Federation of American Hospitals®

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1736-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician Owned Hospitals; Proposed Rule, Federal Register (Vol. 85, No.156), August 12, 2020

Dear Administrator Verma:

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 across settings in both urban and rural areas. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on the above Notice of Proposed Rulemaking (Proposed Rule) published in the Federal Register (85 Fed. Reg. 48772) on August 12, 2020.

EXECUTIVE SUMMARY

Physician-Owned Hospital Expansion

The FAH strongly opposes CMS's proposal to effectively remove all limits on expansion by physician-owned "high" Medicaid facilities, including the frequency with which such a facility can request a capacity expansion; the caps on the number of operating rooms, procedure rooms, and beds that can be approved; and the requirement that expansion must only occur on the main campus. For multiple reasons, the proposal is much broader than purported in the Proposed Rule and its impact will far surpass only Medicaid patients, while opening the door for significant gaming by physician-owned hospitals (POHs) and thus undermining Congressional intent to strictly limit POH expansion.

There is no requirement that a high Medicaid facility in fact serve a high number of Medicaid patients. Instead, a "high" Medicaid facility is one that simply has a higher percentage of Medicaid admissions than the other hospitals in the same county. Our analysis reveals 24 facilities that either currently – or soon could – qualify. It also identifies one POH that qualifies as a "high" Medicaid facility with a FY 2018 Medicaid discharge percentage of only 1.9 percent in a county with only two facilities. Yet, hospitals in the neighboring counties have FY 2018 Medicaid discharge percentages of approximately 13 percent, 15 percent, and 22 percent. This points to the distinct possibility that this so-called "high" Medicaid POH, which also has far lower rates of uncompensated care costs and emergency room services, cherry picks patients, shifting the burden to neighboring county hospitals – exactly the behavior Congress intended to curtail when it enacted limits on POH expansion. And under the Proposed Rule, there are no limits to how often, how much, what services, and where, within a 35 mile limit, this "high" Medicaid POH could expand – or even that the POH must remain a "high" Medicaid facility under the relaxed standard that applies. The Proposed Rule also seeks feedback on removing any opportunity for the neighboring hospitals to comment on the POH's request to expand, which we strongly oppose as this may be the only opportunity for CMS to obtain accurate data. In short, the proposal contravenes congressional intent and serves no public policy purpose.

OPPS Payment Methodology for 340B Purchased Drugs

As in previous years, the FAH supports CMS's 340B payment policy and maintains that CMS must continue to implement any such payment reduction prospectively in a budget neutral manner within the OPPS. Further, the FAH reiterates its position that if further judicial review of that policy results in a retrospective reversal of the policy, the Medicare Act does not permit CMS to make any prospective offsets to achieve actual or retrospective budget neutrality. Thus, the FAH would strongly oppose any effort to offset any remedy for 340B hospitals or to otherwise achieve budget neutrality by implicitly or explicitly recouping payments made for non-drug OPPS items and services in 2018 and 2019.

Proposed Elimination of Inpatient Only List

The FAH strongly opposes CMS's arbitrary proposal to eliminate the Inpatient Only (IPO) list, which designates those procedures that are not payable under the OPPS because they can only be appropriately provided on an inpatient basis. The assignment of procedures to the

IPO list takes into account key clinical considerations that preclude the procedure from being provided to Medicare beneficiaries on an outpatient basis: (1) the invasive nature of the procedure, (2) the need for postoperative care, and (3) the underlying physical condition of the patient who would require the surgery. The IPO list serves as an important programmatic safeguard, ensuring that Medicare beneficiaries undergoing any of the 1,740 procedures on the IPO list receive inpatient care and monitoring, and its proposed elimination without any supporting clinical analysis arbitrarily removes an important patient safety mechanism. In addition, eliminating the list imposes administrative burdens on physicians and hospitals, increases beneficiaries' financial burden, and erodes the value of Part A coverage.

ASC Covered Procedures List Criteria

The FAH strongly supports CMS's proposal to continue to apply current policies and criteria for updating the ASC Covered Procedures List (ASC-CPL) and opposes both alternative options for modifying the process and criteria for additions to the ASC-CPL. The current standards and exclusion criteria for the ASC-CPL appropriately prioritize patient safety while still allowing the ASC-CPL to evolve with advancements in surgical care, and they should therefore remain in place. Although ASCs can safely perform a growing array of surgical procedures without having the capacity to provide inpatient care in the case of complications and without having satisfied other hospital conditions of participation (or being licensed and accredited as hospitals), ASCs should not be treated as the equivalent of hospital outpatient departments. ASCs are not regulated as hospitals, and since November 29, 2019, ASCs have not been required to have written hospital transfer agreements or hospital physician admitting privileges. Thus, procedures that pose significant patient safety risks (e.g., procedures that generally result in extensive blood loss, that require major or prolonged invasion of body cavities, directly involve major blood vessels, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy) should continue to be excluded from Medicare coverage in ASCs to ensure that Medicare beneficiaries receive these services in a setting that allows for rapid intervention and elevation of the level of care in the case of life-threatening complications.

The FAH also opposes adding THA to the ASC list in light of clinical concerns, expanded beneficiary coinsurance obligations for ASC procedures compared to hospital outpatient procedures, and the risks of providing payment for THA in physician-owned ASCs that are not subject to physician self-referral restrictions.

Hospital Quality Star Rating Methodology

The FAH applauds CMS's recognition for the opportunity of a much needed refresh and appreciates the proposals aiming to ensure the methodology is transparent, understandable, with clear cut-points and targets, and accurately reflecting the quality of care provided in the facilities. Until this is achieved and the changes are implemented, however, the FAH urges CMS to suspend the Star Ratings from the Hospital Compare website.

I. Proposed Wage Index Changes (Part II.C.)

The FAH commends CMS's continued commitment to supporting rural hospitals by mitigating the negative feedback look 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.[1] 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 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. As such, the FAH commends CMS's proposal to continue its policy of increasing the wage index values for hospitals in the lowest quartile of the wage index values across all hospitals. ***The FAH, however, prefers 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 for CY 2021.*** Non-budget neutral implementation of this policy would avoid unnecessarily reducing OPPS reimbursement, particularly in the midst of the ongoing COVID-19 pandemic.

The Proposed Rule also proposes to adopt the updated OMB delineations and related IPPS wage index adjustments to calculate the CY 2021 OPPS wage indices. Typically, OMB bulletins issued between decennial censuses have only minor modifications to labor market delineations. However, the April 10, 2018 OMB Bulletin No. 18- 03 and the September 14, 2018 OMB Bulletin No. 18-04 included more modifications to the labor market areas than are typical between decennial censuses, including a total of 34 counties and 10 hospitals changing from urban to rural, a total of 47 counties including 17 hospitals or critical access hospitals (CAHs) changing from rural to urban, and 19 urban counties that would shift from one Core-Based Statistical Area (CBSA) to a newly proposed or modified CBSA. The FAH supports CMS's proposal to use the new OMB Bulletin No. 18-04 delineations, consistent with the IPPS FY 2021 wage index changes.

The FAH also supports CMS's proposal to mitigate reductions in the hospital wage index due to the adoption of the updated OMB delineations and other factors by applying a 5 percent cap on any decrease in a hospital's CY 2021 wage index, though we also strongly recommend that CMS not apply budget neutrality to offset the costs of this sound transition policy**.**

II. OPPS Payment Methodology for 340B Purchased Drugs (PartV.B.)

In the Proposed Rule, CMS proposes to adjust the rate on a budget neutral basis for separately payable drugs and biologicals (other than drugs on pass-through and vaccines) acquired by a hospital outpatient department under the 340B program to ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP (*i.e.*, a net payment rate of ASP minus

[1] MedPAC June 2018 Data Book, Section 2: Medicare Beneficiary Demographics (July 20, 2018).

28.7 percent). In CYs 2018 through 2020, CMS has applied a payment methodology of ASP minus 22.5 percent for these drugs and biologicals, effectuated in a budget neutral manner.

Regardless of the final rate CMS applies, as in previous years the FAH supports CMS's 340B payment policy and maintains that CMS must continue to implement any such payment reduction prospectively in a budget neutral manner within the OPPS, consistent with the requirements of 42 U.S.C. § 1395*l*(t)(9)(B). Thus, the FAH supports CMS's proposal to adopt an increase to the conversion factor to account for any change in 340B drug payment policy. Doing so would provide a net benefit to as many as 82 percent of all hospitals paid under the OPPS, including 89 percent of rural hospitals, 74 percent of government hospitals, and even 42 percent of 340B hospitals.

The Proposed Rule also includes a review of ongoing litigation concerning CMS's 340B payment policy in CYs 2018 and 2019, suggesting that if further judicial review of that policy results in a retrospective reversal of the policy, CMS would also reverse the associated budget neutrality adjustment for those years.[2] The FAH reiterates its respectful disagreement with CMS's assertion that CMS must or may craft a budget neutral remedy for its CY 2018 and 2019 340B-acquired drug payment policy. To the contrary, the Medicare Act does not permit CMS to make any prospective offsets to achieve actual or retrospective budget neutrality. ***To the extent that CMS is ultimately required to provide a remedy for 340B hospitals through a prospective payment increase designed to compensate such hospitals for any past underpayments, that payment increase cannot be adopted in a budget neutral fashion because any offsetting payment reduction would unlawfully recoup past payments that were properly made by CMS for non-drug OPPS items and services***. Thus, the FAH would strongly oppose any effort to offset any remedy for 340B hospitals or to otherwise achieve budget neutrality by implicitly or explicitly recouping payments made for non-drug OPPS items and services in 2018 and 2019.

III. Site Neutral Payment for Off-Campus Clinic Visits (Part VII)

The FAH opposes continuation of the payment reduction for hospital outpatient clinic visits (HCPCS code G0463) furnished in an excepted, off-campus provider-based department (PBD). CMS has characterized this policy as a "method to control unnecessary increases in the volume of covered outpatient department services" under 42 U.S.C. § 1395*l*(t)(2)(F), but after two years of this policy, provides no data or analysis as to whether the payment reduction is in fact operating as such a method rather than as a blunt payment cut. The Proposed Rule does not assess the extent to which the volume of covered outpatient clinic visits has declined under this policy. Nor does it assess the extent to which the payment cut adversely impacts *necessary* covered outpatient clinic visits. And it does not endeavor to distinguish between the impact of section 603 of the Bipartisan Budget Act of 2015 (Section 603) and CMS's payment reduction for clinic visits in excepted, off-campus PBDs on the volume of unnecessary (and necessary) covered outpatient department services. These omissions are troubling as commenters to the CY 2019 Proposed Rule emphasized the significant limitations of the data that CMS relied on when originally proposing and adopting the payment reduction for hospital outpatient clinic visits in excepted, off-campus PBDs.

[2] 85 Fed. Reg. at 48,884.

The proposed continuation of the payment reductions in CY 2021 is particularly troubling in light of the ongoing public health emergency due to COVID-19. Hospitals (including their off-campus PBDs) have played a vital role in the national response to COVID-19 and have suffered significant revenue impacts with the delay and cancellation of outpatient items and services. CMS, however, wholly fails to address these changed circumstances or their anticipated impact on outpatient clinic visits in CY 2021. Rather, the Proposed Rule provides no rationale for the apparent assumption that an unnecessary increase in the volume of covered outpatient clinic visits would occur in the midst of the COVID-19 pandemic absent continuation of CMS's site-neutral payment reduction. Nor does it provide a rationale for the assumption that the continued payment reduction would operate as an appropriate volume-control measure in these vastly changed circumstances. ***In short, despite the passage of time and significantly changed circumstances of a nationwide public health emergency, CMS proposes to blindly and improperly continue its policy without examining whether the payment reduction would actually operate as a "method to control unnecessary increases in the volume of covered outpatient department services" under 42 U.S.C. § 1395l(t)(2)(F) in CY 2021***.

In addition, as explained in the FAH's comments to the CY 20019 OPPS/ASC Proposed Rule, CMS's site neutral policy for excepted, off-campus PBDs continues to be flawed because it makes no allowance for the physician's professional judgment concerning the most appropriate site of service for the patient, ignores the significant costs borne by hospital outpatient departments, jeopardizes patient access to needed services, and is at odds with Congress' express determination in Section 603 that excepted PBDs are entitled to full OPPS reimbursement. Moreover, the FAH maintains that CMS's continued application of the payment reduction for services described by HCPCS code G0643 and billed with the "PO" modifier in a non-budget neutral fashion is improper and unlawful. Under 42 U.S.C. § 1395*l*(t)(9)(B), adjustments under subsection (t)(2) are required to be adopted in a budget neutral manner. Budget neutrality is not only required, but it is also appropriate in order to mitigate the risk that the payment cuts will adversely impact beneficiary access, particularly in the midst of the COVID-19 public health emergency.

IV. Payment for Partial Hospitalization Services (Part VIII)

The FAH supports the CMS decision in the Proposed Rule to (1) use the geometric mean per diem cost methodology for Partial Hospital Program (PHP) rates in accordance with its existing methodology for both hospital-based PHP and CMHC rates and (2) establish a separate cost floor for each category; $121.92 CMHC's and $222.76 Hospital-Based.

CMS stated that access to outpatient mental health services in the partial hospitalization setting is "better supported when the geometric mean per diem cost does not fluctuate greatly". The FAH concurs with this assessment and we believe the proposed policy will help ensure beneficiary access to this critical Medicare covered benefit will remain intact. Less volatility and adequate Medicare PHP rates year to year will ensure PHP programs retain their fiscal viability in the long term.

V. The IPO List Should be Retained as a Critical Patient Safety Tool and to Ensure that Procedures Are Appropriately Paid and Provided Under Medicare Part A (Part IX) (Proposed 42 C.F.R. 419.22(n))

The FAH strongly opposes CMS's proposal to eliminate the IPO list, which designates those procedures that are not payable under the OPPS because they can only be appropriately provided on an inpatient basis. The assignment of procedures to the IPO list takes into account key clinical considerations that preclude the procedure from being provided to Medicare beneficiaries on an outpatient basis: (1) the invasive nature of the procedure, (2) the need for postoperative care, and (3) the underlying physical condition of the patient who would require the surgery.[3] The IPO list serves as an important programmatic safeguard, ensuring that Medicare beneficiaries undergoing any of the 1,740 procedures on the IPO list receive inpatient care and monitoring, and its proposed elimination without any supporting clinical analysis arbitrarily removes an important patient safety mechanism.

Instead, the FAH supports retaining the IPO list—which consists of procedures that are currently performed appropriately and safely only in the inpatient setting—as well as CMS's current process for removing procedures based on clinical criteria. The five criteria established by CMS to evaluate procedures for potential removal address the extent to which outpatient departments are equipped to provide the procedure to the Medicare population, whether the simplest procedure described by the code may be furnished in most outpatient departments, whether the procedure is related to codes that have already been removed from the IPO list, whether the procedure is furnished in numerous hospitals on an outpatient basis, and whether the procedure can be appropriately and safely furnished in an ASC. By annually applying these clinical and patient safety-oriented criteria on a case-by-case basis, CMS can ensure that the IPO list only covers those procedures that continue to be inappropriate for the Medicare population in the outpatient setting. Under the Proposed Rule, however, these clinical considerations would not come into play and Part A coverage would turn largely on the physician's expectations concerning the length of stay under the 2-midnight rule. ***The FAH opposes the proposed, arbitrary elimination of the IPO list as it would create inappropriate safety risks for Medicare beneficiaries, impose administrative burdens on physicians and hospitals, increase beneficiaries' financial burden, and erode the value of Part A coverage***.

The Proposed Rule identifies a handful of concerns with the IPO list, largely drawn from decades old comments provided in responses to CMS's original IPO list proposal.[4] These considerations—namely, deference to clinical judgment, the promotion of advances in surgical care, and intervening changes in the practice of medicine—do not support the elimination of the IPO list. Rather, patient safety, clinical considerations, administrative burdens, and beneficiary financial considerations all support the continued use of the IPO list.

The IPO List Reduces Administrative Burdens Without Eroding Professional Judgment. As a general matter, the FAH agrees that the appropriate site of service for a particular procedure should typically be determined by surgeons and patients. But it does not

[3] 65 Fed. Reg. 18,434, 18455 (April 7, 2000).

[4] 85 Fed. Reg. at 48,909 (citing 65 Fed. Reg. 18,442, 18,455).

follow from this general observation that physician judgment is undermined by recognizing those procedures that cannot be appropriately provided to Medicare beneficiaries on an outpatient basis and should not be payable under the OPPS. By way of example, CMS's long-standing recognition that the leg amputation described by CPT code 27592 (amputation, thigh, through femur, any level; open, circular (guillotine)) should only be provided to Medicare beneficiaries on an inpatient basis and paid under the IPPS simply reflects the invasive nature of the procedure and its indisputable and inherent risks. By categorically restricting coverage for these amputations based on the clinical evidence as inpatient only procedures, CMS appropriately advances patient safety without meaningfully limiting any physician's clinical judgment.

Meanwhile, the proposed elimination of the IPO list along with the continued operation of the 2-midnight rule would inappropriately result in level-of-care determinations based largely on the patient's expected length of stay and would increase the paperwork and administrative burdens where a patient is admitted for a short stay to undergo a procedure that should only be performed on an inpatient basis. When finalizing the 2-midnight rule in 2013, CMS stated its "belie[f] that inpatient-only procedures are appropriate for exclusion from the 2-midnight benchmark" and assured beneficiaries and providers that "inpatient-only procedures currently performed as inpatient 1-day procedures will continue to be provided as inpatient 1-day procedures" under the final rule.[5] Thus, the 2-midnight rule explicitly endorsed categorical inpatient treatment for procedures on the IPO list, preserving CMS's clinical determination that inpatient admissions are appropriate for these procedures in all cases. This approach ensures that procedures designated as inpatient-only can be provided on an inpatient basis *regardless of the expected length of stay*, unless and until CMS determines outpatient coverage is appropriate after considering the five clinical criteria for removal from the IPO list.

Under the Proposed Rule, however, CMS would effectively eliminate Part A coverage for these invasive 1-day procedures except in circumstances where the physician exercises his or her clinical judgment to order an inpatient admission "based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event" and the medical record supports these factors.[6] The inherent burden of establishing that an inpatient 1-day procedure qualifies for inpatient treatment on a case-by-case basis creates burdens for physicians and hospitals and risks the inappropriate migration of inpatient 1-day procedures to the outpatient setting. In addition, the factors used for these case-by-case determinations were developed against the backdrop of the IPO list and thus focus on patient-specific considerations without generally accounting for factors that govern inclusion on the IPO list (*e.g.*, the invasive nature of the procedure and the general need for postoperative care). In short, the elimination of the IPO list alongside the 2-midnight rule suggests that an inpatient admission for a 1-day procedure that was on the IPO list before its elimination would only be permissible based on case-by-case, patient-specific considerations.

This significant change increases the administrative and documentation burden associated with an inpatient admission for an invasive surgical procedure where medical advancements have reduced the average length of stay but significant risks remain, particularly in the Medicare

[5] 78 Fed. Reg. 50,496, 50,947 (Aug. 19, 2013)

[6] 42 C.F.R. § 412.3(d)(3).

population (*e.g.*, carotid stenting or transcatheter aortic valve replacement (TAVR)). The Proposed Rule provides no rationale for this substantial change in policy, nor does it address the provider burdens or patient risks inherent in shifting 1-day procedures currently on the IPO list to the outpatient setting except where case-by-case factors warrant inpatient admission.

The elimination of the IPO list would also risk eroding Part A coverage for skilled nursing facility (SNF) care following an inpatient procedure, increasing the risk to Medicare beneficiaries that experience post-procedure complications. At present, every Medicare beneficiary undergoing a procedure on the IPO list is admitted as an inpatient, in part to ensure that the patient receives adequate post-procedure monitoring for complications. If complications arise, the patient's inpatient stay might extend past three days, qualifying the beneficiary that is now at high-risk for adverse outcomes or readmission for SNF Part A coverage to ensure adequate and appropriate post-acute skilled nursing care. Without the IPO list, however, there's a risk that the physician will delay inpatient admission until *after* complications arise because, before that point, discharge prior to the second midnight might be possible. Although the time the patient spends in observation care is considered for purposes of the 2-midnight rule, it is not considered for purpose of the three-day qualifying hospital stay, such that a Medicare beneficiary admitted in this manner will not qualify for Part A SNF coverage unless his/her inpatient stay spans three midnights in addition to the time spent in observation. Not only does this erode the value of Part A SNF coverage, but it also places beneficiaries at risk for inadequate post-acute care and readmission.

In short, the necessity of an inpatient admission for a procedure on the IPO list should be beyond clinical question, but the Proposed Rule would require case-by-case scrutiny of these inpatient admissions when the patient can be discharged before the second midnight. This approach inappropriately focuses clinical judgment on the length of stay and case-by-case exceptions despite the categorical appropriateness of inpatient admissions for procedures included on the IPO list.

The IPO List Does Not Operate to Impede Advancements in Surgical Care and Medical Advancements Do Not Support Elimination of the IPO List. The Proposed Rule draws heavily from the comments of "[s]everal major hospital associations"[7] in response to CMS's proposal to create the IPO list in 2000. In those comments, hospital associations expressed concern that the IPO list would have an adverse effect on advances in surgical care.[8] In the intervening two decades, however, these concerns have not materialized. Rather, the FAH's members have seen and contributed to significant advancements in surgical care, and CMS has in turn responded to these developments by annually evaluating procedures for removal from the IPO list based on clinical criteria, engaging stakeholders through notice-and-comment rulemaking. Through this process, CMS has sought to continually evolve the IPO list so that it reflects rather than limits advances in surgical care. Because the IPO list has largely evolved with medical advancements, it continues to focus on those procedures that are only appropriate to the inpatient setting in the Medicare population despite advancements in surgical care.

[7] 65 Fed. Reg. 18,434, 18,442 (Apr. 7, 2000).

[8] 85 Fed. Reg. at 48,909 (citing 65 Fed. Reg. at 18,442).

The Proposed Rule suggests that, because "significant developments in the practice of medicine that have allowed numerous services to be provided safely and effectively in the outpatient setting, . . . the IPO list is no longer necessary to identify services that require inpatient care."[9] These medical advancements, however, have not eroded the utility of the IPO list because, as the Proposed Rule documents, the IPO list has evolved with advances in surgical techniques and surgical care protocols so that the IPO list continues to be confined to those procedures that are only appropriate on an inpatient basis in the Medicare population notwithstanding these developments. For example, the IPO list includes brain biopsies, craniotomies, lung transplants, heart and lung transplants, and coronary artery bypass with six or more venous bypass grafts. The Proposed Rule does not indicate that clinical advancements allow for these procedures to be safely and appropriately performed in the outpatient setting. Nor could it—these procedures are extraordinarily invasive, necessitate significant postoperative care, and are performed on high-risk patients, making inpatient admission necessary and appropriate in all cases. Likewise, the Proposed Rule does not indicate that medical advancements render the 266 musculoskeletal-related procedures proposed for elimination from the IPO list in 2021 appropriate for the outpatient environment. Rather, the Proposed Rule bluntly removes procedures from the IPO list despite the fact that outpatient departments are not equipped to provide the services to the Medicare population, the simplest procedures described by the codes are not furnished in most outpatient departments, and the procedures are furnished in few or no hospitals on an outpatient basis.

Elimination of the IPO List Erodes the Part A Benefit and Increases the Financial Burden on Beneficiaries. The elimination of the IPO list will also create financial burdens for Medicare beneficiaries because Medicare Part B coverage is associated with more significant cost-sharing obligations as compared to Part A coverage. Although the Part B coinsurance amount for a service is capped at the applicable Part A hospital inpatient deductible amount for that year, this cap does not adequately limit the beneficiary's cost-sharing obligation for outpatient services. A beneficiary that had previously paid the entirety of his or her inpatient deductible amount for that year would still be faced with a coinsurance obligation for the outpatient procedure when s/he would have incurred no further cost-sharing obligations if the procedure had been performed on an inpatient basis. Likewise, payment of the maximum outpatient coinsurance amount for a procedure would not satisfy a beneficiary's inpatient deductible obligation for a subsequent admission in the same year.

In addition, the outpatient cost-sharing limit applies on a service-by-service basis, so beneficiaries may incur coinsurance obligations up to the cap for *each* service. The Proposed Rule notes that most of the procedures on the IPO list would be assigned to a comprehensive APC (C-APC) upon removal, limiting beneficiaries to a single, capped coinsurance obligation for the C-APC.[10] But, even if each procedure is assigned to a C-APC, beneficiaries may still receive items and services that are separately payable when furnished with a C-APC (*e.g.*, a procedure assigned to a new technology APC) and thus may incur coinsurance obligations for multiple items and services. Furthermore, a Medicare beneficiary will incur outpatient coinsurance obligations associated with certain outpatient services furnished in the days prior to

[9] 85 Fed. Reg. at 48,909-10.

[10] 85 Fed. Reg. at 48,910-11.

the outpatient procedure, when those services would have been included on the Part A bill under the three-day payment window policy and would have resulted in no further cost-sharing obligations if the procedure had been performed on an inpatient basis. Thus, the coinsurance cap and the use of C-APCs does not adequately limit Medicare beneficiaries' cost-sharing obligations for outpatient services, and the proposed elimination of the IPO list would expand Medicare beneficiaries' financial exposure and erode the value of their Part A coverage. These expanded cost-sharing obligations also operate to the financial detriment to Medicaid programs, which are responsible for the Medicare coinsurance obligations of dually eligible beneficiaries.

CMS Lacks Sufficient Data to Assign Procedures on the IPO List to APCs. Although the Proposed Rule includes proposed APC assignments for 266 musculoskeletal-related services, it fails to provide any data or rationale for the proposed assignments. In past years, CMS has based APC assignments for procedures removed from the IPO list on the estimated costs derived from available claims data and the 50th percentile IPPS payment for the procedure without major complications or comorbidities to determine the appropriate APC assignment.[11] But the assignments proposed in Table 31 are not supported by any similar analysis or rationale, and without any explanation of the methodology for proposing APC assignments for these procedures that would be eliminated from the IPO lists, stakeholders cannot meaningfully comment on the proposed assignments. At a high level, however, the complexity associated with a number of the listed procedures would warrant the creation of new APCs (*e.g.*, Level 7 or higher Musculoskeletal Procedure APCs).

Implications of Elimination of IPO List on Alternative Payment Models (APMs). The Proposed Rule wholly fails to address how the elimination of the IPO list would impact episode-based and total cost of care models. The growing focus on and expansion of various APMs for Medicare benefits necessitates a clear and transparent plan for addressing the impact of removing procedures from the IPO list on these APMs. In commenting on the Proposed Rule, stakeholders cannot readily engage with CMS on the potential ramifications of removing entire categories of procedures from the IPO list as part of the phased elimination of the list because CMS has not provided any indication as to the extent to which any of the procedures would be expected to migrate to the outpatient setting. It may be that clinical considerations would preclude most of the procedures proposed for removal in CY 2020 from being performed in the outpatient setting on Medicare beneficiaries, which would limit any impact on APMs. But the Proposed Rule suggests that an unspecified number of these procedures could be performed in an outpatient session at an unspecified frequency. To the extent that any outpatient migration is reasonably expected, it is critical that CMS project the magnitude of the effect and propose necessary adjustments to episode-based and total cost of care models if, for example, it is expected that the shift will skew certain procedures toward beneficiaries in poorer general health and with higher risks for complications.

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[11] For example, in the 2020 OPPS Proposed Rule, CMS evaluated the estimated costs for CPT code 27130 (total hip arthroplasty) based on the available claims data and the 50th percentile for MS-DRG 470 against the geometric mean cost for the Level 5 Musculoskeletal Procedures APC series to explain the proposed assignment of the procedure to APC 5115. 84 Fed. Reg. 39,398, 39,460 (Aug. 9, 2019).

Adverse Impact for Medicare Part C Beneficiaries. Finally, the elimination of the IPO list risks adverse impacts for Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, but the Proposed Rule fails to address the collateral harm to these beneficiaries or the associated increased burden and cost of coverage disputes. Although the IPO list was adopted as "a valuable tool for ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting,"[12] it also plays an important role in the Part C context, ensuring that MA organizations provide appropriate inpatient coverage for the invasive and risky procedures that warrant inclusion on the list. And where MA organizations deny inpatient coverage for a procedure that should only be provided on an inpatient basis, the IPO list promotes the efficient resolution of the resulting coverage dispute. ***Without the IPO list, however, it is likely that Medicare beneficiaries that elect Part C coverage will experience increased denials of inpatient coverage for invasive procedures that require intensive postoperative monitoring and care.*** As we have shared in previous comment letters on the MA Program, there has been and continues to be a significant trend among MA organizations of denying coverage and authorizations for inpatient admissions ordered by physicians and reclassifying them as outpatient observations stays. We are now seeing this practice expand to inpatient surgical admissions ordered by physicians and reclassified by MA plans as outpatient surgeries, even in cases where the patient stay crosses two midnights.[13] Elimination of the IPO list risks fueling this trend, jeopardizing the health of Medicare beneficiaries and saddling hospitals with the additional administrative burden of appealing denials and reclassifications for procedures that are not appropriately provided in the outpatient setting.

VI. Inpatient Procedures that Do Not Meet the Criteria for Removal from the IPO List Should Be Excepted from Medical Review Unless and Until Two Years After They Meet the Clinical Criteria for Removal (Part X.B.)

If CMS finalizes the phased elimination of the IPO list despite the concerns set forth above, the FAH urges CMS to modify its medical review exemption so that inpatient admissions for a procedure previously included on the IPO list continue to be exempted from medical review and referrals indefinitely or until two years after CMS determines that the procedure satisfies the clinical criteria for removal from the IPO list. CMS proposes maintaining the current 2-year exemption from certain medical review activities by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs), BFCC-QIO referrals to Recovery Audit Contractors (RACs), and RAC "patient status" reviews for procedures removed from the IPO list as part of the phased elimination of the IPO list.[14] This 2-year exemption period, however, was developed for procedures that CMS determined were clinically appropriate for the outpatient

[12] 78 Fed. Reg. 75055 (Dec. 10, 2013).

[13] In the past, the FAH has requested that CMS require MA organizations to use the 2-midnight rule in determining patient status. The proposed elimination of the IPO list is particularly troubling against the backdrop of MA organizations' failure to apply the 2-midnight rule, and the FAH is concerned that, without the IPO list, MA organizations will override physician judgment and patient choice to deny inpatient coverage for procedures that necessitate extended post-operative monitoring and should only be performed on an inpatient basis.

[14] 85 Fed. Reg. at 48,939.

setting, allowing providers time to update their billing systems and gain experience with respect the newly removed procedures. Here, however, procedures are being removed from the IPO list as part of a phased elimination of the list, even if the procedures continue to be categorically inappropriate for the outpatient setting. For example, the leg amputation described by CPT code 27592 (amputation, thigh, through femur, any level; open, circular (guillotine)) is proposed to be removed from the list despite being clearly inappropriate for the outpatient setting.

In this context of the proposed phased elimination of the IPO list, any medical review of the removed procedures would create administrative burdens and costs for providers without any associated benefit to the Medicare Program or beneficiaries. ***Unless and until a procedure removed as part of the proposed elimination of the IPO list is determined by CMS to be safe and appropriate for Medicare beneficiaries in the outpatient setting, the exception from medical review should continue for that procedure. Furthermore, if and when a procedure is determined by CMS to be safe and clinically appropriate for outpatient delivery, providers should be given two years to update their billing systems and gain experience with respect to the newly removed procedures, consistent with CMS's past practice with respect to procedures removed from the IPO list based on clinical considerations.*** In the interim, an inpatient admission for a procedure on the IPO list should not be subject to patient status reviews and the admission should be categorically presumed to be appropriate based on CMS's prior determination that the procedure is only clinically appropriate when furnished on an inpatient basis.

VII. Specimen Collection for COVID-19 Tests (Part X.C.)

CMS established HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [covid-19]), any specimen source) during the PHE. HCPCS code C9803 is assigned to APC 5731- Level 1 Minor Procedures with a payment rate of $22.98 for 2020 for the duration of the PHE. HCPCS code C9803 is conditionally packaged meaning that it will only be paid separately if it is the only service provided or it is billed with a clinical diagnostic laboratory test that is separately payable. The FAH recommends that CMS retain HCPCS code C9803 and its current APC assignment and status indicator beyond the COVID-19 PHE**.**

VIII. ASC Covered Procedures List (Part XIII.C.1.d)

The FAH strongly supports CMS's proposal to continue to apply current policies and criteria set forth in 42 C.F.R. § 416.2 and 42 C.F.R. § 416.166 for updating the ASC Covered Procedures List (ASC-CPL) and opposes both alternative options for modifying the process and criteria for additions to the ASC-CPL. The current standards and exclusion criteria for the ASC-CPL appropriately prioritize patient safety while still allowing the ASC-CPL to evolve with advancements in surgical care, and they should therefore remain in place. Although ASCs can safely perform a growing array of surgical procedures without having the capacity to provide inpatient care in the case of complications and without having satisfied other hospital conditions of participation (or being licensed and accredited as hospitals), ASCs should not be treated as the equivalent of hospital outpatient departments. ***ASCs are not regulated as hospitals, and since November 29, 2019, ASCs have not been required to have written hospital transfer agreements***

or hospital physician admitting privileges.[15] Thus, procedures that pose significant patient safety risks (e.g., procedures that generally result in extensive blood loss, that require major or prolonged invasion of body cavities, directly involve major blood vessels, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy) should continue to be excluded from Medicare coverage in ASCs to ensure that Medicare beneficiaries receive these services in a setting that allows for rapid intervention and elevation of the level of care in the case of life-threatening complications.

A. Exclusion of Procedures on the IPO List from the ASC-CPL

The FAH strongly supports CMS's proposal to retain the exclusion of procedures designated as requiring inpatient care. As explained above, the FAH urges CMS to retain the IPO list as a critical patient safety measure, in which case the proposed amendment to 42 C.F.R. § 416.166(c)(6) would be unnecessary. If, however, CMS nonetheless eliminates the IPO list despite the concerns express by the FAH and others, the FAH would support CMS's proposed amendment to 42 C.F.R. § 416.166(c)(6), which would ensure that those procedures designated as requiring inpatient care under § 419.22(n) as of December 31, 2020 would continue to be excluded from the ASC-CPL even after the elimination of the IPO list. The elimination of the IPO list is being proposed without regard for the clinical appropriateness of furnishing the services on the IPO list outside of the inpatient setting, and because the procedures removed during the proposed phased elimination of the IPO list continue to only be appropriate for Medicare beneficiaries in the hospital setting, the FAH supports continued application of the December 31, 2020 IPO list as an exclusion criterion for the ASC-CPL.

B. Exclusion Criteria for the ASC-CPL Should Remain in Place

Under both alternative options set forth in the Proposed Rule, CMS would retain the exclusion criteria under 42 C.F.R. § 416.166(c)(6) through (8), but would remove the exclusion criteria in 42 C.F.R. § 416.166(c)(1) through (5). The FAH strongly opposes removal of these exclusion criteria, which have been successfully applied for over a decade and have not impeded the expansion of the ASC-CPL to cover a growing list of complicated surgical procedures where permitted by advancements in surgical care. The five exclusion criteria at issue each target surgical procedures that inherently pose significant safety risks because ASCs do not have hospital resources on site to rapidly provide the higher level of care necessary in the case of complications. By way of example, § 416.166(c)(5) excludes surgical procedures that commonly require systemic thrombolytic therapy. These procedures pose significant patient risks that require rapid intervention in a hospital setting in the event of complications, including embolization and stroke. Despite significant advancements in surgical care since this exclusion criterion was finalized in 2007, the risks of systemic thrombolytic therapy continue to be significant, and the categorical exclusion of procedures requiring such therapy from the ASC-CPL continues to be appropriate. Likewise, the other exclusion criteria at issue—which cover surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, or are generally emergent or life-threatening in nature—should remain in place.

[15] 84 Fed. Reg. 51,732, 51,738 (Sep. 30, 2019).

The Proposed Rule suggests that the concerns warranting adoption of these exclusion criteria have largely been addressed with the passage of time. It is true that significant advancements in medical practice, surgical techniques, and medical technology have permitted a growing list of procedures to be safely performed in an ASC setting, but this is largely because advancements have permitted a growing array of procedures to be performed in a manner that no longer triggers an exclusion criterion. For example, some procedures that previously required major or prolonged invasion of body cavities can now be performed laparoscopically and are no longer excluded under 42 C.F.R. § 416.166(c)(2). Thus, recent advancements in surgical care have minimized the extent to which procedures trigger an exclusion criterion, and these advancements do not call into question the enduring salience of the exclusion criteria in identifying procedures that continue to pose significant and inappropriate safety risks in an ASC setting. In fact, the Proposed Rule does not include any evidence indicating that the patient safety risks associated with procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy have been meaningfully reduced by advancements in medical care or provide any other rationale for eliminating these critical exclusion criteria.

In the Proposed Rule, CMS indicates that surgical advancements have allowed certain ASCs to safely perform procedures "involving major blood vessels," suggesting that this criterion is therefore no longer relevant. The exclusion criterion at 416.166(c)(3), however, was never intended to be applied in a rigid manner, and in fact CMS explicitly opted to maintain flexibility and declined to adopt a defined list of "major blood vessels" in 2007. At that time, CMS stated its belief that "the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures."[16] Subsequently, CMS used this flexibility to add certain coronary procedures to the ASC-CPL in its CY 2020 OPPS/ASC Final Rule. The Proposed Rule does not suggest that this criterion—applied in the context of the clinical characteristics of individual procedures—is no longer salient in assessing patient safety risks. Rather, it merely suggests that the rigid interpretation of this criterion—which was rejected in 2007 and has not been applied—would be inappropriate. Without any supporting rationale for eliminating the context-specific exclusion criterion at 416.166(c)(3), elimination of this exclusion criterion would be arbitrary and inappropriate.

Because the current exclusion criteria at 42 C.F.R. § 416.166(c), in conjunction with the general standards in 42 C.F.R. § 416.166(b), have allowed the ASC-CPL to evolve and expand with surgical advancements while ensuring that procedures that continue to pose significant patient safety risks are restricted to the hospital setting, ***the FAH strongly urges CMS to retain the existing criteria and standards for the ASC-CPL.*** In addition, ***the FAH opposes the addition of the 270 procedures proposed to be added to the ASC-CPL under the second alternative proposal in light of these standards and exclusion criteria.*** In particular, many of the procedures in Table 41 present significant patient safety concerns, arise in emergency situations, and would necessitate the rapid deployment of hospital resources in the event of complications. The Proposed Rule does not provide any rationale or evidence indicating that each of the 270 procedures at issue under the alternative proposal would not be expected to pose

[16] 72 Fed. Reg. 42,481 (Aug. 2, 2007).

a significant safety risk to a Medicare beneficiary when performed in an ASC or that standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following any of these procedures. By way of example, the list includes repair of a blood vessel with vein graft in the neck (CPT 35231), intrauterine fetal transfusions (CPT 36460), ligation of a major artery in the neck (CPT 37651), and appendectomy (CPT 44950). Each of these procedures (and the procedures included in the second alternative proposal more generally) pose significant patient safety risks, and Medicare coverage for these procedures should remain confined to the hospital environment where a patient can receive inpatient care in the event of complications. At the very least, CMS should provide some explanation of why or how each of the listed procedures satisfy the criteria and standards in 42 C.F.R. § 416.166(b) and (c) so that stakeholders can understand the rationale behind the proposal and provide meaningful comment.

C. Proposed Additions to the ASC-CPL for CY 2021

In the CY 2021 Proposed Rule, CMS proposes to add total hip arthroplasty (THA) and ten other procedures to the ASC-CPL for CY 2021. ***The FAH opposes adding THA to the ASC list in light of clinical concerns, expanded beneficiary coinsurance obligations for ASC procedures compared to hospital outpatient procedures, and the risks of providing payment for THA in physician-owned ASCs that are not subject to physician self-referral restrictions.*** The Proposed Rule emphasizes the importance of ensuring that physicians and patients have the flexibility to choose an ASC as the site of surgical care, observing that many ASCs delayed elective procedures during portions of the COVID-19 public health emergency. The COVID-19 pandemic, however, has also impacted elective procedures performed in hospital outpatient departments, acutely depressing revenue. These COVID-19 impacts, however, are best addressed through relief packages like the CARES Act Provider Relief fund, as well as the waivers and flexibilities adopted by CMS over the course of the public health emergency. The question of whether THA should be payable under Medicare Part B in the ASC setting should be evaluated independently of the impacts of the COVID-19 pandemic. In addition, the value of patient and physician choice are tempered where providing ASC coverage for a procedure will *increase* beneficiaries' cost-sharing obligations and referring physicians with an ownership interest in the ASC are not subject to self-referral restrictions.

Higher Coinsurance in an ASC than the Outpatient Department. Medicare's payment for THA in an ASC according to Addendum AA of the Proposed Rule will be $8,923.98, which would result in a Part B coinsurance obligation of $1,784.79. When THA is performed in a hospital outpatient department, however, the Medicare Part B coinsurance amount is capped under section 1833(t)(8)(C)(i) to the inpatient hospital deductible limit ($1,408 in 2020). Thus, a Medicare beneficiary's cost-sharing obligation for a THA performed in an ASC would be $376.79 more than if the procedure had been performed in a hospital outpatient department (based on the 2020 inpatient deductible amount). In addition, because Medicare's payment under the OPPS is determined under the comprehensive-APC methodology, Medicare packages payment of all ancillary services into the OPPS payment resulting in no beneficiary coinsurance beyond the inpatient deductible cap. However, in the ASC, Medicare would pay separately for ancillary services that are integrally related to the surgical procedure, potentially raising beneficiary out-of-pocket costs further. Beneficiaries, however, may not understand these critical payment differences and their impacts on cost-sharing obligations; in fact, many may

wrongly assume that they will enjoy cost savings by undergoing a complicated procedure in an ASC rather than in a hospital outpatient department.

Physician Self-Referral Risks. The foregoing concerns regarding beneficiaries' cost-sharing obligations for invasive procedures like THA are compounded by physician self-referral issues in physician-owned ASCs. The Physician Self-Referral Law, 42 U.S.C. § 1395nn, governs physician referrals to an entity for designated health services where the referring physician (or an immediate family member) has a financial relationship with the entity. Outpatient hospital services are designated health services under the statute, but surgical procedures performed in an ASC are paid as part of a composite payment for a group of services and are not currently subject to the Physician Self-Referral Law.[17] As such, the Physician Self-Referral Law does not govern physician referrals of Medicare beneficiaries to an ASC owned by the physician for a surgical procedure. The FAH is concerned that the combination of expanded coinsurance obligations for THA in an ASC with the lack of a physician self-referral prohibition to an ASC places beneficiaries at risk. ***Until such time as CMS can resolve these issues to protect Medicare beneficiaries, the FAH remains opposed to adding THA to the ASC-CPL.***

IX. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program (Part XIV)

The FAH supports the proposal to expand the review and corrections policy to apply to measures submitted via a web-based tool as well as chart-abstracted measures. For 2021 reporting, three OQR Program measures are submitted by hospitals to CMS via a web-based tool (OP-22: ED Left without being seen; OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; and the voluntary measure OP-31: Improvement in Visual Function within 90 Days Following Cataract Surgery). We agree that it is appropriate for hospitals to have an opportunity to review and correct data on these measures as well as any future measures that may be reported using a web-based tool. We also support the proposed technical changes to codify and update the OQR Program regulatory text at 42 CFR 419.46.

X. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years (Part XV)

The FAH applauds CMS's recognition for the opportunity of a much needed refresh and appreciates the proposals aiming to ensure the methodology is transparent, understandable, with clear cut-points and targets, and accurately reflecting the quality of care provided in the facilities. Until this is achieved and the changes are implemented, however, the FAH urges CMS to suspend the Star Ratings from the Hospital Compare website.

The FAH supports the proposal to codify the Overall Hospital Quality Star Rating methodology through notice and comment rulemaking. Since their initial publication in 2016, the Overall Star Rating has been a prominent feature of Medicare's *Hospital Compare* tool (now *Care Compare)*, and codification will improve the transparency of the underlying methodology to hospitals and other stakeholders. Moreover, the rulemaking process provides stakeholders an opportunity to make formal comment on the methodology used to calculate these ratings and to review CMS's response to all public comments.

[17] 66 Fed. Reg. 923 (Jan. 4, 2001).

The Proposed Rule would make a number of changes to the methodology that has been used by CMS to date in calculating the Overall Hospital Quality Star Rating. As the FAH has previously commented, the star rating methodology should be transparent, understandable, have clear cut-points and targets, and accurately reflect the quality of care provided by hospitals. We appreciate that the CMS proposals are intended to address issues with the methodology that have been previously identified by hospitals. ***The FAH generally supports the proposed changes to the Overall Hospital Quality Star Rating, with the following specific comments and concerns.***

The FAH supports using the most recently available data for calculating the Overall Star Ratings and does not support the proposal to use data that was made public during the previous year. CMS would codify that the Overall Star Ratings are published annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year. This rules out using the data that is newly made public concurrent with the star ratings. While we understand that CMS offers this proposal so that hospitals would have more time to study the underlying data before the star ratings are made public, the FAH believes that using the most recent data for the calculations is the more important priority. There is a built-in data lag on *Care Compare* as in some cases individual measures reflect performance from several years back; delaying use of newer data adds to the disconnect between the published data and current hospital quality performance. ***In addition, CMS should be consistent regarding when the Star Ratings are published each year and which data are used for the calculations.*** Hospitals should not be in the position of making assumptions and possibly being surprised if the timing changes from year to year. The expected timing should be made clear in the final rule, and any future changes should be shared well in advance through the QualityNet website and other regular communication channels.

In keeping with our previously stated principles, the FAH strongly supports the proposal to eliminate use of the Latent Variable Model (LVM) when calculating measure group scores. The LVM has resulted in Star Ratings that change in ways that cannot be predicted by a hospital's underlying performance and therefore can be difficult to explain to anyone unfamiliar with the details of the LVM. Use of a simple average to calculate measure group scores will be easily understood and will allow hospitals to anticipate changes in the Star Ratings based on changes in performance on the underlying quality measures.

The FAH supports the proposed continued inclusion of CAHs and the future addition of Veterans Health Administration (VHA) hospitals in the calculation of the Overall Star Rating. The CAHs report quality data voluntarily, and have the opportunity to request their data not be publicly reported (and therefore unavailable for use in the Overall Star Rating calculation) or that the assigned star rating not be posted on *Hospital Compare.* Future policymaking regarding VHA hospitals should consider how comparable these facilities are to the bulk of hospitals for which quality performance is displayed.

The FAH supports the proposed peer grouping of hospitals, although CMS should work to educate the public on how to interpret Star Ratings that are calculated by peer group. Assessing hospital performance by national peer group is useful to hospitals for purposes of quality improvement because it allows for comparisons of similar facilities. However, Medicare

beneficiaries and other consumers are more likely to compare hospitals within their geographic area. If these hospitals happen to fall into different star rating peer groups a direct comparison of star ratings may not be appropriate, and the public will need to be guided on how to use the star ratings in comparing hospitals. CMS has suggested that for stakeholders the hospital summary score available in the downloadable database could serve as the basis of a national comparison because it is calculated before hospitals are sorted into peer groups, but this would not be a practical solution for members of the public who seek to compare hospitals.

CMS should continue to assess how the peer groups are defined. Ideally, the peer groupings used to calculate the Overall Star Rating would be refined and reflect differences in the types of services provided by hospitals. Under the proposal, CMS estimates using the January 2020 data release that 73 percent of hospitals fall into one of the three peer groups (hospitals with scores for all five measure groups), which limits the value of peer grouping. In addition, CMS reports that CAHs comprise about half the hospitals in the peer group for hospitals with three measure group scores, noting that the proposed peer grouping approach will not be finalized if CAHs are not included. Because CAHs report quality measure data voluntarily and have the option of suppressing the public reporting of their data prior to calculation of the star rating, CMS should address how it will determine whether a sufficient number of CAHs have reported data that can be used for the star ratings calculation for a year.

The FAH believes that the readmission measure group should be scored in the same way as these measures are scored for the Hospital Readmissions Reduction Program (HRRP). Under the proposal, for purposes of the Overall Star Rating, CMS would stratify the readmissions measure group scores by the hospital's proportion of Medicare and Medicaid dual eligible patients using the same quintiles used in the HRRP. We agree that it is appropriate that there be consistency in the scoring for these two purposes. However, the June 2020 report of the HHS Assistant Secretary for Planning and Evaluation recommends replacing stratification by dual eligibles when scoring readmission measures with separate public display of a hospital's performance on the readmission measures for patients who are dual eligibles and others. If in the future, CMS eliminates or changes the stratification approach used in the HRRP, a parallel change should be made in the calculation of scores for the readmission measure group in the Overall Star Rating.

Other elements of the proposed methodology include reducing the number of measure groups from seven to five; continuing the existing scheme for weighting measure group scores (22 percent each for Mortality, Readmissions, Patient Safety and Patient Experience and 12 percent for Timely and Effective Care); continuing policies for the measure selection and exclusion, and continuing the use of k-means clustering for setting the cut-points for the five star levels. The FAH does not oppose these proposals.

Once use of the new methodology is operationalized, CMS should continue to work with stakeholders to identify additional improvements that may be needed in the future. The FAH appreciates that the proposed regulatory text identifies responsiveness to stakeholder input as a goal along with transparency in methods, use of scientifically valid methods and alignment with *Care Compare.* As our hospitals gain experience with the new methodology, further

changes may be offered for ensuring that the Star Ratings reflect true differences in hospital quality performance.

The FAH continues to believe that the patient safety composite measure PSI-90, or its components measures, should not be included in the Overall Star Rating and urges CMS to remove them from quality programs. The PSI-90 measures use claims data to identify patients who have experienced a safety event. While useful to identify patients whose treatment experience requires further investigation, it is not a reliable reflection of a patient safety event and as such could be misleading. This lack of reliability in the identification of a safety event renders the PSI-90 measure a poor measure to use in public reporting or pay-for-performance programs.

XI. Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department Services (Part XVII)

The FAH strongly advises that CMS reconsider its proposal regarding prior authorization for certain hospital outpatient services given the potential impact on payment to providers and the health and welfare of patients that would result from delays in receiving needed medical services.

CMS has equated increases in utilization above the national average as being unnecessary without fully exploring the reasons for the increase. While CMS may have looked for external factors that may explain the increase in utilization, it has not done a sample medical review to determine whether increases are necessary or unnecessary. If CMS were to do a sample medical review and find that the large majority of these services were necessary, prior authorization would not be justified. Prior authorization would only be imposing an unnecessary burden on hospitals, physicians and patients for medically necessary services. Medical review could also show whether increases are largely justified but that there are particular physicians or other providers responsible for unnecessary increases where targeted prior authorization may be merited. Moreover, the Proposed Rule wholly fails to address whether concerns regarding increases in utilization of outpatient department services continue to be salient in the midst of the COVID-19 public health emergency. In response to the pandemic, the volume of hospital outpatient services has declined as hospitals and patients delay or cancel many elective procedures. Pre-COVID-19 utilization data does not reflect the vastly changed circumstances in our health care delivery system, and it is inappropriate to use this data to impose new prior authorization requirements.

As we indicated in comments on the CY 2020 OPPS/ASC Proposed Rule, we remain concerned that the prior authorization policy could potentially delay treatment and seriously jeopardize a beneficiary's health or ability to regain maximum function. These risks are particularly acute in the context of the COVID-19 pandemic, where elective procedures are already subject to temporal constraints based on changes in the community transmission rate and other volatile public health factors in addition to the patient's clinical condition. Further, the FAH believes that before expanding a prior authorization requirement to additional services, CMS should also evaluate the implementation and impacts of the current prior authorization requirements for select procedures. If the large majority of prior authorization requests for those services subject to the requirement in CY 2020 were approved, this

evidence would suggest that the prior increase in service utilization did not represent unnecessary growth in service volume. Such results may also indicate that any diminution in the rate of growth for these services reflects the policy's adverse impact on beneficiary access to necessary services rather than the desired reduction in unnecessary service volume. ***Further, the burdens that prior authorization imposes with no clear benefit is inconsistent with the Administration's "Patients Over Paperwork" initiative***.

The FAH reiterates the position we took last year that the policy will place providers in an untenable position of potentially providing the needed services immediately, without authorization, and risking payment for all services related to the treatment even if the patient had an urgent need for the medical services. While the provider could request a reconsideration or appeal a denial, CMS's proposed policy would force significant administrative burden on a provider in order to receive payment, even in the most urgent of medical situations.

A. Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department Services (Part XX)

In the CY 2021 OPPS/ASC Proposed Rule, CMS proposes to establish prior authorization for an additional 2 categories of services: 1) Cervical Fusion with Disc Removal; and 2) Implanted Spinal Neurostimulators. (85 FR 49028). Under the prior authorization process, hospitals would request provisional affirmation of coverage before the service is furnished to the beneficiary and before the claim is submitted for processing. The prior authorization request would have to include all relevant documentation necessary to show that the service meets Medicare coverage, coding and payment rules. A claim submitted for a service subject to a prior authorization requirement that has not received a provisional affirmation of coverage would be denied. Additionally, a service for which provisional affirmation was received may still be denied, based on technical requirements or information not available at the time that affirmation was provided. Provisional affirmation or non-affirmation decisions would be made within 10 business days (2 business days in the case of an expedited review request where a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function). A non-affirmation decision would not be appealable.

A provisional affirmation denial would include any claims associated with the service, including anesthesiology services, physician services, and/or facility services. CMS claims section 1833(t)(2)(F) of the Act as its authority for prior authorization. While the FAH believes it is questionable whether section 1833(t)(2)(F) of the Act provides authority to apply prior authorization at all to any services, it is very clear that this authority is only limited to "the prospective payment system established by the Secretary in accordance with this subsection" (e.g. the OPPS). The Secretary has no authority to apply prior authorization to anesthesiology services and other physician services that are paid under section 1848 of the Act.

Cervical fusion and implanted spinal neurostimulators are procedures that are often provided to patients with chronic intractable pain. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review

payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. ***CMS's prior authorization policy is in direct contradiction with the spirit of the SUPPORT Act in that it diminishes incentives to provide non-opioid treatment alternatives.*** Prior authorization may result in delays in the provision of these services, which could mean that the patient will instead take powerful opioids to control pain rather than using a non-opioid alternative treatment. In light of the opioid crisis—which the Secretary has determined to be a nationwide public health emergency, the FAH has significant concerns about subjecting these particular procedures to medical review.

For implantable neurostimulators, CMS indicates that it "fully accounted for changes that occurred in 2014 related to electrodes being incorporated into the 63650 code" when accounting for the service volume change. The FAH does not know to what this sentence refers. Our review of CPT and other sources does not show any coding changes for CPT code 63540 in 2014. This review shows this code as being unchanged since 1994.

In the Proposed Rule, CMS notes that the average annual increase in volume was 17 percent for implanted spinal neurostimulators between 2016 and 2018. While the FAH's analysis of Standard Analytic File (SAF) data validates this trend, our review of the data also shows utilization increasing 6 percent in 2013, 2 percent in 2014, decreasing 4 percent in 2015 and decreasing 7 percent in 2019. It is not clear why the growth rates for implantable spinal neurostimulators show significant increases in the 2016 to 2018 period but they appear to be atypical compared to the 3-year period preceding 2016 and the one year following 2018. Such an atypical period of growth between 2016 and 2018 suggests something was occurring during this time rather than that growth was unnecessary and should be subject to prior authorization. We encourage CMS to do a more detailed medical review of the utilization of these procedures to determine why growth in the 2016 to 2018 period was atypically high.

With respect to cervical fusion, CMS indicates that the use of code 22551 "almost tripled" in 2012. CPT code 22551 was removed from the IPO list as of January 1, 2012 (76 FR 74355) which would explain its utilization growth for that year and subsequent years as these procedures transitioned to the outpatient setting consistent with CMS policy. CPT code 22552 remained on the IPO list until 2016 but, because it is an add-on-code, CMS's policy means that it would have been line item denied, since the payable/primary procedure was not restricted to the inpatient setting even though add-on codes are not paid extra under the OPPS. This policy makes no sense. If a base code can be done outpatient, its add-on codes should also be permissible on an outpatient basis.

Beginning in 2016, CPT code 22552 was removed from the IPO list and is part of a complexity adjustment for C-APCs (80 FR 70468 and 80 FR 70331 respectively). Large growth in combined utilization for CPT codes 22551 and 2252 occurred just one year later in 2017 which is clearly associated with the add-on code utilization suddenly being allowable when previously it may have been performed as an outpatient service but denied as inpatient only on an outpatient claim. It is clear that it is CMS policy and not unnecessary utilization that is resulting in the high growth rate for these procedures in the hospital outpatient setting. For this

reason, the FAH believes procedure codes 22551 and 22552 should not be subject to prior authorization.

B. Patient Health and Well-Being Will Be Affected by Delays in Medical Care

CMS indicates that provisional affirmation will be provided within 10 days of a request and 2 days where a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function. The FAH is concerned about the potential for CMS's policy to delay treatment for 10 days where the request may not meet the requirements for expedited review but the patient is still suffering from a painful and debilitating condition such as chronic intractable pain. ***In situations where a delay in receiving medical care could seriously jeopardize the beneficiary's life, health or ability to regain maximum function, any responsible health care provider will furnish the needed services immediately and not wait 2 days for a response from Medicare***. Yet, absent the prior authorization, CMS's proposed policy would deny payment for all services related to the treatment even if the patient had an urgent need for the medical services. While the provider could request a reconsideration or appeal a denial, CMS's proposed policy would force significant administrative burden on a provider in order to receive payment, even in the most urgent of medical situations.

XII. Revisions to Laboratory Date of Service (DOS) Policy (Part XVIII)

Protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) laboratory tests are not considered molecular pathology tests subject to the CMS packaging policy. However, several stakeholders have suggested that they believe the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service. CMS proposes to modify the lab date of service rule to apply the same date of service to these tests as molecular pathology tests and ADLTs. This proposed revision to the laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs to bill Medicare directly for those tests instead of seeking payment from the hospital when the service is not-packaged and the DOS rule is met. The FAH supports this policy.

XIII. Physician-Owned Hospitals (Part XIX)

The FAH strongly opposes CMS's proposal to effectively remove all limits on expansion by physician-owned "high Medicaid facilities," including the frequency with which such a facility can request a capacity expansion; the caps on the number of operating rooms, procedure rooms and beds that can be approved; and the requirement that expansion must only occur on the main campus. We also would strongly oppose any removal or limitation of the opportunity for community input on expansion requests from high Medicaid facilities.

CMS projects in the Proposed Rule that only one physician-owned hospital (POH) per year will request an expansion exception on the grounds that it is a high Medicaid facility. CMS further believes the proposal is unlikely to lead to more frequent expansion exceptions. This suggests that CMS believes the proposal is narrow and likely to have little impact. We disagree.

For multiple reasons, the proposal is much broader than purported in the Proposed Rule and its impact will far surpass only Medicaid patients, while opening the door for significant gaming by POHs and thus undermining Congressional intent to strictly limit POH expansion.

The FAH and the American Hospital Association (AHA) engaged DeBrunner & Associates to analyze the Medicare cost report data for POHs, including high Medicaid facilities. Overall, the analysis shows that there are at least 14 POHs that could qualify as a high Medicaid facility based on the most recent Medicare cost report data (FY 2016-2018) and another six POHs that are on the cusp of qualifying (i.e., they met the high Medicaid requirements in FYs 2017 and 2018 and thus could qualify depending on their FY 2019 data). Still four other POHs met the high Medicaid requirements in FY 2018 and thus could qualify depending on their FYs 2019 and 2020 status.[18] In total, the analysis revealed 24 facilities that either currently – or soon could – qualify as a high Medicaid facility and thus benefit from the broad expansion policies CMS put forth in the Proposed Rule.

The analysis also reveals the low bar needed for some facilities to meet the high Medicaid requirements. For example, one of these "cusp" POHs had the highest Medicaid discharge percentage in the county at a mere 3.3 percent in FY 2018. If it maintained this "high" Medicaid status for only one more year (FY 2019), it would qualify for an expansion exception request. Moreover, its uncompensated care costs as a percentage of its overall operating costs in FY 2018 are minimal at 1.1 percent, and its occupancy rate is under 45 percent. This particular POH clearly is not critical for ensuring access to care for Medicaid patients, yet it could request to expand without limits under CMS's proposal. This is clearly not what Congress had in mind when it established the narrow "high" Medicaid facility exception to its overall policy to strictly limit the expansion of POHs.

The FAH discusses our specific key concerns with the proposal below.

The Proposal Creates Incentives to Game Opportunities to Become High Medicaid Facilities

The proposal creates incentives for facilities to "game the system" by creating opportunities to become a high Medicaid facility, by meeting low thresholds. Under the proposal, there no longer would be a limit on the percentage increase of a high Medicaid facility's baseline number of operating rooms, procedure rooms, and beds. In addition, POHs would no longer be limited to expansion on their main campus and thus could expand beyond to off-campus locations as well.

This will provide POHs with a significant incentive and the ability to game the system. For example, without the main campus limitation, a high Medicaid facility could merge with or purchase a non-POH, which could be operated as a "remote location" of the POH and share its Medicare provider number, thereby greatly increasing the number of operating rooms, procedure rooms, and beds.

[18] DeBrunner & Associates analysis of FFY 2016-2018 Medicare Cost Reports, September 2020. 214 Physician owned hospitals were identified for purposes of this analysis.

Further, if as a result of such a merger the provider would lose its status as a high Medicaid facility due to a dilution of the provider's percentage of Medicaid admissions, the provider would still be able to engage in the expansion because there is no provision in the statute or the regulations that requires a facility to maintain its "high" Medicaid status or that permits a rollback of an approved expansion, once granted. By the same token, in any circumstance, even absent a merger, once the high Medicaid POH secures an expansion, the high Medicaid requirement disappears. ***The facility could become the lowest Medicaid provider in its county, and it would still retain the full complement of expansion beds, operating rooms and procedure rooms***.

Therefore, a POH would have an incentive to become a high Medicaid facility simply to take advantage of the expansion exception, but no incentive to maintain their "high" Medicaid status after receiving the exception. We note that the ability to achieve this status is enhanced in states that have expanded their Medicaid programs under the *Affordable Care Act* (ACA). Illustrating the disincentive to maintain the designation list, the DeBrunner & Associates analysis identified a POH (POH A) that qualified as a high Medicaid facility when its expansion exception request was approved by CMS, but which is no longer the high Medicaid facility in the county.

<u>There is Not a High Bar to Qualifying as a High Medicaid Facility</u>

There is ample opportunity for gaming the system, as discussed above, because in many counties there is not a high bar to qualifying as a high Medicaid facility. ***There is no statutory requirement that a high Medicaid facility in fact serve a high number of Medicaid patients. Instead, a high Medicaid facility is one that simply has a higher percentage of Medicaid admissions than the other hospitals (which may be very few in number) in the same county***. SSA § 1877(i)(3)(F). A 2016 study found that, on average, only 2.2 percent of patients admitted to POHs are Medicaid patients, a percentage that is less than 1/5th of the percentage of Medicaid patient admissions to non-POHs.[19]

More specifically, ***the DeBrunner & Associates analysis shows, for example, one POH that qualifies as a "high" Medicaid facility with a FY 2018 Medicaid discharge percentage of only 1.9 percent*** (POH B). Yet, that 1.9 percent constitutes the highest percentage of Medicaid patients in the county, ***a county with only two facilities***. This suggests that this county treats virtually few, if any Medicaid patients, and that Medicaid patients likely are treated in neighboring counties. The analysis shows that, with respect to POH B, ***hospitals in the neighboring counties treat significantly higher percentages of Medicaid patients. These facilities have FY 2018 Medicaid discharge percentages of approximately 13 percent, 15 percent, and 22 percent, which points to the distinct possibility that POH B treats patients for which it receives more lucrative payment (patient cherry picking), which results in neighboring county hospitals having to provide access to Medicaid patients – exactly the behavior Congress intended to curtail when it enacted strict limits on POHs***.

[19] Dobson & Davanzo, Analysis of FY 2018 MedPAR Data, September 2020.

Moreover, the data shows that POH B, especially in comparison to hospitals in neighboring counties, has significantly lower rates of uncompensated care costs as well as discharges with emergency room services, 2.3 percent and 11.4 percent, respectively.[20] In contrast, the neighboring county hospitals have uncompensated care costs as a percentage of overall operating costs ranging from 5 percent to 11 percent and discharges with emergency room services ranging from 63 percent to 92 percent. As evidenced by the data, permitting POH B an uncapped expansion would not promote access to care for Medicaid patients. And, as discussed above, once a high Medicaid facility's exception request is granted, there is no requirement for the POH to maintain that status, as illustrated by POH A.

The examples above undermine any argument that CMS's proposed policy reversal is intended to support hospitals serving a high number of Medicaid patients. Rather the policy reversal could operate to support POHs that do not serve large numbers of Medicaid patients or those that meet a relatively "high" threshold but do so for a relatively short period of time.

Further, since "high" Medicaid facilities treat all patients, and may in fact treat very few Medicaid patients, as in the POH A example above, the proposal if finalized would allow POHs to expand with regard to all patients, not just Medicaid patients. As such, a POH that doubles its capacity from, for example, 75 to 150 beds, could fill those additional beds and, indeed, all the facility's beds, with non-Medicaid patients. The data show that the existing POHs whose expansion exception requests have been approved by CMS generally doubled in size under the approved request and this could increase exponentially under the proposal since it removes all limits on expansion and does not require that such expansion facilitate or maintain the POH's continued service to Medicaid patients.

There Are No Limits on "High" Medicaid Facility Expansion and Off-Campus Facilities

The FAH has grave concerns that the proposal would remove all limits on the ability of a high Medicaid facility to expand, including permitting unlimited off-campus facilities. ***Once a hospital meets the definition of a high Medicaid facility (even if temporarily) and its exception request is granted, it could expand without any limitation and without any requirements for when that expansion would occur.*** A POH could expand to double or triple or more in size, through both an on-campus expansion or the purchase or building of an off-campus facility (or multiple off-campus facilities). Further, the POH could undertake and complete that expansion sometime in the distant future after it no longer qualifies as a high Medicaid facility.

Further, there are no limits on service line expansion. Therefore, ***a POH could choose to build or purchase an off-campus facility of any size, entirely dedicated to hips and knees or other specific service lines and with no Emergency Department, with devastating consequences for neighboring full-service community hospitals.*** Nothing in the proposal would prevent a proliferation of these new POHs.

[20] DeBrunner & Associates analysis of FFY 2016-2018 Medicare Cost Reports, September 2020.

There Are No Guidelines for CMS to Deny or Amend an Exception Request

The FAH is concerned that if CMS removes all limits on expansion for high Medicaid facilities, the Agency eliminates its discretion to deny requests for expansion, as the proposal will remove any requirements for approving or denying such requests, and the underlying regulations do not provide any guidelines for such actions. This raises the question of whether a denial by CMS could be legally challenged by a POH as "arbitrary and capricious" and is another factor that could incent expansion exception requests, as there may not be any reasonable basis for denials of these requests.

CMS Has Not Presented a Cogent Rationale or Medicare or Medicaid Program Benefit for Reversing Its Longstanding High Medicaid Facility Policy

The Proposed Rule does not articulate a need for the proposed policy reversal nor any benefit to the Medicare or Medicaid program. If finalized, the proposal will eviscerate Congress's intent to place strict limits on the expansion of POHs, with only imagined benefits to the Medicare or Medicaid programs. In fact, ***the proposal is more likely to harm these programs by increasing the number of POHs despite years of independent data showing that self-referrals to physician-owned hospitals result in cherry-picking of the healthiest and wealthiest patients, excessive utilization of care, and patient safety concerns at significant cost to patients and the Medicare program.***

Congress purposefully put tight restrictions on the growth of POHs in the *Affordable Care Act* (ACA), and the exceptions to the limits on expansion of POH operating rooms, procedure rooms and beds were intended to be very clearly and carefully circumscribed. ***CMS has not identified any access to care concerns for Medicaid recipients that have been caused by the present limits on POH expansion nor identified any instances in which POHs would increase the number of Medicaid patients they serve but for the limits on expansion. In short, the proposal contravenes congressional intent and serves no public policy purpose***.

The lone commenter to the CY 2012 OPPS Proposed Rule that addressed the proposal for uniform requirements/limitations in the exception on expansion stated that applying parallel requirements to both "applicable hospitals" and "high Medicaid facilities" would result in an efficient and consistent process. CMS responded "[w]e agree with the commenter regarding our application of parallel requirements." 76 *Fed. Reg.* 74,524 (Nov. 30, 2011). The FAH agrees with the 2012 commenter and CMS's response that the same requirements and limits on expansion should apply to POHs applying for an exception regardless of whether they are applying under the "applicable hospital" exception or the "high Medicaid facility" exception. The FAH also believes the current policy has worked as Congress intended and should be maintained by CMS.

CMS has not offered a rational explanation for the sudden reversal of its longstanding position. To the contrary, CMS states in the Proposed Rule that it continues to believe that the "current regulations, for which the Secretary appropriately used his authority and which treat high Medicaid facilities the same as applicable hospitals, are consistent with the Congress' intent to prohibit expansion of physician-owned hospitals generally." 85 *Fed. Reg*. 49,038 (Aug. 12,

2020). The only rationale proffered in the Proposed Rule for the change in policy is that CMS believes that its current regulations "impose unnecessary burden on high Medicaid facilities." But CMS does not provide any specifics supporting this statement. For example, ***CMS does not point to any particular high Medicaid facility that has been or would be harmed, or describe the nature of the alleged "burden," or how the Medicare program or Medicaid patients would be better served by so radically relaxing restrictions on expansion by high Medicaid facilities***. As discussed previously, CMS has not issued guidelines that even identify "high" Medicaid facilities – just facilities that are higher than other hospitals located in the same county.

While CMS ties its proposal to the *Patients over Paperwork* initiative, this connection is tenuous at best as CMS also states that it does not believe that the proposal would result in any change in burden under the Paperwork Reduction Act. Specifically, without explanation, the Proposed Rule says CMS does not anticipate any change in the annual number of respondents, that more frequent expansion requests would be unlikely, and that it is not changing the information being collected. The data we examined strongly suggests otherwise. As such, there is no clear proposed benefit to CMS's proposed change in policy. While administrative simplification is suggested as the reason for this proposed policy change, the only clear impact of the proposal if finalized will be to undermine Congress's goal of limiting Medicare utilization by POHs.

We also note that CMS projects that only one POH per year will request an expansion exception on the grounds that it is a high Medicaid facility. This raises the question as to whether the proposal is merely meant to benefit a few specific hospitals, which is not a rational basis for establishing such a broad-based policy change.

CMS Should Maintain the Requirement for Community Input

CMS is considering whether it should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities. ***The FAH strongly opposes any removal or limitation of the opportunity for community input on expansion requests from high Medicaid facilities***. Although CMS states in the Proposed Rule that obtaining community input "could" delay or add complexity to the approval of an expansion request, it does not identify any instances in which this has occurred.

We also note that CMS discusses that elimination of the community input requirement could in fact *cause* a delay and/or *increase* complexity because CMS would have to independently verify the data provided by the POH. This counterintuitive logic highlights the very reason why community input is essential – and foundational to the notice and comment process underlying public rulemaking. It is critical for maintaining a transparent process that provides CMS with the necessary data for verifying or disproving a requestor's high Medicaid facility status as well as State licensure for the requested expansion.

Local community hospitals are not only best able to comment on the need for expansion, but also are arguably the only opportunity for CMS to verify that a POH requesting an expansion exception is an eligible applicant. In conducting the analysis referenced herein, DeBrunner & Associates found that a not insignificant percentage of the

available county data was inaccurate (in some cases due to an incorrect spelling of a county name – a seemingly simple error but with enormous consequences for decision-making) and thus it may be difficult to determine whether a POH does in fact have the highest Medicaid admissions percentage in the county. In these cases, it is imperative that CMS maintain the public comment process to hear from other community hospitals and verify the eligibility of POH's applying for this exception and associated expansion.

For the reasons above, the FAH strongly opposes CMS's proposal and urges its withdrawal.

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

Sincerely,