.

Rural Emergency Hospitals and Physician Self-Referral Updates

The FAH fully supports the creation of the new provider category for rural emergency hospitals (REHs), recognizing that REHs represent an innovative model for delivering care in rural and underserved communities. ***The FAH, however, strongly opposes CMS' proposal to***

create a new REH exception to the physician self-referral law to permit physician ownership of REHs without critical protections designed to protect against both program and patient abuse. The proposed REH exception inappropriately circumvents Congress's express direction regarding physician-owned hospitals (POHs) and is unnecessary to support the development of REHs. ***Rather than adopting the proposed REH exception, the FAH urges CMS to simply allow existing POHs that convert to REHs to maintain their grandfathered status under an established POH exception.***

The physician self-referral law, commonly known as the Stark Law, aims to protect both patients and federal health care programs from the inherent conflict of interest created when physicians self-refer their patients. Briefly, the Stark Law prohibits physician referrals to an entity for designated health services (DHS) where the referring physician (or an immediate family member) has a financial relationship with the entity, unless an exception applies. This rule broadly prohibits POHs unless the requirements of either the rural provider exception or the whole hospital exception are satisfied. With the enactment of the Affordable Care Act (ACA), Congress significantly narrowed these statutory exceptions to prevent the creation of new POHs after 2010, to limit expansions of POHs, to ensure that ownership and investment interests are bona fide, and to improve POH transparency and patient protections.[15] In so doing, Congress acted on decades of research on the adverse impacts of POHs and adopted express rules prohibiting the expansion of POHs except in limited circumstances.

CMS' proposed REH exception would permit new physician ownership and investment in REHs and apply to all referrals and billing for DHS furnished by an REH. Although the proposed REH exception includes provisions that mirror various requirements applicable to POH expansions under the whole hospital exception and the rural provider exception, the proposed exception would not fully incorporate these requirements. Importantly, the REH exception would not include a limitation on the percentage of total value of ownership/investment interests, a prohibition on facility expansion, required disclosure of conflicts of interest, and patient safety requirements. ***While the FAH recognizes the importance of REHs and ensuring that capital is available to support access to care in our rural communities through this new provider type, the creation of a new Stark Law exception to more broadly permit physician investment in or ownership of REHs that were not previously POHs invites gamesmanship and risks the very harms Congress sought to address with the ACA's limitations on POHs.***

As noted in the Proposed Rule, REHs are excluded from the definition of "hospital" for most Medicare purposes. But this fact does not preclude CMS from treating REHs as hospitals for Stark Law purposes and applying the rural provider exception and/or whole hospital exception to REHs by reference to their pre-conversion status. Under this alternative approach, an eligible POH could convert to an REH while retaining its "grandfathered" status under the rural provider exception or the whole hospital exception and without the need to unwind physician ownership and investment. In fact, CMS has previously taken a similar approach for critical access hospitals (CAHs), including CAHs in the definition of "hospital" for Stark Law

[15] Social Security Act § 1877(d)(2)(C), (d)(3)(D), (i).

purposes,[16] even though Congress excluded CAHs from the definition of "hospital" for most Medicare purposes.[17]

The Proposed Rule, however, declines to follow this established path and instead proposes to bypass the ACA limitations on POHs set forth in 42 U.S.C. § 1395nn(d) and craft a new physician ownership exception under 42 U.S.C. § 1395nn(b)(4). In advancing this new REH exception, CMS relies on its "belie[f] that physicians and their immediate family members may be an important source of needed capital for REHs[, and concern] that limiting the amount of physician ownership or investment in an REH to the level of such ownership or investment in the original hospital on March 23, 2010 could limit the services available to its patients and the community in which it is located and run counter to the purpose of section 125 of the CAA." The Proposed Rule, however, does not offer any specific analysis or data to supports this assumption. Nor could it—no rural hospital or CAH has yet had an opportunity to convert to REH status, and it may well be that physician ownership or investment in REHs is unnecessary to securing emergency services in rural communities that can no longer support continued inpatient services.

Moreover, the proposed use of CMS' authority to adopt new Stark Law exceptions that do "not pose a risk of program or patient abuse"[18] to broaden physician ownership of REHs is inappropriate when Congress has already acted on research demonstrating the risks posed by POHs by limiting POH expansions. Years of independent data confirm that self-referrals to POHs result in cherry-picking of the healthiest and wealthiest patients, excessive utilization, and patient safety concerns at significant cost to beneficiaries and the Medicare program. And there is no indication that Congress intended the creation of the new REH provider type to be used to permit new physician ownership of converted rural hospitals and CAHs. In the absence of congressional direction indicating that a new Stark exception is permissible to ensure adequate investment in REHs, it would be inappropriate to disregard Congress' considered judgment regarding the risks of POHs by crafting an REH exception that provides a loophole for physicians to newly acquire or invest in former rural hospitals and CAHs. ***Rather, the FAH urges CMS to treat REHs as hospitals for purposes of the physician self-referral law, thus allowing POHs that convert to REHs to continue to qualify for the existing exceptions.***

Should CMS nonetheless finalize an REH exception, ***at a minimum, the FAH strongly urges CMS to broadly incorporate the requirements applicable to POHs into such an REH exception.*** In particular, the FAH is concerned that proposed 42 C.F.R. § 411.356(c)(4) does not include prohibitions on facility expansion, critical transparency requirements, and patient safety requirements.[19] For example, physician-owned REHs, like POHs, should be required to submit annual reports to CMS on ownership and investment interests, ensure that referring physician owners or investors make appropriate disclosures to patients, and disclose physician ownership or investment on the REH's public website and public advertising. These requirements provide crucial information to regulators, referred patients, potential patients, and the community. Such

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[16] *See* 42 C.F.R. 411.351.
[17] 42 U.S.C. § 1395x(e).
[18] 42 U.S.C. § 1395nn(b)(4).
[19] *See* 42 U.S.C. § 1395nn(i)(1)(B), (1)(C)(i), (1)(C)(ii), (1)(C)(iv), (1)(D)(i), (1)(E), (2), (3); 42 C.F.R. § 411.362(b)(2), (b)(3)(i), (b)(3)(ii)(A), (b)(3)(ii)(C), (b)(4)(i), (b)(5), (c).

transparency alone is insufficient to address the inherent risks of program and patient abuse associated with new physician ownership of converted rural hospitals and CAHs, but foregoing the transparency and disclosure requirements applicable to POHs magnifies these risks.

The FAH also expresses deep concern with the absence of limitations on expansion of physician-owned REHs under proposed § 411.356(c)(4). In recent years, we have seen POHs seek to exploit the high Medicaid facility exception to craft expansion requests that fail to serve the needs of Medicaid beneficiaries, and the failure to limit the expansion of physician-owned REHs would likewise risk expansions that fail to serve the needs of rural communities. For example, a POH, Doctors Hospital at Renaissance (DHR), has submitted an extraordinary request to expand to an inpatient facility approximately 55 miles away from its grandfathered facility without identifying any reason that an exception to the prohibition on POH expansion is needed to address patient access issues in the county that would be served by the new facility. In fact, as noted in the FAH's and AHA's comments opposing the request, the proposed new facility is in a county that already has *more* inpatient acute care beds per capita than the county served by DHR's current facility.[20] Rather than expanding on-campus services at the existing facility under a previously granted exception, DHR proposed to enter an already well-served community and even planned to transfer patients as necessary over 50 miles to its main hospital campus despite low capacity at that facility. Expansions like the one requested by DHR risk distorting hospital markets, skewing hospital payer and case mix, and raising the costs of health care in impacted communities. ***The FAH therefore continues to urge CMS to repeal its December 2020 amendments to 42 C.F.R. § 411.362(c)(1) and to restore the on-campus requirement for high Medicaid facility expansions. Likewise, to the extent that CMS adopts an REH exception, the FAH urges CMS to limit the expansion of any such physician-owned REHs in the same way that the expansion of POHs is limited under the Stark law.***

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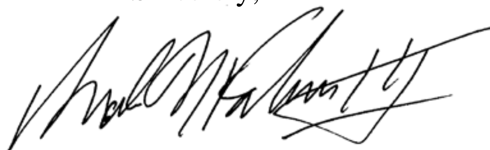
The FAH appreciates the opportunity to submit these comments on these important issues. If you have any questions, please contact me or any member of my staff at (202) 624-1534.

Sincerely,



[20] Letter from Stacey Hughes & Charles N. Kahn III to The Hon. Chiquita Brooks-LaSure, CMS-1774-PN (Mar. 11, 2022), at https://downloads.regulations.gov/CMS-2022-0034-0012/attachment_1.pdf.