



Charles N. Kahn III
President and CEO

September 11, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, DC 20201

RE: CMS-1678-P, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Vol. 82, No. 138), July 20, 2017

Dear Administrator Verma:

The Federation of American Hospitals (“FAH”) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay acute, inpatient rehabilitation, long-term acute care, psychiatric and cancer hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. The FAH appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (“CMS”) on the above proposed rule (“Proposed Rule”) published in the Federal Register (82 Fed. Reg. 33,558) on July 20, 2017. Our comments below are organized generally by the topical and numerical headings and subheadings as in the Proposed Rule.

II. E. Proposed Adjustment for Rural Sole Community Hospitals and Essential Access Community Hospitals

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

III. A. Proposed OPSS Treatment of New CPT and Level II HCPCS Codes

CMS requests comments on the proposed APC and status indicator assignments for CY 2018 for the CPT and Level II HCPCS codes implemented on July 1, 2017, all of which are listed in Table 14 of the proposed rule.

The FAH supports the assignment of HCPCS code Q9986, Injection, hydroxyprogesterone caproate (Makena), 10 mg, to status indicator “K” and APC 9074. However, we are requesting that CMS review the calculated payment rate for new HCPCS Code, Q9986 as it appears to be inaccurate. The July 2017 OPSS Update (Transmittal 3783), Table 7 indicates that this new HCPCS code is “per 10 MG” with a payment rate of \$2.72 (July 2017 Addendum B and Proposed NPRM Addendum B). Prior to July 1st, 2017, Makena® (NDC # 64011-0247-02 and NDC # 64011-0243-01) was reported under HCPCS code J1725 which had a dose and measure of “per 1 MG” and a payment rate of \$2.74 (April 2017 Addendum B). Makena® also has a WAC price of \$30.57 per 10 MG. It appears that when the new HCPCS code was added with a description of 10 MG instead of the prior 1 MG, the payment rate was not appropriately adjusted to reflect the dosage change.

- Makena® Injection 250 mg/mL (NDC# 64011-0247-02) \$764.35 per 1 ML vial
- $\$764.35 / 250 \text{ mg} = \$30.57 \text{ per } 10 \text{ MG}$

We request that a review of the payment rate beginning July 1, 2017 be made and an adjustment made in PRICER to reflect an appropriate payment rate based on the dose description of “per 10 MG” for HCPCS Code Q9986.

V. B. 7. Alternative Payment Methodology for Drugs Purchased Under the 340B Drug Discount Program

In the CY 2018 OPSS Proposed Rule, CMS proposes to adjust the rate 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 22.5 percent. CMS intends that the savings from the reduced payments for separately payable drugs and biologicals purchased under the 340B program are included in the budget neutrality adjustments under the requirements in 42 U.S.C. § 1395l(t)(9)(B). CMS then requests public comment on whether “all or part of the savings generated” should be applied through offsetting increased payments elsewhere. 82 Fed. Reg. at 33,634 and 33,712.

If CMS finalizes its proposed payment reduction for separately payable drugs acquired under the 340B program, the FAH fully supports CMS’s decision “to implement this payment reduction in a budget neutral manner *within the OPSS . . .*” 82 Fed. Reg. at 33,711, col. 3 (emphasis added). We note in particular that in CMS’s impact analysis, CMS states that the proposed payment reduction would increase payment rates “for other items and services paid under the OPSS by an offsetting aggregate amount.” *Id.* at 33,712, col. 1. The FAH notes that the budget neutrality requirement upon which CMS relies in this Proposed Rule—42 U.S.C. § 1395l(t)(9)(B)—historically has been understood as requiring budget neutrality within the OPSS. Consequently, the FAH is surprised by CMS’s request for comment on whether it should apply “all or part of the savings” to increase payments “under part

B generally,” or elsewhere. *Id.* The FAH strongly urges CMS to follow its long-standing interpretation of Congress’s budget neutrality requirement and offset the full amount of the aggregate payment reduction through offsetting payment increases within the OPSS. As we note below, we believe such a reading is compelled by the relevant statutory authority.

The budget neutrality authority under the OPSS statute does not permit the Secretary to redistribute any savings under the OPSS outside of the OPSS. CMS relies in the Proposed Rule on 42 U.S.C. § 1395l(t)(9)(B), which states:

(B) Budget neutrality adjustment

If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

Paragraph (9) is entitled, “Periodic review and adjustments components of prospective payment system,” and subparagraph (A), which triggers the budget neutrality provision CMS cites in the Proposed Rule, requires the Secretary review and revise “the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)” to take into account various factors and information. 42 U.S.C. § 1395l(t)(9)(A). Because the nature of the change CMS has proposed here does not fall into any of the specific adjustments listed in subparagraph (A), we surmise that CMS considers this to be one of the “other adjustments described in paragraph (2).” Paragraph (2) of subsection (t) begins with the phrase “*Under the payment system—*” and while CMS has not identified into which adjustment in paragraph (2) this proposed adjustment would fall, the most reasonable fit is subparagraph (E): “[T]he Secretary shall establish, *in a budget neutral manner*, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) *and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals*” 42 U.S.C. § 1395l(t)(2)(E) (emphases added).

Congress clearly intended that budget neutrality be reached within this prospective payment system. In 42 U.S.C. § 1395l(t)(9)(B), “expenditures under this part” means “expenditures from the Part B Trust Fund.” Congress likely included “under this part” to make clear that, in the context of budget neutrality, the term “expenditures” does not include beneficiary coinsurance and copayments. CMS has not offered and we have not found any authority to support a reading that subparagraph (t)(9)(B) establishes a budget neutrality concept for the Part B Trust Fund. Moreover, we have not identified a single instance where the Secretary has implemented budget neutrality as between all of the various Part B payment systems.

CMS has consistently interpreted its budget neutrality authority as both an inflexible requirement from Congress, and one that is ascertained as within the OPSS. For example, in the CY 2003 Final Rule, commenters expressed concern that the OPSS was severely underfunded when it was established. *See* 67 Fed. Reg. 66,718, 66,753 (Nov. 1, 2002). CMS responded, in part: “We do not believe that the OPSS system is severely underfunded, nor do we believe that the statute gives us flexibility in the determination of budget neutrality. Congress set the OPSS system to be budget neutral to the total payments under prior payment methods” *Id.* CMS stated: “With respect to budget neutrality, section 1833(t)(9)(B) of the Act [42 U.S.C. § 1395l(t)(9)(B)] makes clear that any adjustments to the OPSS made by the Secretary may not cause estimated expenditures to increase or decrease.” *Id.* at 66,754.

Separately, the last sentence of (t)(9)(B) is instructive for two reasons. One, CMS has stated in this Proposed Rule that it is using its authority under 42 U.S.C. § 1395l(t)(14)(A)(iii)(II) to make the proposed change to the payment rate for drugs acquired under the 340B program. *See* 82 Fed. Reg. at 33,634. By limiting the inapplicability of adjustments made under (t)(14) to years 2004 and 2005, Congress intended that adjustments under (t)(14) would otherwise be subject to budget neutrality requirements under (t)(9)(B) or paragraph (2)(E). Second, it reinforces the baseline statutory construction of the OPSS statute, which is that budget neutrality remains the default requirement, unless Congress provides explicit authority to the contrary. *See, e.g.,* 42 U.S.C. § 1395l(t)(7)(I); (t)(14)(H); and (t)(16)(D)(iii).

For the following reasons, the FAH encourages CMS to offset the proposed payment reductions through an increase to OPSS base payment rates or through an increase to the conversion factor. First, the unavailability of data regarding drugs acquired under the 340B program and paid under OPSS makes it difficult to predict the amount of the payment reduction. As CMS acknowledges in the Proposed Rule, “Because data on drugs that are purchased with a 340B discount are not publicly available, it is not possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting amount of the adjustment that is necessary to ensure budget neutrality through higher payment rates for other services.” 82 Fed. Reg. at 33,712, col. 1. Indeed, CMS’s estimate of a \$900 million annual impact is likely significantly understated. Consultants engaged by FAH and others have estimated an impact in the range of \$1.2 to \$1.6 billion.

Second, CMS anticipates that changes in provider behavior and in the market likely will reduce the financial impact of the payment reduction. *Id.* Based on these factors, CMS anticipates the “need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount within the OPSS” *Id.* With these confounding factors in mind, along with a potential gradual phase-in of the proposed payment reduction (*see id.* at 33,635), the FAH encourages CMS to implement budget neutrality through the mechanisms CMS routinely uses and annually adjusts—OPSS base payment rates or the conversion factor. The FAH respectfully disagrees with any proposal to offset savings through payment increases outside of the OPSS, and targeted increases within the OPSS would create significant uncertainty for hospitals because of the confounding factors described above. Any unpredictability is best mitigated through across-the-board increases to base payment rates or to the conversion factor.

The FAH believes that the budget neutrality requirement cited by CMS obligates CMS to apply all of the savings generated to offsetting payment increases in the OPSS. Because of the inherent uncertainties described above, the FAH strongly urges CMS to offset any payment reductions by broad increases in a budget neutral manner within the OPSS, either through an adjustment to the OPSS base payment rates or through an increase to the conversion factor.

CMS intends to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B program. CMS believes it is appropriate to presume that a separately payable drug reported on an OPSS claim was purchased under the 340B program, unless the hospital identifies that the drug was not purchased under the 340B program. Should CMS move ahead with adding a modifier to differentiate drugs purchased under the 340b program from those that are not, we urge CMS to implement the modifier in a manner that adds minimal administrative burden, considering the following:

1. Payment status indicators for drug HCPCS codes have historically been subject to substantial change on an annual basis and are also subject to quarterly changes. In addition, drugs eligible for separate payment are packaged when reported on a claim with a procedure paid under a C-APC. While we recommend CMS only require reporting of a 340b modifier on drug HCPCS that are eligible for separate payment, we urge CMS to instruct Medicare contractors to accept the modifier on all drug HCPCS codes to prevent operational burden that may be caused if hospitals have to determine on a claim by claim basis whether a drug is eligible for separate payment due to the complexity of drug packaging policies and quarterly OPSS updates.
2. Most State Medicaid programs require hospitals to append a modifier to drug HCPCS codes on outpatient claims to identify the drugs purchased under 340b. Because no specific modifier exists for 340b drugs today, the State Medicaid programs utilize varying locally defined modifiers to identify these drugs. This creates a burden for 340b hospitals who treat patients in multiple states. ***The FAH urges CMS to reverse its current proposal which will require a modifier to identify drugs that were not purchased under the 340b program and instead add a new modifier to identify drugs that were purchased under the 340b program.*** This will ensure that 340b drugs are correctly identified and reported to both Medicare and Medicaid programs. This will also ensure crossover claims will be correctly interpreted by State Medicaid programs so that they can appropriately represent them to manufacturers when requesting rebates on drugs not purchased under 340b. Implementing a national modifier to identify drugs purchased under the 340b program should reduce the administrative burden for 340b hospitals because it would provide a single modifier to report for Medicare and all State Medicaid programs. Under the current proposal hospitals participating in the 340b program would have to append one modifier for drugs not purchased under the 340b program and other modifiers, based on State requirements) for drugs purchased under the 340b program.

3. ***Hospitals that do not (or cannot as is the case with tax-paying hospitals) participate in the 340b program have higher expenses for drugs and should not be further penalized by adding additional burden through requiring them to report 340b modifiers indicating they did not purchase drugs under the 340b program.*** The FAH urges CMS to reverse its current proposal to add a modifier to identify drugs that were not purchased under the 340b program to instead add a modifier to identify drugs that were purchased under the 340b program.
4. Hospitals participating in the 340b program are able to purchase drugs under the 340b program and can also purchase drugs under the Apexus Prime Vendor Program (PVP) for which only 340b facilities are eligible. If CMS adds modifier reporting requirements, CMS must clarify whether the modifier applies only to drugs purchased under 340b which are subject to a ceiling price payment from the manufacturer or if the modifier proposal would also apply to drugs purchased by a 340b registered facility, but purchased under the Apexus Prime Vendor Program for which only 340b facilities are eligible. The proposed rule specifies that the modifier requirement would not apply to vaccines, but other drugs may be purchased under the PVP.

VIII. B. 4. Proposed Payment for Partial Hospitalization Services/Minimum Service Requirement

Patients who meet the admission criteria for partial hospitalization services need intensive, highly structured therapeutic services and we acknowledge the partial hospitalization program (PHP) requirement that patients must be able to cognitively and emotionally participate in the active treatment process and to tolerate the intensity of a PHP program. However, we maintain that (1) the 20 hours per week requirement should not be based on attendance, (2) it is not an appropriate measure of “clinical intensity,” and (3) CMS should convene an expert panel to examine multifaceted ways to measure “clinical intensity.”

PHP regulations state that a patient’s acuity must require 20 hours per week of programming, *as evidenced in their plan of care*, but do not state that a patient must *attend* 20 hours per week as a condition of payment. In the preamble to the 2009 OPPS/ACS final rule CMS states “the patient eligibility requirement that patients require 20 hours of therapeutic services is evidenced in a patient’s plan of care rather than in the actual hours of therapeutic services a patient receives.” These programs should be required to demonstrate that a treatment plan for 20 hours of service was developed and implemented and to document the reasons why a patient was not able to participate in the full 20 hours of service.

CMS created the 20 hours per week metric for the purpose of measuring clinical intensity, but there are not data or studies to indicate this CMS devised metric is an ideal or even appropriate proxy for clinical intensity in a PHP. Properly certified patients – with high levels of commitment to the program, with intensive and individualized plans of care, and with demonstrated clinical progress – are not always able to fully participate in the weekly requirement of 20 hours of service. There are many reasons for this, including a patient is ill and cannot come to the program for a day or becomes ill and must leave before the end of the day. Nearly 70 percent of individuals diagnosed with a mental health conditions have a co-occurring

medical diagnosis and more than half have one or more chronic diseases. Therefore, a patient may miss a day and fall short of 20 hours for medically necessary reasons that are in their clinical best interest.

An additional example of why 20 hours per week is a poor proxy for clinical intensity, is that many patients experience difficulty adjusting to a new medication, a common occurrence in PHPs. This difficulty cognitively adjusting to the new medication might make 20 hours of intense therapeutic services clinically suboptimal for the patient and they may be best served initially by not attending for the full 20 hours. However, this determination cannot be made until a treatment plan is designed and implemented for the patient.

In these examples, the existing CMS standards were met, the patients benefited, and the PHP offered the clinically appropriate services but 20 hours per week of attendance was not met. Clearly, this type of coverage policy is not a good proxy for clinical intensity or a good metric for the quality of a PHP.

Given these facts and the lack of evidence to suggest widespread misuse of the PHP benefit CMS should not institute a code edit for 20-hours per week until they convene a meeting of experts from the field to discuss, develop, and recommend ideas on how best to ensure the appropriate clinical intensity in PHPs. We recommend that CMS work with the group and towards establishing an appropriate and multifaceted determination of clinical intensity within a PHP.

We look forward to working with CMS and the Department of Health and Human Services and other PHP industry stakeholders to ensure that Medicare beneficiaries continue to have access hospital outpatient mental health and partial hospitalization services.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

- **The FAH strongly recommends that the Total Knee Arthroplasty (TKA) procedure remain on the CMS Inpatient Only (“IPO”) list.**

It is important to note that with respect to TKA, the CMS Claims Processing Manual (Chapter 4, §180.7) states "Inpatient only services are...surgical services that require inpatient care because of the nature of the procedure, the typical underlying physical condition of patients who require the service, or the need for at least 24 hours of postoperative recovery match or monitoring before the patient can be safely discharged."

All of these conditions have always and to this day continue to apply to total knee as well as hip arthroplasty procedures.

- ***The nature of the procedure***

Total knee and hip replacements remain invasive procedures, requiring significant sedation and anesthesia, the nature of which requires Medicare patients mostly of advanced age, and mostly with a significant number of comorbidities to recover in a supervised environment. These procedures require a significant degree of pain control in the postoperative setting that

may be more complex to manage in Medicare patients than in younger, less comorbid commercial populations. The procedures significantly impact the beneficiary's ability to ambulate, resulting in a degree of postoperative recovery to ensure proper ambulation, self-care and oftentimes rehabilitation to maintain the operative joint and to ensure appropriate recovery of or improvement to preoperative degrees of functioning. CMS's most recent published data (2016) still shows the average LOS for the TKA DRG of 2.8 days.

- ***The typical underlying physical condition of patients who require the service***

Medicare beneficiaries as a group are older and more frail than commercial populations, and have significantly greater degrees of comorbid conditions. Medicare beneficiaries will therefore face greater complications, recovery times and rehabilitation needs than commercial populations to recover from surgery for the reasons stated above. Comments made in previous periods regarding commercial populations:

“[R]ecent innovations have enabled surgeons to perform TKA on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC). In this context, “outpatient” services include both same day outpatient surgery (that is, the patient goes home on the same day that the outpatient surgery was performed) and outpatient surgery that includes one overnight hospital stay for recovery from the surgery...”

simply are neither relevant nor applicable to the Medicare population.

- ***The need for at least 24 hours of postoperative recovery time or monitoring***

Medicare's own data makes it clear that at least 24 hours of postoperative recovery time or monitoring is routine for this DRG as CMS's most recent published data (2016) still shows the average LOS for the TKA DRG of 2.8 days. CMS has also evaluated such procedures in the past in terms of, “commenters should assess whether this procedure would be expected to pose a significant risk to beneficiary safety when performed in an ASC, whether standard medical practice dictates that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure (“overnight stay”).” As noted above the Medicare patient population requires longer post-operative care and more skilled rehabilitative care following these orthopedic procedures. Total knee and total hip procedures place patients at risk for several complications including but not limited to deep vein thrombosis, pulmonary embolism, significant ambulatory dysfunction increasing the risk for falls, infection, and mental status issues resultant from anesthesia, sedation and pain treatments. Each of these requires treatment to mitigate the risk, and monitoring to ensure that complications due to the conditions or their treatments do not occur in the postoperative setting. Each also require monitoring and active adjustments in treatment depending on the trajectory of the recovery. All the situations would pose significant threats to beneficiaries if these procedures were to be performed in outpatient environments. Anticipated impacts would be increases in complications, falls, worse operative outcomes, extended readmissions, among other negative outcomes.

Along those lines the Medicare population frequently has limited home resources making early discharge unsafe as these patients require significant post-discharge support. In some areas of the country, home care services are limited and Medicare beneficiaries must have skilled care

in a hospital or SNF available. However, Medicare only covers SNF care for patients who experience a length of stay greater than 3 days. Discharging these patients early without adequate rehabilitation would increase the likelihood of further medical concerns that may result in readmissions which will result in higher expenses for the beneficiary, the Medicare program, and the hospital.

The Hospital Outpatient Prospective Payment - Final Rule with Comment and Final CY2017 Payment Rates (CMS 1656-FC) states that, “covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPSS, that would not be expected to pose a significant risk to safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure.” Based on the positions stated above, it is clear that performance of these procedures outside a hospital inpatient setting would pose a significant risk to beneficiary safety, especially in an ASC, which does not have the full range of supports typically available in a hospital environment.

CMS 1656-FC continues, “Therefore, we expect that the procedures described by these codes can be safely performed in an ASC without the need for an overnight stay.” Again CMS’s data suggests that the average LOS for these procedures clearly surpasses an overnight stay, and in fact surpasses the Two Midnight Rule period that CMS uses to determine that care is “generally appropriate” for inpatient services and Part A payment.

Furthermore, CMS 1656-FC continues, “In the CY 2013 OPSS/ASC proposed rule (77 FR 45153), we proposed to remove the procedure described by CPT code 27447 from the IPO list. However, the majority of the commenters disagreed with the CY 2013 proposal and believed that it would be unsafe to perform outpatient TKA for Medicare beneficiaries. (We refer readers to 77 FR 68419 for a discussion of these comments.) After consideration of these public comments, we decided not to finalize the proposal, and the procedure described by CPT code 27447 remains on the IPO list.” The FAH takes the position that this decision was correct in 2013, and remains correct today.

- **The FAH requests that CMS impose a permanent moratorium on Recovery Audit Contractors (“RAC”) reviews of patient status for total knee arthroplasty or, at a minimum, confirm that after any moratorium is lifted, a RAC will only be permitted to undertake such a review upon a referral by a Quality Improvement Organization (“QIO”)**

While CMS’s proposal for a two-year moratorium on Recovery Audit Contractors (“RAC”) review of patient status for total knee arthroplasty is a step in the right direction, the FAH urges CMS to impose a permanent moratorium in deference to physicians’ clinical judgment and in order to reduce rather than exacerbate the problematic backlog of pending appeals of denied Medicare claims. CMS proposes a two-year prohibition on RAC review for total knee arthroplasty patient status performed in an inpatient setting “to allow time and experience for these procedures under this setting.” Notably, CMS acknowledges in the Proposed Rule that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician, based on the beneficiary’s individual clinical needs and preferences and on the reasonable and necessary standard. This rationale

supports a permanent moratorium rather than the temporary suspension CMS proposes. *The FAH therefore urges CMS to uphold its deference to the physician’s clinical judgment in deciding on the most appropriate setting for a given patient and permanently restrict RAC reviews of patient status for total knee arthroplasties.*

In addition, it would be inappropriate for CMS to allow RAC patient status reviews for total knee arthroplasty in light of the current backlog of administrative appeals of denied Medicare reimbursement claims. Despite representations that the Secretary is “making good-faith efforts to address the backlog” and the backlog’s persistence is the result of funding constraints rather than the Secretary’s discretionary programmatic decisions, the United States Court of Appeals for the D.C. Circuit recently expressed concern that the “Secretary’s RAC-related interventions appear to be curiously weak medicine for an agency facing mandamus.” *AHA v. Price*, No. 17-5018 (D.C. Cir. Aug. 11, 2017). CMS’s proposal to permit RAC review of inpatient total knee arthroplasties after just a two-year moratorium would exacerbate rather than ameliorate the backlog because it would undoubtedly lead to some increase in appeals of denied claims. *In keeping with CMS’s commitment to undertake good-faith efforts to address the appeals backlog, the FAH requests that CMS impose a permanent moratorium on RAC reviews for inpatient total knee arthroplasties.*

In the event CMS does opt to allow RAC reviews for patient status for total knee arthroplasty, the FAH urges CMS to confirm that, after the moratorium is lifted, a RAC will only undertake a patient status review upon a referral by a Quality Improvement Organization (“QIO”). At present, patient status reviews are initially conducted and managed by QIOs. Only in the event the QIO determines that a provider exhibits persistent noncompliance with Medicare payment policies does the QIO refer the provider to the RAC. The Federation requests clarification that, in the event RAC reviews are permitted for patient status for total knee arthroplasty, RACs will only become involved in these reviews after a QIO completes the initial review process and determines that referral to a RAC is appropriate, consistent with the current process for patient status reviews.

- **The FAH also has serious concerns about TKA removal from the IPO List at this particular time, given the unpredictable downstream impacts on the Comprehensive Care for Joint Replacement (CJR) and BPCI episode-payment models.**

Both the BPCI and CJR models include TKA, and active testing of both models will extend into CY 2018 or beyond (2018 for BPCI and 2020 for CJR). Lower extremity joint replacement (LEJR) episodes are among those chosen most often by BPCI voluntary hospital participants, and the CJR model mandates hospital participation in LEJR episodes. BPCI and CJR have their roots in the IPPS: episodes are triggered by IPPS admissions to prespecified MS-DRGs; payment methodology is through the IPPS in prospect followed by retrospective reconciliation against IPPS-based benchmarks; and waivers for the CJR program were created based upon relevant IPPS regulations. The CJR model was built upon aspects of the BPCI framework but certain hospitals are mandated to participate (based on their geographic location) and the payment model is more standardized. CJR currently includes more than 700 hospitals;

they are located in more diverse geographic areas and are more heterogeneous (e.g., size, ownership) than BPCI participants. Neither of these inpatient-based models was designed to incorporate outpatient TKA and the proposed rule offers no pathways for doing so.

Given its longer remaining duration, the CJR model will be more heavily impacted than BPCI. Potential CJR effects and their implications include the following:

- An overall decline in the number of patients treated through the CJR model seems highly probable.
 - The proposed rule offers no projection of the magnitude of the effect.
 - The decline may vary unpredictably among and within participating MSAs.
- The residual population treated through the CJR model very likely will differ from the original design.
 - CJR patients will be more likely to be in poorer general health, at higher risk for immediate and delayed postoperative complications, and more likely to require more intensive post-acute care services (e.g., SNF versus Home Health).
 - Performance on the model's quality measures may be poorer than projected, affecting the quality-determined discount factor applied at reconciliation.
 - Financial projections for the CJR model, both by CMS and by hospitals, may no longer be valid.
- Costs and payments may be less appropriately aligned.
 - Costs appear likely to increase with rising average patient acuity.
 - MS-DRG relative weight changes will lag the acuity changes.
 - The benchmark prices would not include CY 2018 (and later) data until CJR performance year 5; benchmark prices for performance years 3 and 4 would not reflect the changed inpatient population's higher costs.
 - Inappropriately low benchmarks would increase hospital risk for Medicare repayment rather than net positive reconciliation.
- Analysis and evaluation of the model's results may be degraded.
 - Fewer patients will result in fewer episodes available for analysis for both cost and quality outcomes.
 - Some statistical methods may not be feasible and subset analysis will be limited.
 - The power of the model to detect significant changes in cost or quality may be lowered.

If TKA were to be removed from the inpatient only list, these changes and their implications will necessitate CMS making changes to its CJR methodology to ensure model target prices account for the potentially higher risk profiles of Medicare beneficiaries who would continue to receive TKA procedures in inpatient settings. The need is evidenced by hospital experience in the current model. For example, one Federation member participating in multiple CJR sites reports a wide disparity in post-acute care costs correlated to patient acuity measured using ASA groupings, from an average of \$200 for normal health patients to \$8800 for patients classified with the highest acuity level. Given that lower acuity patients are likely to migrate to

the outpatient setting should CMS proceed with its proposal, without making the appropriate changes to adjust for that migration, participating hospitals will receive inadequate Medicare payments for these patients.

The BPCI initiative likely will suffer many of the same impacts as CJR. The voluntary BPCI participant hospitals are a group that is more likely to be prepared to undertake outpatient TKA, and those hospitals may choose to proceed with outpatient TKA rather than continuing with BPCI TKA episodes. The residual BPCI patients may thereby be sicker and more in need of intensive post-acute care. Further, expecting hospitals to adjust their BPCI clinical and financial operations to reflect a smaller eligible population, and one that is sicker, with only 9 months of BPCI remaining, is unrealistic and imposes a heavy administrative burden (and an uncertain fiscal burden) on hospitals who have volunteered to test payment options for the Medicare program. Fewer patients will mean a less robust analytic and evaluation plan with reduced probability of significant, generalizable conclusions. Finally, CMS has indicated in several proposed rules that development is underway of BPCI successor models, presumably to be available when or soon after BPCI ends. Finalized successor models and their testing could be delayed or halted by BPCI instability, slowing the evolution to value-based payment within the Medicare program.

The lack of a clear and transparent plan for adjusting BPCI and CJR to address the effects of TKA removal is another reason why the FAH urges CMS not to remove TKA from the IPO List.

- **The FAH is very concerned about the overlap of the proposal to remove TKA from the IPO List with recently proposed major revisions to the CJR.**

On August 17, 2017, CMS published a proposed rule (CMS-5524-P) making major revisions to the CJR model; the rule is open for comment through October 16, 2017. The revisions would markedly reduce the number of MSAs and their contained hospitals that would be mandated to participate in CJR. Hospitals no longer subject to mandatory participation would have a one-time opportunity to opt-in to remain in CJR. Overall, the number of participant hospitals is projected to decrease from around 700 to about 475, and likely there will be no remaining LEJR low-volume or rural hospitals. There is no indication from CMS that the effects of the proposal for TKA removal from the IPO list were considered when the revised CJR participation projections were developed.

The welcome proposal to sharply cut mandatory participation will clearly reduce the number of patients and episodes in the CJR model test. The degree to which declines due to outpatient TKA and to CJR revision will overlap is uncertain. The profile of hospitals that will leave CJR also is unclear; high-performing hospitals that might have chosen to remain voluntarily in CJR may also be those who will be early (and successful) adopters of outpatient TKA.

CMS states that the proposed CJR revisions are designed in such a way as to preserve the statistical validity of the CJR evaluation plan despite decreased participant numbers. Certainly, the analysis will be more vulnerable to incomplete or inaccurate results reporting and to any data

processing errors. Any further data loss due to TKA performance in the hospital outpatient setting may limit the probability of definitive results from CJR. Finally, the net fiscal effects of TKA removal from the IPO List and major revisions to CJR seem likely to be significant for both participating hospitals and for CMS. **The FAH recommends that removal of TKA from the IPO List should not be finalized given the uncertain impact such an action would have on the proposed major revisions to CJR.**

- **Removal of Total Hip Arthroplasty from the IPO List would amplify the effects on CJR of outpatient TKA and the proposed major CJR revisions.**

In the CY 2018 OP/ASC proposed rule, CMS invites comments about the propriety of removing Total Hip Arthroplasty (THA; CPT code 27130) and Partial Hip Arthroplasty (PHA, CPT code 27125) from the IPO List. As was done for TKA, CMS presents length-of-stay data with an average stay of 2.7 days in uncomplicated THA/PHA cases, but again without any accompanying post-acute care utilization profile or breakout of the entire THA population by uncomplicated and complicated cases. CMS suggests that patients with “a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient PHA or THA procedure”, but provides no estimates of what portion of Medicare THA/PHA patients would fall into this group.

The FAH opposes the removal of THA and PHA from the IPO List for several reasons. First, as indicated earlier the patient safety profile of outpatient THA and PHA in the non-Medicare population is not well-established. An extensive review and guidelines document about THA released by a large orthopedic professional association in March 2017, did not even examine THA or PHA in the outpatient setting as a patient safety/risk factor. Second, an important subgroup of the THA/PHA group requires surgical intervention for treatment of fracture. The urgent surgery subgroup tends to be older and more frail, thereby not well suited to outpatient THA/PHA.

Third, all the considerations involving the interface between outpatient TKA and the CJR and BPCI models also apply to outpatient THA. The combined effect of outpatient TKA and THA could be sufficient to reduce the impact of the CJR model and make its evaluation difficult, particularly given the newly proposed CJR revisions. **The FAH strongly recommends that consideration of removing THA from the IPO list be deferred.**

- **Removal of TKA, THA or PHA requires that CMS suspend these measures from relevant quality programs.**

Finally, the FAH notes that the Hospital Readmissions Reduction Program (HRRP), the Hospital Value-Based Purchasing Program (HVBP), and Inpatient Quality Reporting Program include measures of hip and knee arthroplasty addressing readmissions, complications, and Medicare payment during a 30-day episode of care. If CMS removes either or both these procedures from the inpatient-only list, performance on these quality measures will change to reflect the increased complexity of the beneficiaries seen in the inpatient setting. The FAH requests, therefore, that should CMS remove hip and knee arthroplasty from the inpatient only list, it should suspend the hip and knee arthroplasty measures from the HRRP and HVBP

programs until performance levels can be recalibrated to reflect the change in patient mix. This is particularly important for the hip and knee arthroplasty measure included in the VBP Program, where performance for both achievement and improvement points is assessed against benchmarks established during an earlier baseline period.

X. A. Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

- **The FAH requests that CMS Continue to Provide Payment Under the OPPS for All Items and Services Furnished in an Excepted PBD Regardless of the Volume or Types of Services Previously Furnished in the Excepted PBD**

The FAH appreciates and supports CMS's decision not to propose limitations on service line expansions in excepted, off-campus PBDs due to operational complexities and administrative burdens on hospitals, CMS, and CMS contractors. *The FAH further supports CMS's proposal to maintain this policy and decline to impose any additional restrictions on excepted PBDs while it monitors provider behavior over the coming years in ways that do not unreasonably burden hospitals or patients.* In the aftermath of the enactment of Section 603 on November 2, 2015, the acquisition of physician practices and the creation of new, off-campus PBDs has declined markedly in accordance with Congress' intent. Any regulatory scheme that further restricts the ability of providers to serve their communities through existing, excepted PBDs is therefore unnecessary to accomplish Congress' goal and would in fact be inconsistent with Congress' intent to grandfather existing, off-campus PBDs. Additional regulatory restrictions on excepted, off-campus PBDs would also unduly burden providers and the communities they serve. The FAH is particularly concerned that service line or volume limitations for excepted, off-campus PBDs would improperly penalize those providers with excepted PBDs that were not operating at capacity during any baseline period used to prospectively limit service volumes or types.

CMS again requests comments addressing potential limitations on clinical service line expansions or volume increases at excepted off-campus PBDs. *The FAH reiterates its concerns that limiting the types of services furnished by excepted PBDs and reimbursable under OPPS or capping the volume of OPPS-reimbursable services furnished by excepted PBDs would run contrary to Congress' direction, is unworkable, and would be administratively burdensome.* As described in the FAH's September 6, 2016 comment letter on the CY 2017 OPPS proposed rule (CMS-1656-P) and the FAH's January 3, 2017 comment letter on the CY 2017 OPPS final rule with comment period (CMS-1656-FC), both of which are incorporated herein by reference, service line or volume limitations on OPPS-reimbursable services furnished in excepted PBDs should not be imposed because they are not statutorily authorized, would unduly penalize excepted PBDs that were operating below capacity in any baseline period, would disincentivize efficiency-oriented innovations that improve the capacity of excepted PBDs, would penalize the reorganization of existing outpatient services among excepted PBDs in ways that better serve the community, and would improperly conflate organic growth with acquisition-fueled growth. The FAH appreciates CMS's indication that, if it proposes a future limitation on OPPS-reimbursable services furnished in an excepted PBD, it will address the FAH's concerns regarding the selection of an appropriate baseline period that better captures the service types or volumes offered by the PBD when operating at or near capacity. (82 Fed. Reg. 33,647.) In such a

situation, the FAH would also urge CMS to adopt a robust exceptions process to address situations where service volumes or types during the baseline period are inconsistent with the excepted PBD's actual capacity and range of services because, for example, the provider temporarily suspended or reduced services at an excepted PBD during a baseline period.

In addition, from an operational standpoint, data are not readily available to create and annually update a rational service line or volume limitation. It would be complex and burdensome to undertake the necessary annual adjustments to any volume cap based on market basket increases to the OPSS payment rates, changes in utilization among Medicare beneficiaries, demographic changes in the communities served by an excepted PBD, and efficiency improvements in certain service lines. Likewise, annual updates to a limitation on service types would need to address the dynamism around APCs and bundling, regular modification to the Healthcare Common Procedure Coding System ("HCPCS") codes comprising APCs, and the natural evolution of the practice of medicine.

Finally, the passage of the 21st Century Cures Act further confirms the FAH's view that Congress did not intend for excepted, off-campus PBDs be limited by the scope or volume of services furnished prior to November 2, 2015 and that it would be unreasonable to do so. Under section 16001 of Public Law 114-255 ("Section 16001"), a PBD is deemed to be excepted in 2017 based exclusively on the date it submitted its provider-based attestation. Section 16001 also creates an alternative exception for PBDs that were mid-build prior to November 2, 2015, as long as the provider adds the PBD to its hospital enrollment and timely submits a provider-based attestation and certification of mid-build status. A limitation on excepted items and services based on volume or on service types would wholly undo Congress' clear intent to exempt newer PBDs to the same extent as existing PBDs. In addition, it would be incongruous with Congress' statutory scheme if a provider that was mid-build for a wholly new PBD for advanced imaging prior to November 2, 2015 enjoyed more favorable treatment for that mid-build PBD than a provider that had a long-standing surgical PBD and a binding contract prior to November 2, 2015 to expand that PBD to offer advanced imaging services. The FAH maintains that it is unreasonable to interpret section 1833(t)(21)(B) to favor PBDs newly constructed after November 2, 2015 under the mid-build exception over longstanding, excepted PBDs that expanded to offer new types or higher volumes of services after November 2, 2015. *The FAH, therefore, respectfully urges CMS to decline to implement any service volume or line limitations for excepted PBDs, recognizing Congress' intent to curtail the creation of new PBDs rather than limit the operation of existing or mid-build PBDs.*

- **The FAH requests that CMS reconsider its policy on the relocation of excepted PBDs and broadly permit excepted PBDs to relocate as needed without jeopardizing their excepted status.**

In the Proposed Rule, CMS does not address the relocation of excepted PBDs, implicitly proposing that its current policy prohibiting the relocation of excepted PBDs except when granted an exception "for extraordinary circumstances". The FAH reiterates the views expressed in its comment letter on the CY 2017 OPSS proposed rule (CMS-1656-P), which are incorporated by reference herein. *The FAH strongly urges CMS to reconsider this policy and broadly permit excepted PBDs to relocate in a range of circumstances that are consistent with the intent of section 603 but do not fall within the extraordinary circumstances (e.g., natural*

disasters) covered by the current relocation exception. Such circumstances would include the expiration of the lease for the PBD, problems with the physical structure currently housing the PBD, changes to street names or numbers, a landlord's exercise of an option under the lease to relocate a tenant PBD, or the provider's organic growth and commitment to meeting changing needs.

- **The FAH strongly urges CMS to Use a Physician Fee Schedule (“PFS”) Relativity Adjuster of 60 Percent Rather than 25 Percent.**

In the Proposed Rule, CMS proposes halving reimbursement to nonexcepted off-campus PBDs, despite acknowledging the absence of any new data to support such a change. In the CY 2017 OPSS/ASC final rule with comment period (81 Fed. Reg. 79,713), CMS finalized the PFS as the “applicable payment system” for most covered items and services furnished by nonexcepted, off-campus PBDs. It then established payment policies under the PFS for items and services furnished by nonexcepted, off-campus PBDs starting January 1, 2017 in the CY 2017 interim final rule with comment period (81 Fed. Reg. 79,720 through 79,729) (“CY 2017 IFC”). Based on an analysis of the PFS and OPSS payment rate differential for 22 frequently billed codes, the PFS and OPSS payment rate differential for evaluation and management services, and the ambulatory surgical center (“ASC”) fee schedule and OPSS payment rate differential, CMS arrived at a 50 percent PFS Relativity Adjuster. CMS further indicated its intent to keep this transitional policy in place “*until such time that [it] had more precise data to better identify and value items and services furnished by nonexcepted, off-campus PBDs and billed by hospitals*” (82 Fed. Reg. 33,982). At the time, the FAH and other stakeholders expressed concern that this analysis underestimated the PFS-to-OPSS payment ratio, advanced a more refined methodology for CMS’s consideration, and urged CMS to adopt a PFS Relativity Adjuster of 64 percent.

For CY 2018, CMS proposes narrowing the data underlying the PFS Relativity Adjuster and basing the PFS Relativity Adjuster exclusively on its comparison of evaluation and management payment rates under the PFS and OPSS (HCPCS code G0463, CPT codes 99201 – 99205, and CPT codes 99211 – 99215) despite acknowledging the absence of any new data to inform the PFS Relativity Adjuster. Instead, CMS expresses a desire to ensure that it does “not overestimate the appropriate overall payments for these services” (82 Fed. Reg. 33,983). To achieve this goal, CMS wholly ignores the PFS and OPSS payment rate differential for 22 frequently billed codes and the ASC-to-OPSS payment rate differential, fails to use the full PFS practice expense amount, and does not account for the significant impact of packaging on OPSS payment.

Contrary to CMS’s assertion, the FAH’s analysis shows that the current 50 percent PFS Relativity Adjuster already underestimates appropriate payment levels for items and services furnished in nonexcepted, off-campus PBDs because it was calculated without using the full non-facility practice amount and without accounting for packaging difference between the PFS and the OPSS. ***The FAH strongly opposes any further reduction in the PFS Relativity Adjuster. Undertaking a reduction in the absence of new data by excluding significant and relevant data points would be an arbitrary and capricious exercise of CMS’s authority. Instead, the FAH urges CMS to take a larger picture of the relevant data, which includes the payment rate differential between the full non-facility practice expense amount under the PFS and OPSS***

for hospital outpatient visits (adjusted for packaging) and between the full non-facility payment amount under the PFS and OPFS for 22 other commonly billed codes (adjusted for packaging). Doing so would support a significantly higher PFS Relativity Adjuster of 60 percent.

- A. The FAH Recommends Including the 22 Frequently Billed HCPCS Codes Previously Identified by CMS in its Comparison of the PFS and OPFS Payment Rate Differential.

In evaluating the HCPCS codes frequently billed in CY 2016 on the 13X claim form with the “PO” modifier signifying that they were furnished in an excepted, off-campus department of a hospital and paid under the OPFS, the FAH identified approximately 23.7 million claim lines. Of these, hospital outpatient visits (HCPCS Code G0463) accounted for roughly 10.3 million claim lines. The other 22 HCPCS codes identified in CMS’s CY 2017 IFC account for nearly 5.2 million claim lines, or 39.9 percent of claim lines excluding hospital outpatient visits. ***The FAH strongly supports using these 22 HCPCS codes in any comparison of PFS and OPFS reimbursement rate because they provide a more complete picture of the wide breadth of items and services commonly provided in off-campus PBDs.*** Although the FAH shows that these 22 HCPCS codes along with evaluation and management codes and packaging adjustments support a PFS Relativity Adjuster of 60 percent, we note that CMS’s own analysis in the CY 2017 IFC concludes that 50 percent is an appropriate PFS Relativity Adjustment when payment differentials for these 22 HCPCS codes are considered alongside the payment differential for evaluation and management codes and the ASC-to-OPFS payment differential. ***The FAH further contends that the data concerning these 22 HCPCS codes and evaluation and management payment rates should be adjusted to use the full non-facility practice amount and to account for packaging, as described below, when setting an appropriate PFS Relativity Adjuster for CY 2018.***

- B. The FAH Recommends that CMS use the Full Non-Facility Practice Expense Amount to Compare PFS and OPFS Payments.

In the Proposed Rule, CMS exclusively relies on a comparison between the OPFS national payment rate for HCPCS code G0463 (\$102.12) and the difference between the non-facility and facility PFS payment amounts under the PFS using CY 2017 rates for the weighted average of outpatient visits billed by physicians and other professionals in an outpatient hospital place of service. By way of example, CMS calculated that the difference between the non-facility payment rate and the facility payment rate under the PFS in CY 2016 as \$21.86 for CPT code 99213 (21 percent of the OPFS payment rate) and \$29.02 for CPT code 99214 (28 percent of the OPFS payment rate).

This calculation, however, is based solely on a portion of the non-facility PFS rate and not the full payment rate that Medicare makes under the PFS for practice expenses in a physician’s office (the full PFS non-facility practice expense amount).¹ Thus, CMS did not use

¹ The full PFS non-facility practice expense amount is the non-facility practice expense resource value unit (“RVU”) multiplied by the conversion factor. For example, for CY 2016, CPT code 99214 has a non-facility practice expense RVU of 1.42, which, when multiplied by the conversion factor of 35.8043, yields a full PFS non-facility practice

the full Medicare payment under the PFS for practice expenses when comparing payment rates for clinic visits. Instead CMS used an amount that represents only the direct costs of the visit and includes no compensation for the indirect costs that a hospital continues to incur when a service is provided in the hospital outpatient department, irrespective of whether it is excepted under section 603. Previously, in the CY 2017 IFC, CMS similarly used a portion of the non-facility PFS rate instead of the full payment rate for a number of the 22 HCPCS codes analyzed.²

The FAH recommends using the full non-facility PFS practice expense payment in all cases as a hospital continues to incur indirect costs when a service is provided in the off-campus outpatient department. Section 603 does not require that CMS implement site-neutral payment between physician offices and nonexcepted, off-campus PBDs or even reference site neutrality. Instead, Section 603 merely directs the Secretary not to pay for services provided in a nonexcepted, off-campus PBDs under the OPPI and instead pay for these services under the “applicable payment system.” Further, section 603 does not change the status of a non-excepted off-campus PBD as being part of a hospital. If site neutrality was the goal of section 603, Congress could have stripped these sites of their provider-based status and required them to be treated like physician offices. Because these sites retain their provider-based status, it is critical that CMS recognize that non-excepted off-campus PBDs are hospital departments with indirect costs that should inform the appropriate reimbursement rate.³ ***If CMS used the full amount that Medicare makes for practice expenses, the PFS payment as a percent of the OPPI payment would be 35.4 percent rather than 21 percent for CPT code 99213 and 49.8 percent rather than 29 percent for CPT code 99214. The PFS payment as a percent of the OPPI payment for the 22 HCPCS codes used in the CY 2017 IFC would also be substantially higher than the 45 percent weighted average used by CMS to support a 50 percent PFS Relativity Adjuster in CY 2017.***

In the following table, we illustrate how the comparison of the estimated PFS technical payment amount and the OPPI rate would change if the full PFS practice expense payment amount were used rather than the difference between the non-facility and the facility amount for the two most common evaluation and management services (current procedural terminology (“CPT”) codes 99213 and 99214) and the 5 procedures⁴ among the 22 HCPCS codes where the

expense amount of \$50.84.

² The logic of using this methodology is certainly belied by the use of CPT code 90834 in the weighted average calculation. If CMS were to pay the difference between the non-facility and facility practice expense payments for CPT code 90834, CMS would pay the hospital only \$0.36 for use of the hospital’s facility during a 45-minute psychotherapy session. On its face, this amount would be inadequate to cover the practice expenses associated with the service in any setting.

³ While FAH rejects the notion of site neutrality, using CMS’s own logic results in a PFS Relativity Adjuster that will pay less than a site neutral amount for all but seven of the 22 services used to determine the CY 2017 Relativity Adjuster (e.g. column 5 of Table 9 is less than 25 percent) and one of the two evaluation and management services used to determine the CY 2018 Relativity Adjuster.

⁴ Table X.B.1 indicates six procedure codes where CMS used the difference between the non-facility and facility PFS amount in the comparison but payment is not differentiated by non-facility and facility for one of these procedure codes (96365).

PFS payment is differentiated between facility and non-facility sites. In each case, the inclusion of the full PFS practice expense rate increases the estimated PFS payment rate by between 3.4 and 21.4 percentage points.

Table 1 - PFS Non-Facility Practice Expense as a Percent of the OPPS

Code	Title	CY 2016 PFS Payment Amount Used by CMS	CY 2016 OPPS Payment Rate	PFS as % of OPPS	CY 2016 PFS Full Non-Facility Practice Expense	Revised PFS as % of OPPS	Percentage Point Difference
99213	Office/outpatient visit est	\$ 21.86	\$ 102.12	21.4%	\$ 36.16	35.4%	14.0%
99214	Office/outpatient visit est	\$ 29.02	\$ 102.12	28.4%	\$ 50.84	49.8%	21.4%
93798	Cardiac rehab/monitor	\$ 11.10	\$ 103.92	10.7%	\$ 14.68	14.1%	3.4%
90853	Group psychotherapy	\$ 0.36	\$ 69.65	0.5%	\$ 3.94	5.7%	5.1%
20610	Drain/inj joint/bursa w/o us	\$ 13.96	\$ 223.76	6.2%	\$ 28.64	12.8%	6.6%
11042	Deb subq tissue 20 sq cm/<	\$ 54.78	\$ 225.55	24.3%	\$ 77.70	34.4%	10.2%
90834	Psytx pt&/family 45 minutes	\$ 0.36	\$ 125.04	0.3%	\$ 11.10	8.9%	8.6%

The largest increases in the PFS payment rate as a percentage of the OPPS payment rate are for evaluation and management services, upon which CMS exclusively relies when proposing the CY 2018 PFS Relativity Adjuster. Using the full PFS practice expense amount provides a fuller and more appropriate comparison of PFS to OPPS payment rates for evaluation and management services as well as other HCPCS codes commonly billed by hospitals with the “PO” modifier, particularly when these numbers are adjusted to account for packaging under the OPPS.

C. The FAH Strongly Urges CMS to Adjust for Packaging Differences Between the PFS and the OPSS

In the CY 2017 IFC, CMS excluded evaluation and management codes from the calculation in Table X.B.1, acknowledging that the “extensive packaging” that occurs under the OPSS for services provided along with clinic visits would heavily skew the calculation. (81 Fed. Reg. at 79,723; 82 Fed. Reg. 33,980.) Instead, CMS considered its comparison of the PFS-to-OPSS payment rate for evaluation and management services alongside its calculation of the PFS-to-OPSS payment rate differential for the other 22 common HCPCS codes in the CY 2017 IFC. In the Proposed Rule, however, CMS proposes exclusively relying on a calculation of the PFS-to-OPSS payment rates for evaluation and management services, making no adjustment for the impact of “extensive packaging” on clinic visits and completely excluding the payment rate comparison for other common services.

In its comments to the CY 2017 IFC, the FAH presented its analysis of the amount of packaging included in the 22 commonly billed HCPCS codes to address this known limitation to CMS’s analysis. We have updated this analysis for the 22 commonly billed HCPCS codes in Table 2, below, which shows the calculations of packaging percentages for single procedure claims used in rate-setting in the CY 2017 IFC. Overall, we estimate the geometric mean for the OPSS relative weights was approximately 22 percent of the total cost.

Table 2– PFS as a Percentage of OPSS Adjusted for Packaging Estimate
Mean Procedures Costs and Mean Packaging Costs

HCPCS	Short Descriptor	Procedure	Packaging	Procedure plus packaging	Percentage packaging
	<i>Total: Top 22</i>	\$ 172.73	\$ 49.71	\$ 222.44	22%
96372	Ther/proph/diag inj sc/im	\$ 50.18	\$ 79.76	\$ 129.95	61%
71020	Chest x-ray 2vw frontal&latl	\$ 64.84	\$ 19.29	\$ 84.13	23%
93005	Electrocardiogram tracing	\$ 34.72	\$ 146.35	\$ 181.07	81%
96413	Chemo iv infusion 1 her	\$ 181.97	\$ 191.42	\$ 373.39	51%
93798	Cardiac rehab/monitor	\$ 207.96	\$ 0.05	\$ 208.01	0%
96375	Tx/pro/dx inj new drug addon	\$ 52.11	\$ 0.04	\$ 52.15	0%
93306	Tte w/doppler complete	\$ 508.76	\$ 13.53	\$ 522.30	3%
77080	Dxa bone density axial	\$ 99.11	\$ 27.71	\$ 126.82	22%
77412	Radiation treatment delivery	\$ 215.72	\$ 39.11	\$ 254.83	15%
90853	Group psychotherapy	\$ 115.59	\$ 0.52	\$ 116.11	0%
96365	Ther/proph/diag iv inf init	\$ 145.91	\$ 117.57	\$ 263.48	45%

20610	Drain/inj joint/bursa w/o us	\$ 272.52	\$ 96.75	\$ 369.27	26%
11042	Deb subq tissue 20 sq cm/<	\$ 450.70	\$ 99.97	\$ 550.67	18%
96367	Tx/proph/dg addl seq iv inf	\$ 71.05	\$ 0.19	\$ 71.23	0%
93017	Cardiovascular stress test	\$ 229.44	\$ 78.39	\$ 307.83	25%
77386	Ntsty modul rad tx dlvr cplx	\$ 603.76	\$ 9.09	\$ 612.84	1%
78452	Ht muscle image spect mult	\$ 769.34	\$ 555.53	\$ 1,324.87	42%
74177	Ct abd & pelv w/contrast	\$ 288.25	\$ 110.40	\$ 398.65	28%
71260	Ct thorax w/dye	\$ 175.14	\$ 91.39	\$ 266.53	34%
71250	Ct thorax w/o dye	\$ 131.93	\$ 15.72	\$ 147.65	11%
73030	X-ray exam of shoulder	\$ 72.42	\$ 43.43	\$ 115.85	37%
90834	Psytx pt&/family 45 minutes	\$ 156.38	\$ 0.93	\$ 157.31	1%

Notes:

- Calculations based on CY 2016 data used in CY 2017 rate-setting.
- Proposed Rule data and policies were followed.
- Based on costs for single procedure claims used in CY 2017 IFC rate setting.
- Costs have been standardized to account for wage index.
- Means are arithmetic.

The table above shows a weighted average packaging portion of 22 percent with a range from a low of 0 percent to a high of 81 percent. We believe that to do a more appropriate comparison between PFS and OPPS rates, the CMS analysis needs to adjust the OPPS payment amounts to address packaging. Therefore, as a reasonable approximation, we recommend adjusting the OPPS denominator to be 78 percent of the value (to account for the 22 percent of packaging). Using the full PFS non-facility practice expense amount (as described in the previous section) and adjusting for a packaging portion of 22 percent, the PFS-to-OPPS ratio for the 22 commonly billed HCPCS codes identified by CMS is 60 percent.

This packaging calculation does not include evaluation and management services, which are extensively packaged under OPPS. As such, it likely underestimates the true extent of packaging under OPPS for items and services commonly billed by off-campus PBDs. Nonetheless, even if we use 22 percent as an (under)estimate of packaging for evaluation and management services and adjusted the ratio of full PFS non-facility practice expense amounts to OPPS amounts accordingly, the PFS-to-OPPS ratio would increase to 45 and 64 percent for CPT codes 99213 and 99214, respectively. Along with the other 22 commonly billed HCPCS codes, this would produce a weighted average PFS-to-OPPS ratio of 57 percent. Again, this ratio would increase if the calculation accounted for the more extensive packaging for evaluation and management services. As such, when evaluation and management services are included, an overall PFS-to-OPPS ratio of 60 percent is an appropriate estimation of the actual ratio using presently available data.

Based on this packaging analysis, and, importantly, further refining the methodology to incorporate data for the 22 commonly billed HCPCS codes, to use the full non-facility practice expense in lieu of the difference between the non-facility and facility PFS amount to account for the indirect costs associated with off-campus hospital department services, the estimated PFS-to-OPPS ratio far exceeds the 50 percent PFS Relativity Adjuster used for CY 2017 or the 25 percent PFS Relativity Adjuster proposed for CY 2018. The FAH, therefore, strongly urges CMS to increase the payment rate to 60 percent of OPPS for nonexcepted items and services furnished in off-campus PBDs. In any case, a reduction from the 50 percent PFS Relativity Adjuster used in CY 2017 is not supported by any change in the data and it is inappropriate to exclude a wide swath of relevant data in order to achieve a reduction in the PFS Relativity Adjuster. As noted above, CMS underestimates the PFS-to-OPPS payment ratio when it excludes commonly billed HCPCS codes other than evaluation and management codes, declines to use the full PFS payment for non-facility practice expenses, and fails to undertake any adjustment for packaging under the OPPS.

X. C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act (PAMA) requires CMS to establish a program that promotes appropriate use criteria (AUC) for advanced diagnostic imaging whereby the clinical decisions support mechanism (CDSM) would be consulted prior to a clinician ordering an advanced diagnostic imaging. The legislation directed CMS to implement the program in stages: establishing AUC; establishing ways for clinicians to consult with AUC (i.e., via CDSMs); requiring consulting with and reporting of AUC by clinicians; and identifying outlier clinicians. There are some exceptions to the program, such as ordering imaging for an individual with an emergency medical condition, if the ordering clinician documents the condition that manifested as sufficiently severe to bypass the AUC process.

The AUC program was originally slated to begin January 2017, but CMS has proposed delaying the implementation date for ordering clinicians to consult with specified AUC – and for furnishing clinicians to submit claims-based documentation – until January 1, 2019. CMS proposes that clinicians can begin voluntarily consulting and reporting in July 2018 pending readiness of CMS claims processing systems. CMS also proposes the development of new HCPCS codes and modifiers for the furnishing clinician to report the consultation information.

The FAH appreciates CMS’s recognition of the complexity of implementing the AUC program by undertaking a phased-in implementation. The FAH supports this delay – as well as CMS’s proposal to pay claims regardless of whether the claims contain the required information during the first year – as positive first steps in developing a more flexible, user-friendly AUC program. As the FAH stated in comments to previous years’ Proposed Rules, our members generally are supportive of using AUC. However, they remain concerned about current timeline expectations and the growing complexity of the program with limited potential benefit in its present form.

Now is the time for CMS to pause and reevaluate the AUC program to ensure that it is focused on the goal of helping clinicians with decision-making rather than resulting in a “check-the-box” exercise. At a minimum, the FAH recommends that CMS further delay the

implementation date, paired with a real, robust test period, as opposed to a voluntary reporting period that will begin too soon and end too quickly. Testing of the CDSM systems should use real claims and engage hospitals in test submissions similar to testing for the switch from ICD-9 to ICD-10. Additionally, more time is needed for the development of the new codes and modifiers CMS discusses in the Proposed Rule, as well as for providers to add to them to their coding and billing systems. CMS could improve the consultation and reporting process for clinicians by requiring that the CDSMs provide the necessary billing codes and modifiers to the clinician consulting the AUC. This would significantly ease the burden on providers of converting the AUC results for billing and reporting purposes.

The FAH has additional recommendations for improving the AUC program, including the treatment of emergency imaging services and ensuring that beneficiaries can receive timely services when the ordering clinician does not appropriately consult CDSM. Specifically, emergency departments (EDs) should be excluded from the AUC program entirely due to the significant hardship emergency clinicians will incur attempting to meet the current exclusion criteria. This burdensome process will divert precious time away from treating the patient during an emergency and severely disrupt EDs' workflow. Additionally, clinicians do not always know whether a patient is truly emergent upon initial presentation; attempting to bifurcate workflow and treatment protocols depending on whether the clinician feels the patient meets the emergency exclusion will lead to confusion and inconsistency across clinicians and providers.

Finally, the FAH recommends modifications to the program to ensure that it is the ordering clinician who is incentivized and required to consult CDSMs. Specifically, any payment reductions or restrictions should be associated with the ordering clinician instead of the furnishing provider. Denying payment to the furnishing provider penalizes that provider rather than the ordering clinician and will likely impact beneficiary access to imaging services. At a minimum, CMS should develop a pathway for a furnishing provider to perform and receive reimbursement for advanced imaging when the ordering clinician either does not consult CDSM or does not properly record that consultation. For example, the furnishing provider could note "Not Applicable" on the claim for reimbursement in the case of non-compliance by the ordering clinician. This mechanism is essential to ensure that beneficiaries receive necessary, timely services.

X.D. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHS) and Certain Small Rural Hospitals

CMS is proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for critical access hospitals (CAHs) and small rural hospitals having 100 or fewer beds for CY 2018 and 2019. *The FAH appreciates this proposal, and believes it is a step in the right direction. We urge CMS, however, to extend the enforcement moratorium permanently.* We agree with CMS's discussion in the proposed rule that some small and rural hospitals and CAHs have insufficient staff available to furnish direct supervision, especially due to difficulties in recruiting physician and non-physician practitioners to practice in rural areas. Also, we agree that with respect to critical specialty services, direct supervision by a hospital emergency department physician or non-physician practitioner is particularly difficult because of the volume of emergency patients or lack of specialty expertise.

Finally, we believe that quality of care is maintained for beneficiaries when using general physician supervision as compared to direct physician supervision for outpatient hospital therapeutic services. This is reinforced by the fact that all services furnished to a beneficiary must be ordered by the responsible physician, which helps to ensure oversight and accountability.

Enforcement of the direct supervision policy in two years, however, would force small and rural hospitals and CAHs to limit their hours of operation or cut services, resulting in reduced access to outpatient care in communities already struggling to ensure healthcare delivery. This is counter to CMS's goal of ensuring patients' access to quality and affordable healthcare delivery in rural communities. Therefore, we urge CMS to permanently adopt a policy that permits skilled health care professionals to perform outpatient procedures so long as supervising professionals are immediately available to furnish assistance and direction throughout the performance of the procedure.

X. F. Potential Revisions to the Laboratory Date of Service Policy

CMS is proposing potential changes to the current laboratory DOS policy, which would allow laboratories to bill Medicare directly for molecular pathology tests and ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act and have been granted ADLT status by CMS, when the specimen is collected during a hospital outpatient procedure and the test is ordered after the patient is discharged from the hospital outpatient department. One approach under consideration would create a new exception to the DOS policy for molecular pathology tests and ADLTs that meet the criteria of section 1834A(5)(A) of the Act and have been granted ADLT status by CMS that would require that their date of service be the date the test was performed rather than when the specimen was obtained.

Alternatively, CMS requests comments on potentially modifying the 'under arrangements' provisions in § 410.42 and § 411.15(m). Specifically, requesting comments on whether an exception should be added to § 410.42(b) and/or § 411.15(m)(3) for molecular pathology tests and ADLTs that are excluded from the OPSS packaging policy under 42 CFR 419.2(b) and how such an exception should be framed.

The FAH supports adding flexibility to the laboratory test billing rules for tests that are paid under the same methodology regardless of which entity bills for the test. The current policy is administratively burdensome for hospitals and laboratories and can create delays and other barriers to laboratory testing. However, we are concerned that creating a new date of service policy that varies based on the whether the patient was an inpatient or outpatient when the specimen was collected and what type of test was ordered after discharge will lead to additional burden and confusion for hospitals and laboratories. We recommend CMS consider changes to the under arrangements requirements in lieu of modifying the date of service rules for laboratory tests. Since there are times when the laboratory tests ordered following discharge include other tests in addition to ADLTs and/or molecular pathology tests, it may be less burdensome to allow the hospital to bill for all the tests ordered rather than some tests having to be billed by the hospital and the other tests by the lab. Therefore, we also recommend that any change CMS finalizes allow flexibility where either the hospital or the laboratory that performs the test may

bill the Medicare program directly. We urge CMS to carefully consider administrative burden on the laboratories and hospital when applying the exception so that additional complexities are not inadvertently created.

XII. A. 3. Proposed Updates to the ASC Payment System/Definition of ASC Covered Surgical Procedures

CMS seeks comment on procedures that may be candidates for inclusion on the ASC surgical procedure list using a standard that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure ("overnight stay"). CMS also defined "surgical" procedure as "any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American medical Association (AMA) Defines as 'surgery' ..." As CMS notes in the proposed rule, the definition would exclude from ASC payment certain invasive, "surgery-like" procedures, such as cardiac catheterization or certain radiation treatment services assigned codes outside the CPT surgical range.

The current definition takes into consideration the complexity of the procedure and its appropriateness for Medicare payment in the ASC environment and uses the CPT(r) code range 10000-69999 to define surgery. CMS then evaluates each surgery to determine which services do not pose a significant safety risk to patients, creating a requirement for an overnight stay when performed in an ASC, and separately paid under the OPSS. CMS also considers procedures outside the prescribed CPT range, where covered procedures are clinically similar. CMS seeks comments on whether certain cardiac catheterization services, cardiac device programming services, and electrophysiology services should be considered to be added to the covered surgical procedures list.

The FAH has serious reservations about expanding the list of cardiac services that could be performed in the ASC without better clinical understanding and evaluation of the clinical consequences for the Medicare population. Patients evaluated by their physician as outpatients and determined to need anatomical visualization seem to meet the standard, being relatively safe and generally requiring no overnight stay. However, the FAH suggests that before expanding the list of services that CMS convene expert panels and solicit scientific evidence to support the expansion of the ASC services to include cardiac procedures.

The FAH recognizes that technology is improving and procedures such as stents and radial artery catheterization are performed on non-Medicare insured patients in ASCs. However, before further action is taken to expand the ASC services to include cardiac procedures for Medicare patients, CMS should also develop a clear definition for the services and seek additional comments on specific proposed refined services to be considered. Without defined criteria and clear clinical research indicating which procedures would be appropriate for an ASC, the FAH strongly urges CMS to refrain from expanding the services that are permitted in the ASC setting.

XIII. Requirements for the Hospital Outpatient Quality Reporting Program

The FAH has a history of supporting public reporting in payment programs, and recommending that the information reported to the public be accurate and comparable across providers. In addition, the FAH believes that the measures used in any of the quality reporting or pay-for-performance programs should provide value in the data generated in proportion to the intensity of the data-collection effort. Our experience is that this has not always been the case. Across all programs, too many measures have been introduced prematurely leading to significant implementation issues. The cost of fixing these issues is substantial and falls on the hospitals/facilities, contractors, and CMS. These costs could and should be avoided so that time and resources could more appropriately be devoted to patient care and quality improvement rather than fixing technical issues.

Accounting for Social Risk Factors. In the proposed rule, CMS seeks comments pertaining to accounting for social risk factors for a variety of quality and payment programs. The FAH has long believed that appropriately accounting for social risk factors, such as sociodemographic status adjustment, is essential for accurately assessing health care provider performance for public reporting and accountability programs, particularly with respect to outcome measurement. The FAH is pleased to offer some guiding principles for implementing social risk factor adjustments.

First, while stratification like the approach recently finalized for the HRRP is a reasonable first step for addressing social risk factors, stratification should be viewed as a stopgap tool, not a permanent solution. Second, a clinician's share of patients who are dual eligible beneficiaries should also be viewed as a short-term proxy for assessing the extent to which a hospital has patients facing social risk factors. Third, any adjustment for social risk factors must be accompanied by a process in which hospitals and other providers receive confidential reports showing their results. Fourth, public reporting of social risk factor-adjusted information on *Hospital Compare* or a similar site must be useful to patients, families, and providers. The FAH encourages CMS to engage providers and other stakeholders in any modeling of possible new displays of performance information that reflects risk factor-adjustment or stratification.

Removal of Measures. The FAH supports the proposed removal of six Outpatient Quality Reporting (OQR) Program measures. As stated above, hospital resources for quality improvement should be targeted to measures that are meaningful, actionable, and likely to improve patient care. The FAH agrees with CMS that measures that are redundant, are "topped out," or that do not produce meaningful and actionable information to providers, consumers, and CMS should not be included in quality reporting programs. The FAH notes that hospital resources are required to manage every mandatory OQR Program measure, even those that are claims-based. The intensity of resources applied to this and other quality reporting programs is not confined to the reporting piece itself, it is also in the analysis and interpretation of results and steps taken to work with departments to improve performance.

Delay of OAS CAHPS. The FAH also supports delay in implementation of the Outpatient and Ambulatory Services Consumer Assessment of Healthcare Providers and Services (OAS CAHPS) patient survey for the OQR Program. As pilot testing of this survey is currently underway, the FAH agrees that CMS should wait and consider the pilot testing results before finalizing its implementation. In addition, this composite measure should not be added until it receives endorsement from the National Quality Forum (NQF). Reporting these CAHPS surveys requires substantial resources, and it would be inappropriate to make the survey mandatory before the survey questions are settled and operational issues are clarified.

Further, while CMS is assessing next steps with the OAS CAHPS, the FAH suggests that a systematic review be undertaken of the methodology used across the entire CAHPS family of measures (HCAHPS for inpatient stays as well as OAS CAHPS and CAHPS surveys for other settings). That review should consider how the CAHPS survey models can effectively use current technology to engage patients in evaluation of their care. The FAH believes that if patients can complete a CAHPS survey on-line it could improve survey response rates as well as allow for faster assessment of data. The FAH appreciates CMS clarifying the differences in access to patient-level data in the OAS CAHPS and HCAHPS. This clarification will assist hospitals in determining how to move forward with OAS CAHPS.

Possible eCQM Reporting. CMS seeks comment on the potential addition of an electronic clinical quality measure (eCQM) to the OQR Program, specifically a version of the current measure OP-2: Fibrinolytic Therapy within 30 Minutes of Emergency Department (ED) Arrival. While FAH supports the movement toward electronic reporting via data collection directly from the electronic health record (EHR), we urge CMS not to pursue mandatory reporting of eCQMs for the OQR Program until the numerous challenges currently impeding electronic reporting for the inpatient population have been resolved. CMS should not be adding to the burden that hospitals and vendors already are experiencing with inpatient eCQMs including measure specification gaps, misaligned measure interpretation between CMS and The Joint Commission, and an inability of CMS to promptly respond to questions posed by hospitals and vendors. Hospitals cannot interpret and act on performance on eCQMs without knowing whether there are underlying incomplete or inconsistent measure specifications or data mapping problems. As with all other measures, eCQMs should be reviewed and endorsed by the NQF and recommended by the Measure Applications Partnership prior to addition to the OQR Program.

In addition, our members report ongoing frustrations with submission of eCQMs to CMS. CMS should only proceed with adding eCQMs to the outpatient program when it can ensure that its ability to process the QRDA Category 1 files, confirm for providers that their files have been received and processed, and respond, along with the Office of the National Coordinator, in a timely way to providers' questions.

Public Display of OP-18c. With respect to the proposed public display of hospital performance on OP-18c: Median Time from ED Arrival to ED Departure, the FAH encourages CMS to consider how to present this information in a way that is meaningful to consumers. The length of time spent by patients in an ED may be influenced by community factors such as the number of psychiatric beds available in a community. Therefore, the median time from ED arrival to ED departure may be a factor other than inefficient throughput on the part of the

hospital. Hospitals are often working during the ED stay to arrange follow-up care in the context of limited community resources or unavailable family support. The FAH encourages CMS to consider including additional community information points to the quality display that would provide a more fulsome picture of the environment in which the ED operates.

Comments on OP-35. The FAH is concerned about the usefulness of the measure OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy, which was adopted in the 2017 OPDS Final Rule for implementation with the 2020 payment determination and subsequent years. The rationale provided for the development of this measure and its additions to the OQR program was that cancer care is a priority area for outcome measurement. CMS provided data about the percentage of cancer patients receiving chemotherapy and the cost of such care, but did not supply any statistics regarding the number or percentage of patients seeking care in the ED or inpatient setting following outpatient chemotherapy.

CMS notes in the proposed rule that the Measure Applications Partnership conditionally supported OP-35 with the recommendation that the measure be submitted to NQF for endorsement with a special consideration for sociodemographic status adjustments and the selection of exclusions. However, to date, the NQF has not endorsed this measure.

Results of the dry run of this measure are now available, and they show that the occurrences of patients receiving outpatient chemotherapy and then returning to an ED are relatively rare, with a national-observed rate of 4.8 percent for ED visits within the 30-day period and 14.3 percent for qualifying inpatient admissions within a 30-day period. More significantly, the dry run data showed that 57 percent of hospitals had too few cases to be statistically compared to the national average. As a result, the measure is only applicable to 1,536 facilities.

The FAH urges CMS to reconsider the usefulness of adding measure OP-35 to the OQR program for CY2020 payment determinations and subsequent years. As discussed above, this measure is plagued with several flaws: performance on this can only be assessed for a minority of hospitals; the ED and inpatient occurrences the measure is meant to capture are rare; and the measure has not received NQF endorsement.

Extraordinary Circumstances Exception Process: The FAH supports the proposed name change for the recognition of extraordinary circumstances exception processes that could impact reporting of quality measurement information. The FAH appreciates the alignment of the terminology “extraordinary circumstances” and the methodology for granting the exceptions across all the quality reporting programs.

XV.A. Request for Information on CMS Flexibilities and Efficiencies

We appreciate CMS’s request for comments on regulatory, subregulatory, policy, practice, and procedural changes that would reduce unnecessary burdens for hospitals, physicians, and patients, improve quality of care, decrease costs, improve program integrity, ensure that patients and their providers and physicians are making the best health care choices possible, and make the health care system more effective, simple and accessible.

In mid-May, the FAH submitted to HHS an extensive list of regulatory reform items that we believe warrant review and action by CMS. That list is attached as Attachment A to this comment letter, and includes a broad range of issues, *e.g.*, proposed reforms to CMS's post-acute care (PAC) payment policies, Medicaid DSH and supplemental payment policies, and Medicare compliance policies.

We believe the regulatory items on this list would make important improvements to a number of CMS's priority initiatives. For example, HHS should ensure that the Center for Medicare & Medicaid Innovation (CMMI) acts only within its designated authority to voluntarily test alternative payment models (APM), not make permanent or mandatory changes to the Medicare program. Additionally, HHS should indefinitely suspend the troubled Hospital Star Ratings system while the Agency collaborates with stakeholders on appropriate risk adjustment. Further, HHS should provide hospitals with flexibility to relocate their provider-based departments to meet community needs and still retain hospital outpatient payments. These items, and additional regulatory relief and program reform items included in the FAH list, are highlighted further below.

Delivery System Reform

The Important and Appropriate Role for CMMI

The FAH supports the purpose of the CMMI to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality of care, with an emphasis on models that improve coordination, quality, and efficiency of health care furnished to Medicare and Medicaid beneficiaries. Such models could, for example, include a voluntary population-based demonstration project under which networks are paid prospective monthly capitated payments for coordinated care furnished to Medicare beneficiaries. Episode payment models, when realistically constructed with sufficient stakeholder preparation time, hold promise as part of CMS's strategy to move from volume to value, and we appreciate the opportunity to be involved with testing these innovative care models.

However, the FAH shares concerns expressed by Secretary Price and others that CMS has overstepped its authority with respect to mandatory demonstrations. We believe that any proposed or finalized requirement for such mandatory provider and supplier participation runs counter to both the letter and spirit of the law that established the CMMI and its scope of authority to test and expand models under section 1115A of the Social Security Act.

Any permanent or mandatory changes to Medicare payment systems must be enacted by Congress after taking into account results of models that have been tested. CMS may not impute that Congress granted the agency this authority. The Agency's aggressive and incorrect interpretation of the statute raises issues of impermissible delegation of lawmaking authority where none was intended. This is especially true because Congress precluded administrative or judicial review of a substantial number of matters of CMMI demonstration authority. CMS has successfully demonstrated that it is fully capable of testing models under section 1115A solely through providers of services and suppliers that volunteer to participate in those models. Experience with the Bundled Payment for Care Improvement (BPCI) program shows a

substantial number and range of providers and suppliers willing to participate in carefully crafted models. Encouraging voluntary participation by providers and suppliers was the intent of Congress in enacting section 1115A, the manner in which previous demonstrations were conducted, and is the proper and appropriate use of legislatively granted demonstration authority.

CMS's policy mandate under the Comprehensive Care for Joint Replacement (CJR) and the Episode Payment Models (EPM) was imposed on providers and suppliers without any testing, as required under section 1115A, and failed to account for difference in types of providers or suppliers, or their particular circumstances. We appreciate and support CMS's proposed rule to cancel the EPM rule, as many hospitals would have been challenged significantly in developing these capabilities, including small hospitals that often have limited financial resources, those that are located in lower income geographic regions, or that incur high amounts of uncompensated care, have low case volume on which to spread financial risk, do not yet have experience with episode-based payment, or lack existing networks with physicians and other providers. The potential consequences for patient care are real. These challenges and potential consequences continue regarding CJR, including hospitals that would be mandated to continue participation in CJR under CMS's recent proposal to maintain a more limited CJR mandate.

Keys to Delivery System Reform

Provider investment and payment adequacy. APMs need to have the ability to recover their significant investment in infrastructure necessary for providers to coordinate and manage care for beneficiaries with chronic illnesses (e.g., clinical staff, case managers, upgrades in health information technology and exchange), while at the same time providing some level of predictability and certainty in prices and payments. Medicare beneficiaries with chronic conditions have an expectation that hospitals will continue to provide them with access to a broad range of services, and hospital investment in new infrastructure as well as the rehabilitation of aging infrastructure will be necessary in order for hospitals to continue serving the community adequately. Thus, delivery system reform program must be structured to ensure providers have the opportunity to offset their up-front investment costs.

Transition period. Transformative policies should be adopted incrementally, beginning with voluntary participation and broadening as more providers gain experience with managing financial risk and patient care across the continuum. The transition must be measured and orderly so that the marketplace can adjust to the new incentives of value based purchasing and a culture oriented more towards social and community services and population health. The financial viability of providers participating in APMs needs to be protected through this transition in order to maintain beneficiary access to necessary care.

Flexibility. APMs should continue to offer providers the flexibility to choose different levels of risk-taking—in terms of the types of patients and services at financial risk, the length of time over which care is delivered, and the amount of financial risk—in order to promote broad participation.

Need for Appropriate Administrative Waivers to Allow Hospitals the Needed Flexibility to Delivery System Reform Goals While Managing Legal and Regulatory Risk

As the FAH has noted in commenting on past CMMI bundled payment proposals, the need for protection from various legal and regulatory risks that are inherent in developing coordinated care arrangements between hospitals, physicians and post-hospital providers are necessary for payment model success. Thus, CMMI or other similar CMS-led models must include waivers of program integrity laws, such as the federal anti-kickback (AKS), physician self-referral (Stark Law), and civil monetary penalties (CMP) laws to ensure the integrity of gainsharing and preferred provider network arrangements. Further, these waivers must be coordinated through both CMS and the HHS Office of Inspector General (OIG).

In the absence of such waivers, hospitals and their partners could be exposed to significant risks, and law enforcement and whistleblowers are not likely to be swayed from taking action by the public policy goals of these bundled payment programs. If providers do not have legal certainty in their arrangements to share risk or reward with physicians and post-hospital suppliers, then lawsuits are a distinct possibility.

Accordingly, the FAH recommends that CMS set aside its current piecemeal approach to bundled payment fraud and abuse waivers and develop a single, overarching waiver, a “Bundled Payment Waiver” of the Stark law and AKS, applicable to all gainsharing arrangements, developed and administered pursuant to the terms of any CMS-led bundled payment program. The Bundled Payment Waiver would apply to models such as CJR, the EPM model, and any future CMS-led, bundled payment programs, with the understanding that CMS could issue program-specific waivers where circumstances warrant a different approach. We have noted in detail, including in our comments to the March 21, 2017 Proposed EPM Rule⁵, how such a Bundled Payment Waiver could be constructed.

In addition to such an all-inclusive program-specific waiver, we encourage CMS to evaluate other waivers that would remove barriers and help level the competitive playing field among PAC providers, and would furnish these providers with the incentives and tools needed to be able to offer PAC care in a manner that contributes to improved quality and efficiencies, while containing costs. Existing COPs and other regulatory requirements restrict fair competition across PAC providers.

Timely and Regular Data Sharing is Required to Achieve Program Goals

Prior to implementation of a new payment model, it is critical that providers receive relevant and timely historical data, be permitted enough time to analyze the data, and take appropriate action with participant partners. The data must be provided prior to the start of the program, and at regular intervals (*e.g.*, monthly) throughout the program.

To successfully manage risk, hospitals must have sufficient time and data to analyze and understand the composition, characteristics, and needs of their patient population. If

⁵ 82 Fed. Reg. 14464 (March 21, 2017)

healthcare providers are expected to improve patient care and outcomes and enhance their value to other healthcare providers, then they must have greater access to information and data about their patients following their treatment of them. Otherwise, they will not have a meaningful baseline on which to improve.

Appropriate Quality Measurement

In a value-based healthcare delivery model, payment is adjusted to reflect the quality of care delivered under the model. As such, the quality measures used for adjusting payments should have clear links to the condition or treatment upon which the model is focused. Additionally, the measures must be aligned with the parameters of the model. For instance, in the EPM mandatory bundled payment model, CMS proposed using at least two clinical measures that are 30-day measures while the payment model pays for 90-day episodes. This misalignment creates potential issues such as how to generalize results to the 90-day episode. The models should also incorporate measures that are relevant to each part of the delivery model, avoiding measurement gaps. Importantly, prior to implementation of any model, participants need full access to their historical quality data, some of which is available to them only through CMS. Meaningful, collaborative, quality improvement initiatives do not happen overnight, and implementation should not be undertaken until providers have had sufficient time to analyze and act upon their data. Further, quality improvement programs are most likely to succeed when frequent, actionable feedback is provided to program participants. Participants should be provided with automatic performance updates at least quarterly.

Supporting Post-Acute Hospital Care

PAC providers are an essential component of episodic-based care delivery and reimbursement models and a key ingredient toward improving and expanding care coordination and provider collaboration activities.

In order for these models to fully succeed, PAC providers must be provided reimbursement flexibility and regulatory relief, including with APMs, for example, being permitted to carry more risk in bundling programs, while rescinding the 60 percent and three-hour rules. Inpatient rehabilitation facilities (IRFs) could test a CMMI bundling program that would not be derived from the IRF prospective payment system (PPS), but instead would permit IRFs to assume the risk of caring for certain patients over a defined period of time and with sufficient regulatory relief, such as rescinding the 60 percent rule and three-hour rule. PAC providers electing to test a bundling program should receive relief from the effects of burdensome rules and regulations that were designed in the 1980's and early 1990's in the era of fee-for-service reimbursement. These rules include the "60 percent rule," which is intended to distinguish IRFs from acute hospitals and to justify IRF Prospective Payment System (PPS) rates, and the "3-hour rule," which requires that each patient must receive at least 3 hours of therapy per day for at least 5 days per week.

Bundled payment and delivery programs require hospitals and other providers to be more accountable for their referral decisions for post-acute care services, including both outcomes and spending. These shifting dynamics have obviated the need for stringent rules, such as the 60

percent and 3-hour rules. Acute-care hospitals and physicians should have broader flexibility to discharge their patients to the most appropriate level of post-acute care needed to meet their patients' needs. Their decision-making should be influenced by what is best for the patient, and not by whether a patient's diagnosis satisfies the 60 percent rule. Permitting greater shared accountability between hospitals and IRFs would strengthen their relationship and reduce costs by enabling IRFs to pass along savings from accepting payments lower than the IRF discharge-based PPS. Further, the three-hour rule undermines patient-centered care, especially in a bundled payment and coordinated care environment. This intensive therapy requirement should be aligned with the IRF patient's unique medical and therapy needs and rehabilitation physicians' and therapists' clinical judgment, rather than a cookie cutter approach. Flexibility is needed to address patient need, while ensuring the quality of care and cost efficiencies needed for success in a bundled payment program.

Achieving the Promise of HIT

The FAH appreciates the recent flexibilities finalized by CMS in the Inpatient Prospective Payment System (IPPS) Final Rule (e.g., 90-day reporting period for CY2018; flexibility to use either the 2015 Edition CEHRT or the 2014 Edition CEHRT; flexibility to attest to either Stage 3 or Modified Stage 2), as these flexibilities will help hospitals in complying with the Program. However, these flexibilities will not address the underlying Program issues of extensive cost and burden, yet lack of interoperability. Further, they do not address the lack of alignment of the hospital Meaningful Use Program requirements with the Advancing Care Information (ACI) category of the Merit-Based Incentive Payment System (MIPS).

Therefore, the FAH recommends re-evaluating the Meaningful Use Program, particularly the move to Stage 3, to allow for a meaningful evaluation of whether the Program is meeting its goals and to further align the hospital Program with the ACI category of the MIPS for physicians, including eliminating the "all-or-nothing" standard. At a minimum, a 90-day reporting period is needed in any year in which Stage 3 is first implemented – with appropriate and timely notice to affected stakeholders to enable providers to implement system updates and train staff.

Making the Hospital Quality Programs Work

The FAH believes public reporting of provider quality data that is reliable, valid, and meaningful to consumers is vital to creating the patient-centered health care delivery system that we strive to achieve. Numerous studies have shown patient care improvement and greater efficiencies in care provided by acute and post-acute care hospitals through the public reporting and payment programs. However, the three major value-based purchasing programs: Hospital Value-based Purchasing (HVBP), Hospital Readmission Reduction program (HRRP), and the Hospital Acquired Condition Reduction Program (HACRP) have significant overlap and are ripe for reconsideration, including the addition of appropriate risk adjustment for critical sociodemographic status (SDS). The FAH believes these programs should be refined to focus on rewarding both improvement and attainment of established goals.

The FAH supports the CMS work to make provider quality measurement and payment data more transparent, reliable, and useful for patients and their families. Unfortunately, the latest CMS transparency effort - the Hospital Star Ratings system - suffers from significant deficiencies, including the lack of SDS adjustment, resulting in unintended consequences and misleading information that could do more harm to consumers than good. These deficiencies should be addressed.

Further, for the federal quality payment programs to work well, providers need quick and complete access to their own data as well as patient data post-discharge in order to use it for quality improvement. Providing acute and post-acute hospitals with timely and complete patient level data for outcomes measures such as readmissions is essential.

In a refined quality payment structure the number of quality measures should be reduced and only those measures that truly make a difference in patient health and are predictors of value should be implemented. Hospitals also must be able calculate their own measure performance, which currently is not possible with many of the claims-based outcomes measures. In the evolving world of quality payment, the FAH is hopeful that quality measurement data eventually will be drawn directly from the electronic medical record (EMR). However, much additional work is needed before that will become an effective quality measurement tool.

In addition, integral to meeting the goals of the CMS pay-for-value programs is the role of the National Quality Forum (NQF) and its public-private partnership, the Measure Applications Partnership, which provides input into the quality and performance metrics used in those programs for hospitals and other health care providers. The role of the NQF in this process is now well established and accepted and has assisted with providing greater transparency in measure selection for the wide variety of federal payment programs.

An efficiently functioning infrastructure to support federal quality data collection and reporting is essential to producing valid data to inform payment adjustments. The FAH strongly encourages CMS to ensure there are sufficient resources available for appropriate oversight and testing of all data collection and reporting systems to ensure full functionality of the CMS and Centers for Disease Control and Prevention (CDC) data system and warehouses. The hospitals represented by the FAH regularly experience system failures at both CMS and CDC, adding considerable and avoidable costs, in resources and time, to both HHS and the reporting hospitals, and eroding trust and confidence. The payment and quality programs are ineffective if the data being used to inform consumers and calculate payment are inaccurate or incomplete.

Evaluating CMS Regulations

Hospitals are committed to ensuring patients receive high-quality care and believe a comprehensive review and repeal or revision of regulations that are outdated, ineffective, or otherwise overly burdensome will further our shared goals of improving health outcomes and efficiencies in care delivery. As noted earlier, we submitted an extensive list of items, which we believe warrant CMS review and action. Listed below is an example of a regulation that deserves attention.

Ensure Meaningful MIPS Measurement and Maximize Advanced APM Participation

The FAH continues to support a path for the Quality Payment Program (QPP) for 2018 and beyond that ensures meaningful measurement in the Merit-Based Incentive Payment System (MIPS) reporting and that maximizes participation in Advanced APMs. As the FAH commented in response to the June 30, 2017 Proposed Rule⁶, our members support a number of CMS's proposals, while noting areas for improvement as the Program continues to ramp up. With regard to MIPS, the FAH supports CMS's proposals to: allow hospital-based clinicians to utilize hospital quality measures for measurement; increase the performance threshold to 15 points; reward quality improvement; allocate bonus points for complex patients and small practices; and to permit the continued use of the 2014 Edition of CEHRT and a 90-day performance period in the Advancing Care Information performance category. The FAH also made recommendations for improvements, including: additional CMS-led education, including a dynamic forum for FAQs; monthly, or at a minimum, quarterly, CMS feedback; allowing clinicians or groups to opt-in to MIPS participation on an annual basis regardless of whether they exceed any one of the low-volume threshold parameters; creating a mechanism to reward clinicians and groups with consistently high-quality performance; a 90-day performance period across all of the performance categories; and allocating bonus points for rural practices. Additionally, the FAH is suggested improvements to ensure that CMS's proposed flexibilities to providers to use multiple submission mechanisms for reporting measures and activities does not result in an unintended reporting burden for eligible clinicians.

With regard to Advanced Alternative Payment Models (Advanced APMs), the FAH appreciates CMS's proposal not to increase the financial risk parameters for Advanced APMs for 2018 and 2019 and the previously finalized changes to the CJR model that qualifies it as an Advanced APM. However, our members remain concerned about a number of APM-related policies, including the limited number of models that qualify as Advanced APMs, the excessively strict financial risk criterion, and the need for broader exceptions to the Stark and anti-kickback laws and certain civil monetary penalties. CMS can encourage more clinicians to participate in APMs by using its discretionary authority to allow more APMs to be designated as Advanced APMs, such as BPCI. CMS should also consider financial risk options that: provide Advanced APM status to APMs transitioning from one-sided to two-sided risk; begin at lower levels of financial risk that gradually increase over time; and capture upfront APM infrastructure costs in its risk framework. Additionally, given the statutory language regarding what can be counted toward determination that a clinician is eligible for the Advanced APM bonus, as well as CMMI's limited resources, the FAH recommends that CMMI focus on developing Advanced APMs under the Medicare fee-for-service.

Maximizing the Potential of Telehealth

The recent advancements in medical technology have greatly expanded the opportunities for patients to receive care in settings that are convenient to them, and in a timely manner, while being responsive to individual needs. Early health interventions, often accessible only through telehealth technologies, can help curb the growth of health care costs by preventing long-term costly catastrophic health events from occurring. From remote patient monitoring for chronic

⁶ 82 Fed. Reg. 30010 (June 30, 2017)

care management to access to care from specialists, telehealth is an expanding field that is dramatically improving the way health care is provided and can accelerate ongoing efforts to clinically integrate care. Unfortunately, patients are unnecessarily denied access to the use of telehealth technologies because the federal government has not kept pace with the advancement of health care technology.

The FAH believes CMS should more aggressively expand patient access to medical and behavioral health care using telehealth technologies. Currently, Medicare covers only a very limited set of services, and CMS must approve new services for telehealth coverage on a case-by-case basis – a cumbersome and costly process. The FAH encourages CMS to exercise its authority, including CMMI’s demonstration authority, to reform current coverage and payment rules for telehealth and remote monitoring technologies. Considering the use of Medicare’s innovation authority to loosen originating site restrictions is one way to spur the future use of these technologies. Increasing access to care – primary, behavioral health, specialty and subspecialty – through telehealth is an efficient way, to improve health outcomes for beneficiaries in both rural and underserved urban areas.

XV.B. Eliminating Inappropriate Medicare Payment Differentials for Similar Services in the Inpatient and Outpatient Settings

In the FY 2018 proposed rule, CMS states its commitment to “eliminating inappropriate Medicare payment differentials for similar services in the inpatient and outpatient settings,” citing MedPAC’s June 2015 report raising concerns about the appropriateness of inpatient one-day stays. See 82 Fed. Reg. at 20,001, col. 1–2. CMS then requests public comment on ways to identify and eliminate such payment differentials. In response to the policy challenges around clearly defining inpatient versus outpatient hospital services, the FAH has long stated that a payment solution that more suitably compensates for hospital resource utilization and recognizes the central role of the admitting physician in determining the medical needs of the patient is more appropriate than an arbitrary policy that seeks to draw a bright line between inpatient and outpatient services. While the FAH supports CMS’s efforts to “prudently pay for high quality care,” the FAH rejects the presumption that payment differences between services provided in the inpatient and outpatient settings are per se “inappropriate” and must be eliminated. See 82 Fed. Reg. at 20,001, col. 1. For the reasons set forth below, the FAH generally opposes any short-stay payment policy requiring absolute site neutrality, without any regard for hospital resource utilization, physician judgment, or the unique medical needs of a patient.

First, CMS has not identified any specific statutory authority for altering the prescribed inpatient payment rate calculation for medically necessary inpatient services. CMS has long recognized that the “methodology for arriving at the appropriate rate structure is essentially prescribed” in 42 U.S.C. §1395ww(d)(2). See 48 Fed. Reg. 39,752, 39,763 (Sept. 1, 1983)). This Medicare statute defines payments for acute care hospital inpatient services using DRG prospective payment rates, and the statute only allows a Medicare exception to the MS-DRG payment methodology for post-acute care transfers. Short-stay inpatient cases (i.e., inpatient stays lasting less than two midnights) are cases for which, in a physician’s judgment, the condition of the patient justifies the provision of services on an inpatient basis. Absent the applicability of the post-acute care transfer exception, the Medicare Act does not provide for

payment for inpatient services under any system other than the inpatient MS-DRG payment methodology.

Second, CMS's longstanding policy recognizes that physicians determine whether and when to admit a patient to or discharge a patient from inpatient care. Because the determination of when to admit and discharge patients lies with physicians, and not with hospitals, it would be fundamentally unfair to reduce hospitals' payments purely on the perceived inappropriateness of a short inpatient stay, given hospitals' limited involvement with that determination.

The FAH urges CMS to reject the assumption that short inpatient hospital stays and any payment differences as compared with outpatient services are *per se* inappropriate. As we and other stakeholders have explained previously, inpatient hospital services differ materially in terms of resource utilization compared to services rendered in an outpatient setting. In particular, inpatient services tend to be more resource intensive early in a patient's stay. The FAH believes that establishing a per diem or similar system would not appropriately recognize the intensity of resources used early in a patient stay. In its evaluation of short-stay models using a per-diem approach (modeled after CMS's existing transfer policy), the American Hospital Association concluded that this per-diem approach would not be a viable option for reimbursing short inpatient stays because it would not account appropriately for resource use. See, Ltr. from the American Hospital Association to Sean Cavanaugh, CMS, Re: Two-Midnight Policy and Potential Short Stay Payment Solutions (Feb. 13, 2015). The FAH has not identified any model or data that could appropriately measure resource intensity such that one-day stay resource use could be matched uniformly to an accurate payment amount.

Finally, CMS's concern about overpaying for inpatient hospital services in short-stay cases rings hollow in the face of the overall negative Medicare margins incurred by hospitals. For example, MedPAC projects that in 2017, Medicare will pay hospitals at a rate 10 percent lower than hospitals' costs. See, MedPAC, *Report to the Congress: Medicare Payment Policy* (March 2017), 63–64. Moreover, this aggregate Medicare shortfall continues to increase over time, up from –7.1 percent in 2015. *Id.* at 64

XV.C. Request for Information Regarding Physician-Owned Hospitals

The FAH appreciates CMS's request for information on the appropriate role of physician-owned hospitals in the delivery system. There is a substantial history of congressional policy development and underlying research on the impact of self-referral to physician-owned hospitals. The empirical record is clear that these conflict-of-interest arrangements of hospital ownership and self-referral by physicians result in cherry-picking of the healthiest and wealthiest patients, excessive utilization of care, and patient safety concerns. This policy development includes 15 years of work by Congress, involving numerous hearings, as well as analyses by the Health and Human Services Office of Inspector General, the GAO, and the Medicare Payment Advisory Commission (MedPAC). Seven years ago, after a decade of studies and congressional hearings showing the adverse impact of these arrangements, Congress acted to protect the Medicare and Medicaid programs and the taxpayers that fund them by imposing a prospective ban on self-referral to new physician-owned hospitals.

In 2016, using the most recent publicly available data, Dobson | DaVanzo reinforced the findings of Congress, MedPAC, CMS and others. Their analysis in Attachment B compared the performance of non-physician owned full-service community hospitals with physician-owned hospitals identified on the Physician Hospitals of America's (PHA) public-facing website. It provides a clear picture that the characteristics of these PHA hospitals virtually mirror the findings and data collected in the early-to-mid 2000s that drove Congress to enact the law prospectively banning self-referral to new facilities. Among those findings, physician-owned hospitals:

- cherry-pick patients by avoiding Medicaid and uninsured patients;
- treat fewer medically complex patients;
- enjoy all-payer margins nearly three times those of non-physician owned hospitals;
- provide few emergency services – an important community benefit; and
- are penalized for unnecessary readmissions at 10 times the rate of non-physician owned hospitals.

Along the same lines, in its comment letter to the FY 2018 IPPS Proposed Rule responding to CMS's request for public comments, MedPAC noted that its previous findings regarding the risks of patient selection practices as well as the financial risks to the Medicare program from physician-owned hospitals "are still relevant today."

Concerns about physician-ownership of hospitals extends beyond full-service community hospitals. Physician-owned rehabilitation hospitals are also afforded an unfair competitive advantage over non-physician owned IRFs operating in the same market through the effects of the IRF 60% Rule. The 60% Rule requires that at least 60% of an IRF's cases must be derived from a list of 13 medical categories specified by CMS (known as "CMS-13"). If an IRF does not meet this requirement there are dire consequences – it is not recognized by CMS as an IRF and is ineligible for Medicare's IRF payment rates. The dynamics of physician-owned IRFs are disadvantageous to other non-physician owned IRFs in a given market, because there are a finite number of CMS-13 cases in that market.

Allowing physicians to own IRFs without accounting for the effects of the 60% Rule exacerbates the arbitrary nature of the 60% Rule. An underlying characteristic of the 60% Rule is that it effectively ignores the judgment and opinion of physicians who believe a particular patient suffering from the debilitating effects of an illness or condition that is not a CMS-13 diagnosis, such as cancer or cardiac, should receive rehabilitative care in an IRF. In that way, the Rule is akin to centralized decision-making and functions as a direct limitation on, or even rationing of, IRFs' services. In any case, the Rule is not patient-centered. Yet a physician owner of an IRF is able to gain considerable advantage over other non-physician owned IRFs in a given market by virtue of the Rule's effects in that market, because the Rule encourages and incentivizes the physician owner to refer as many CMS-13 cases to their IRF as possible. This, in turn, means other IRFs in that market will have more difficulty satisfying the Rule, especially if the physician owners derive their patient referrals from the same general acute care hospital or hospitals as other non-physician owned IRFs.

The FAH strongly believes that the foundation for current law must be fortified, not weakened. It is noteworthy that Congressional Budget Office scoring of proposals to modify existing law consistently demonstrate that self-referral to physician-owned hospitals increases utilization, which increases Medicare costs and health care costs generally. This is a key reason why the **U.S. Chamber of Commerce** has long supported the ban on self-referral to physician-owned hospitals.

In November 2014, the U.S. Chamber wrote to congressional leadership describing the devastating effects of self-referral to physician-owned hospitals. The letter explains:

“Unbridled, spiraling health care costs is one of the most important challenges facing our health care system today. One legal protection that currently helps combat unnecessary cost increases is a safeguard against certain self-referral practices. When the most profitable patient cases are referred to hospitals where physicians have a financial interest, “cherry-picking” occurs. While this referral practice increases profits for these physician-owned hospitals, such cherry-picking also has the negative impact of leaving the more complicated and poorly reimbursed cases to be treated by neighboring community hospitals.

The Chamber urges Congress to not take a step backward on this policy which has historically enjoyed strong bipartisan support dating back over a decade. Although the Chamber and many lawmakers strongly opposed the Affordable Care Act (ACA) generally in 2010, the Chamber and many bipartisan lawmakers have for years supported the protections and safeguards codified in §6001 of the ACA. This provision is working by appropriately limiting the practice of self-referral to physician-owned hospitals, which increases utilization and costs to businesses and taxpayers, as well as distorting health care markets. The Chamber supports the current self-referral law and opposes any effort to unwind or weaken it.”

Efforts to weaken or overturn the prospective ban would harm patients, community hospitals and local businesses. Fortunately, since the enactment of this ban, the system has stabilized. The instability created by the proliferation of self-referral has calmed. Patients can choose the appropriate facility for the procedures and treatments they need, and health care spending has been kept in check. In those instances where grandfathered arrangements have met the law’s conditions, they have been permitted to grow.

To be clear, the 2010 law is working exactly as planned to protect taxpayers and ensure a more level playing field – one that promotes fair competition. It is a carefully crafted policy with an important safeguard that permits limited expansion of grandfathered hospitals to meet demonstrated community need. Several physician-owned hospitals, in fact, have met the requirements and are currently on the path to expand.

The FAH agrees with the Chamber that, “Balancing entrepreneurial spirit and sound public policy is no easy feat, but Congress achieved the right balance when it prohibited self-referral prospectively while grandfathering current arrangements....”

The law as it stands protects patients, businesses and taxpayers. It also helps ensure that full-service hospitals can continue to meet their mission to provide quality care to all the patients in their communities.

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,

A handwritten signature in black ink, appearing to read "Steve Speil". The signature is fluid and cursive, with a large initial "S" and a distinct "E" and "P".



Charles N. Kahn III
President & CEO

May 17, 2017

The Honorable Dr. Tom Price
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Dear Secretary Price:

The Federation of American Hospitals (FAH) appreciates your commitment to undertake regulatory reform and reduce the regulatory burden on health care providers, as directed by the February 24, 2017 Executive Order. The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our diverse membership includes teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute, and ambulatory services.

Our members are committed to ensuring patients receive high-quality care and believe a comprehensive review and repeal or revision of regulations that are outdated, ineffective, or otherwise overly burdensome will further our shared goals of improving health outcomes and efficiencies in care delivery. The attached document recommends actions the Department of Health and Human Services (HHS) could take to implement regulatory reform across a variety of areas, such as alternative payment models, Medicaid, hospital and post-acute payment policies, and quality measurement and reporting. For example, HHS should ensure that the Center for Medicare & Medicaid Innovation (CMMI) acts only within its designated authority to voluntarily *test* alternative payment models, not make permanent or mandatory changes to the Medicare program. HHS also should indefinitely suspend the troubled Hospital Star Ratings system while the Agency collaborates with stakeholders on appropriate risk adjustment. Additionally, HHS should provide hospitals with flexibility to relocate their provider-based departments to meet community needs and still retain hospital outpatient payments.

Thank you again for your attention to these critically important policies. We look forward to working with you as you continue these efforts and would be happy to meet with you and your staff to discuss any of the recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Bremberg". The signature is fluid and cursive, with a large, sweeping initial "A" and a long, horizontal stroke at the end.

cc:

Seema Verma
Jared Kushner
Andrew Bremberg
Gary Cohn
Mick Mulvaney

REGULATORY REFORM

Alternative Payment Models / MACRA Implementation

- **Halt Mandatory CMMI Models** – *The FAH does not believe that section 1115A authorizes the Centers for Medicare & Medicaid Services (CMS) to mandate provider participation in Center for Medicare & Medicaid Innovation (CMMI) models such as the Episode Payment Model (EPM) or the Comprehensive Care for Joint Replacement (CJR) models. As such, CMS should make them voluntary.* CMMI authority is designed to test models and make recommendations to Congress for permanent or mandatory changes to the Medicare program. Specifically, CMMI’s general authority is to test innovative payment and services delivery models to reduce program expenditures while preserving or enhancing quality of care. The law further directs CMS to evaluate CMMI models and, if appropriate, allows CMS to expand “the scope and duration” of an existing model to a “Phase II,” provided certain requirements are met. CMS is required to report periodically to Congress on CMMI models and make proposals for legislative action on models it deems appropriate. Notably, nowhere does the law expressly state that CMS can make models mandatory.

- **Ensure Meaningful MIPS Measurement and Maximize Advanced APM Participation** – *CMS should set a path for the Quality Payment Program (QPP) for 2018 and beyond that ensures meaningful measurement in the Merit-Based Incentive Payment System (MIPS) reporting and that maximizes participation in Advanced Alternative Payment Models (APMs).* As CMS transitions to the QPP, so far the Agency has chosen a large set of potentially reportable measures from which clinicians can choose. Instead, FAH encourages CMS to rapidly move to a streamlined set of standardized high-priority measures that would align incentives and actions across the health care system. The move to streamlined measures should include allowing hospital-based clinicians to utilize hospital quality measures for measurement under MIPS, as envisioned in the *Medicare Access and CHIP Reauthorization Act (MACRA)*.

In last year’s final QPP rule, CMS projected that the vast majority of physicians would not reach Advanced APM Qualifying Participant (QP) status and thus would not be eligible for the five percent bonus. CMS should allow more APMs to be designated as Advanced APMs, particularly the Bundled Payments for Care Improvement (BPCI) and Medicare Shared Savings Program (MSSP) Track 1. Additionally, as the CJR model is currently underway, CMS should implement the finalized changes to the model on July 1, 2017 in order for CJR to qualify as an Advanced APM. Post-acute care (PAC) providers should also be included in the development of APMs, such as through a “shared accountability” payment methodology that features price flexibility for inpatient rehabilitation facilities (IRFs). Adopting additional options – other than payment amount and patient count – for use in determining the Advanced APM Threshold Score will also increase Advanced APM participation by not disadvantaging multispecialty practices. Finally, CMS should revise the financial risk definitions: to provide Advanced APM status to APMs transitioning from one-sided to two-sided risk; and begin at lower levels of financial risk that gradually increase over time.

- **Recalibrate Bundling Programs – CMS – with robust stakeholder input – should reexamine the bundling programs, such as the BPCI to ensure they are successful in achieving program goals.** Existing health care bundling programs have been rolled out in a manner that is “too much too soon” without the opportunity to evaluate ongoing programs to determine best practices and implement mid-course program adjustments. There is a need to reexamine and recalibrate numerous program requirements to ensure they are operationally feasible and actually improve value-based, coordinated care, such as providing timely data to providers; length of episodes; stop-loss and stop-gain limits; areas used to establish regional prices; downside risk; target price discount factors; payment flexibility for PAC providers to better achieve efficiencies; appropriate waivers under fraud and abuse laws for gainsharing purposes; gainsharing caps; development of preferred provider networks; and duplicative beneficiary notice requirements.
- **Implement Prospective Beneficiary Assignment to Medicare ACOs – CMS should prospectively assign beneficiaries to an Accountable Care Organization (ACO) in Track 1 and Track 2 of the MSSP.** CMS performs a preliminary prospective assignment that provides ACOs with information about the fee-for-service population that is likely to be assigned to it for the performance year. However, the final list of beneficiaries assigned to the ACO is determined based on a retrospective reconciliation completed after the end of the performance year, which drives the calculations of average per capita expenditures for the performance year.

The current retrospective methodology creates significant uncertainty for ACOs, as they are unable to clearly identify the patient population they are responsible for until after the performance year has ended. ACOs are undertaking significant investments to redesign care delivery to better serve patients, and they must have clear information regarding their assigned patient population in order to proactively and effectively serve the patients for whom they are responsible.

- **Increase Flexibility in Developing Preferred Provider Networks for APMs – CMS should waive statutory and regulatory requirements for alternative payment models (APMs), or adopt a more flexible interpretation of current law, that would permit hospitals to offer beneficiaries a “preferred provider list” to promote better care and patient experience. At a minimum, hospitals should be permitted to exclude from the list certain post-acute providers with objectively poor quality scores.** In recent years, the value of preferred provider networks has emerged as a critical factor in facilitating care coordination and optimization of care in APMs. Yet, hospital APM participants are required to provide Medicare beneficiaries with a full list of area home health and skilled nursing facilities in the discharge planning process. This is confusing for patients, has little value, and prevents hospitals from highlighting high quality providers that can best coordinate care under an APM arrangement.
- **Create Single Bundled Payment Program Stark and Medicare Anti-Kickback Waiver – CMS should replace its current piecemeal approach to bundled payment program fraud and abuse waivers and develop a single, overarching “Bundled Payment Waiver” of the Stark physician self-referral law (Stark Law) and Medicare**

anti-kickback statute (AKS), applicable to all gainsharing arrangements under a CMS-led bundled payment program. Alternatively, CMS should consider a new “Bundled Payment Program Exception” to the Stark law, or revisit and modify current Stark law exceptions (e.g., risk-sharing exception) to permit gainsharing under CMS-led bundled payment programs. Outdated laws and regulations, such as the Stark Law and AKS, undermine hospital efforts to achieve successful coordinated care arrangements and participate in new APMs. Gainsharing is a critical component of APMs, such as CJR or the EPM bundled payment programs, and serves to align participating providers’ otherwise disparate financial interests. Yet, to facilitate such gainsharing arrangements, hospitals need legal certainty that such efforts will not run afoul of federal fraud and abuse laws, and an overarching waiver from these laws would provide that certainty and in a timely manner. Gainsharing programs take careful deliberation on the part of numerous stakeholders, involve painstaking drafting of sharing arrangements, and further entail drawn out negotiations with potential gainsharing partners. An overarching waiver, rather than issuance of waivers with a final rule, would allow participants the time needed to enter into effective gainsharing arrangements.

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

Medicaid

- **Preserve Medicaid Supplemental Payments in Managed Care** – *CMS should revisit its recently implemented rule restricting the use of pass-through payments in Medicaid managed care arrangements and restore the ability of states to use this financing mechanism.* Medicaid provider payment rates already fall far short of the cost of care, and by restricting the use of and phasing out supplemental pass-through payments as a permissible financing mechanism, CMS has imposed unreasonable pressure on providers with adverse consequences for patients, especially since approximately 70 percent of Medicaid beneficiaries are enrolled in managed care plans.
- **Withdraw Regulation and FAQs Regarding Treatment of Third Party Payers in Calculating Medicaid DSH Uncompensated Care Costs** – *CMS should rescind its recently finalized regulation, which defined uncompensated care costs for Medicaid disproportionate share hospital (DSH) purposes in a manner not supported by the statute.* In determining a hospital’s specific-DSH limit, CMS has sought to define the cost as the costs of providing care to Medicaid eligible individuals minus payments made

by third-party payers. Such a definition is in direct conflict with the Medicaid statute. CMS's interpretation has resulted in many hospitals facing significantly reduced or eliminated Medicaid DSH payments, which could well limit access to care.

PAMA Implementation

- **Delay PAMA Implementation and Ensure Beneficiaries Receive Timely Services** – *CMS should delay the January 1, 2018 implementation date for ordering providers to consult appropriate use criteria (AUC) and for furnishing providers to submit claims-based documentation.* Specifically, CMS should allow a 12 to 18 month implementation timeframe after CMS approval of the clinical decision support mechanisms (CDSMs) providers can use to consult AUCs. The list of approved CDSMs is not expected until this summer, leaving very little time for providers to work with their health information technology vendors to implement these new requirements under the *Protecting Access to Medicare Act of 2014* (PAMA). Additionally, in order to enable beneficiaries to receive necessary, timely services, CMS should develop a pathway for a furnishing provider to perform and receive reimbursement for advanced imaging when the ordering physician does not consult CDSM.

PAC Payment Policies

- **Retire the LTCH 25 Percent Rule** – *CMS should completely retire the 25 percent Rule as it is no longer necessary in light of the new two-tiered payment system.* The new long-term care hospital (LTCH) patient criteria and two-tiered payment system address the same policy concern that the 25 Percent Rule was initially developed to address: that patients may have been transferred to the LTCH setting to maximize reimbursement and not because the LTCH was the most appropriate care setting. Now that payment at the LTCH PPS standard Federal payment rate is only available for a subset of historic LTCH patients with LTCH approved, very specific conditions, the FAH does not think the 25 Percent Rule is necessary.

Further, the FAH believes it is arbitrary for CMS to pay for care rendered to LTCH-appropriate patients at different rates (e.g., LTCH rate or IPPS equivalent rate) solely based on the number of patients discharged to the LTCH from the discharging hospital. If the patient is appropriately treated and classified such that the LTCH is eligible for reimbursement at the LTCH PPS standard Federal payment rate, the patient's care should be paid as such, regardless of the percentage of discharges to the LTCH from the discharging or transferring hospital.

- **Clarify IRF 60 Percent Rule ICD-10 Compliant Codes** – *For purposes of presumptive testing, CMS should clarify that it will not exclude IRF ICD-10 codes used for a case that would have been included under ICD-9 as a result of the effects of its prior coding modifications.* The FAH is very concerned that the transition to ICD-10 has limited the extent to which IRFs can use the “presumptive testing” methodology to demonstrate compliance with the 60 Percent Rule. Patient cases in impairment group codes for traumatic brain injury, hip fracture, and major multiple trauma are especially vulnerable

to exclusion. These cases were previously eligible and counted, but are now not eligible due solely to the way in which the General Equivalence Mappings translates, which alters the clinical definitions from ICD-9 to ICD-10 in ways IRFs do not recognize. The FAH believes that this is an unintended oversight with negative consequences for IRFs and patients, which CMS could and should seek to correct through rulemaking. This is a straightforward fix that would help ensure the 60 Percent Rule is functioning properly, and as CMS intends – to reduce reliance on the costly and burdensome “medical review” process in favor of its “preferred” method, “presumptive testing.”

More broadly, CMS should consider supporting efforts to eliminate the 60 percent rule, introduced some 30 years ago. It is arguably an anachronism today and impediment to the ongoing transformation of health care delivery into a system of seamless, patient-centered care. The rule imposes significant burden and cost both on government agencies to administer, and on providers to comply, with diminishing and questionable benefit.

- **Expand 60 Percent Rule Data Transparency** – *CMS should provide IRFs with access to their patient-level data submitted for presumptive testing under the 60 Percent Rule.* Currently, IRFs do not know which cases satisfied the rule and which cases did not and have been unable to access this patient-level data from CMS. This information would enable IRFs to reconcile their internal 60 Percent Rule testing procedures against CMS’ presumptive testing procedures and thus reduce the burden and cost of compliance.
- **Publish Clear, Consistent IRF Coverage and Patient Admission Criteria Through a Transparent Public Process** – *CMS should remove the current sub-regulatory restrictions and clarification documents in favor of clear, formal policy implemented through notice and comment rulemaking with stakeholder input.* In 2010, CMS implemented a series of patient admission criteria governing Medicare’s coverage of IRF benefits that have since been the subject of inconsistent interpretation and enforcement by Medicare contractors. For example, the so-called “Three-Hour Rule” has resulted in a series of sub-regulatory restrictions, “regulation by conference call” via Q&A documents, and “clarification” documents pertaining to the extent to which rehab and therapy delivered in individual, group, and concurrent modes satisfy this rule. CMS declares in Proposed and Final Rule preambles and policy manuals that the “preponderance” of therapy provided to IRF patients must be via the individual modality. Yet, Medicare contractors routinely claim their denials of IRF claims involving 50 percent or more of individual therapy is consistent with CMS policy and requirements.
- **Harmonize IRF Appeal Rights Under the PRRB** – *The Department of Health and Human Services (HHS) should grant IRFs access to the Provider Reimbursement Review Board (PRRB) process for Low-Income Patient (LIP) appeals.* While acute care hospitals can appeal DSH payment determinations by their contractors to the PRRB, IRFs’ cannot appeal parallel LIP payment adjustment determinations by their contractors. Instead, IRFs are forced to seek such appeals through the federal court system, which is more burdensome, costly, and time-consuming.

Other Payment and Compliance Issues

- **Reform the RAC Program** – *The Administration should reform the Recovery Audit Contractor (RAC) program by holding RACs accountable for their performance.* The current RAC program design, in which RACs receive payment based on their claim denials, has resulted in overzealous denials, delayed payments to health care providers for appropriate services, and a years-long backlog of appeals. CMS should improve the RAC program by: recouping payments from hospitals (and paying RACs) only after a final Administrative Law Judge (ALJ) decision upholding the denial; creating one reasonable, balanced standard in the manual provisions for patient status determinations; requiring RAC physicians to review and approve denials before issuing them to a provider; automatically overturning RAC denials deemed inappropriate by a RAC Validation Contractor (RVC) and informing providers of RVC determinations; and applying a financial penalty to RACs for poor performance, as measured by appeal overturn rate at the ALJ level.
- **Withdraw Home-Health Pre-Claim Demonstration** – *CMS should withdraw the Pre-Claim Review Demonstration for Home Health Services.* Last year, CMS implemented a three-year Pre-Claim Review Demonstration for Home Health Services initially intended for staggered implementation in five states (Illinois, Florida, Texas, Michigan, and Massachusetts). In March, CMS paused the demonstration for at least 30 days in Illinois, and announced it will not expand the program to Florida in April, as previously scheduled. The demonstration has been fraught with problems, such as delaying claims due to simple paperwork errors rather than potential fraud, as well as excessive and unanticipated wait times in submitting the pre-claims for approval, including issues with using an online portal. These delays significantly affect workflow, negatively affect outcomes for beneficiaries, and interfere with quality improvement and care coordination, rather than achieving the demonstration program’s goal of reducing fraud and abuse.
- **Streamline Medicare Advantage Compliance Training Requirements** – *CMS should streamline the Medicare Advantage compliance training requirements for first tier, downstream, and related entities (FDRs), including hospitals, and exempt FDRs from using the CMS compliance training programs if the FDR has an internal, comprehensive compliance training program that includes training similar to the CMS training.* CMS recently implemented new Medicare Advantage compliance training requirements for hospitals and other FDRs based on use of standardized and more generic training modules developed by CMS. Hospitals take compliance training very seriously, and over many years have developed sophisticated compliance programs designed to meet federal compliance training requirements, while using their own internal comprehensive and personalized compliance training programs that are very specific to the compliance protocols in a specific hospital. While CMS has taken steps to provide hospitals with some flexibility in being able to integrate their own compliance training materials with the CMS modules, these modules continue to cause unnecessary burden and confusion for hospital employees. For example, CMS modules often impose training requirements that are not relevant to a particular hospital, and results in training being offered out of context or in a disjointed manner that is not clear and concise. Further,

CMS has been issuing new compliance training requirements for a coming year after the year has started, while many hospital systems that provide thousands of employees with compliance training, have developed and rolled out their compliance training programs well before the start of the year.

- **Withdraw/Simplify “Program Integrity Enhancements to Provider Enrollment Process” Proposed Rule** – *CMS should withdraw the “Program Integrity Enhancements to the Provider Enrollment Process” proposed rule and reconsider a more narrow, tailored approach.* CMS issued this proposed rule in 2016 to implement statutory requirements to help ensure that entities and individuals who pose risks to the Medicare program and beneficiaries are kept out of or removed from Medicare for extended periods. Under the proposal, a provider or supplier that submits a Medicare, Medicaid, or CHIP enrollment or revalidation application must disclose any current or previous “affiliation,” whether direct or indirect, with a provider or supplier that has had one of four specifically enumerated adverse “disclosable events.” In implementing this statutory provision, the proposed rule is much too broad, unworkable, and unduly burdensome. For example, under the proposed rule, in addition to reporting information about its indirect owners (as currently required), providers and suppliers internally would need to identify all affiliation relationships held by the applicant’s indirect owners, which could include large mutual or pension funds or retirement vehicles that have extremely large and diverse investment holdings, and then determine whether any of these “affiliations” are with a provider or supplier that has had a disclosable event. As ownership in health care providers and suppliers has become more complex and indirect, and increasingly non-health care entities are investing in health care solely as passive investment vehicles, compliance with this requirement will be extremely challenging, if not impossible. It also is highly questionable whether the provisions in the proposed rule would achieve the desired result of reducing fraud, waste, or abuse in federal health care programs.
- **Simplify Public Company Reporting Requirements for Medicare Enrollment** – *CMS should simplify Medicare enrollment reporting requirements for publicly-traded companies.* Specifically, publicly-traded companies should not be required to report any direct or indirect ownership interests held by mutual funds or other large investment or stock-holding vehicles on CMS Form 855. Since the ownership percentage of mutual funds or other large investment vehicles in publicly-traded companies may fluctuate daily, thereby rising above or below the five percent reporting threshold, it is unreasonable and burdensome for publicly-traded providers or suppliers to track and report such changes. In addition, the ability of publicly-traded providers or suppliers to gather necessary information to report these mutual fund or other large investment vehicles is oftentimes unreasonably difficult, if not impossible.
- **Broaden and Increase Flexibility in Anti-Kickback Safe Harbor for Free or Discounted Local Transportation Services** – *CMS should broaden and increase the flexibility in the Medicare anti-kickback safe harbor for free or discounted local transportation services.* We appreciate that the HHS Office of Inspector General (OIG) has finalized safe harbor protection under the Medicare anti-kickback statute for free or

discounted local transportation services. This is a step in the right direction, however, providing more flexibility in the safe harbor would increase patient access to quality and integrative care. For example, the safe harbor should: (i) permit transportation services for any patient who has financial or other need, or to whom such transportation would encourage patient compliance or promote preventive care, rather than limiting the safe harbor to established patients only; and (ii) broaden the existing 25-mile threshold (50 miles for patients in a rural area), as these restrictions undermine the purpose of the safe harbor, especially for “special patient populations” such as patients undergoing cancer treatment or who need special behavioral treatment. Often, the quality medical care needed to best treat their condition is available only at facilities over a much greater distance (than 25 miles).

- **Increase Flexibility in Beneficiary Inducement CMP Exception** – *HHS OIG should provide additional flexibility in the newly-created exception to the Civil Monetary Penalty (CMP) rules regarding beneficiary inducement and whether certain payments to beneficiaries are considered “remuneration” under the CMP rules.* We appreciate that the HHS OIG has finalized an exception to the CMP rules regarding beneficiary inducement so that certain payments to beneficiaries are not considered “remuneration,” including, for example: (i) copayment reductions for certain hospital outpatient department services; (ii) certain remuneration that poses a low risk of harm and promotes access to care; or (iii) certain remuneration to financially needy individuals. This exception is a step in the right direction, and we encourage CMS to provide additional flexibility when interpreting “remuneration” so that hospitals can help patients realize the benefits of their discharge plan and maintain themselves in the community. For example, remuneration that “promotes access to care” should be defined to include nonclinical services that are related to a patient’s health, such as social services or dietary counseling.
- **Create Guidance and Refinements to 60-Day Overpayment Rule** – *CMS should work with stakeholders to refine and provide further guidance regarding certain aspects of the Returning and Reporting Medicare Program Overpayments final rule.* The rule became effective in March 2016 and contains certain broad-based standards that should be further clarified. For example, the regulation requires providers to use “reasonable diligence” to determine whether an overpayment may have occurred. The rule discusses that “reasonable diligence” includes both “proactive compliance activities to monitor claims and reactive investigative activities undertaken in response to receiving credible information about a potential overpayment.” Currently, providers have no guidance about the steps necessary to meet these standards. This is problematic because CMS has been asserting that if a provider does not have a sufficiently “proactive compliance” program or does not sufficiently undertake “reactive investigative activities,” the provider is not protected against penalties even if the provider discovers an overpayment. This subjects the provider to liability under the False Claims Act, which is inequitable given that the threshold requirements in the final regulation are ambiguous and lack adequate guidance for compliance.

Quality Measurement / Reporting

- **Suspend Hospital Star Ratings** – *The Administration should suspend indefinitely the Hospital Star Ratings system and work with the industry and quality experts to ensure that any future star rating system includes appropriate risk adjustment and accurately distinguishes among providers.* The Star Ratings system is deeply flawed and does a disservice to patients, their families, and providers by not providing accurate risk-adjusted information on which to make decisions.
- **Adjust Outcome Measures for Socio-Demographic Status (SDS)** – *The Administration should immediately adjust readmission and other outcome measures used in any federal payment program to accurately account for and capture socio-demographic status differences among hospitals.* Hospitals have been required to report several readmission and outcome measures since 2010. These measures also are used in consequential payment programs such as the Hospital Readmission Reduction program, the Hospital Acquired Condition Program, and the Hospital Value-Based Payment Program. Over time, it increasingly has become clear that the readmission and outcome measures do not reflect accurately the care hospitals provide, and the measures should be adjusted to capture differences among hospitals in the socio-demographic characteristics of the patients they treat.
- **Suspend and Refine Electronic Clinical Quality Measure Reporting Requirements for eCOMs** – *The Administration should delay the Stage 3 Meaningful Use Program in order to gather input from stakeholders prior to further implementation and, at a minimum, allow a 90-day reporting period in each year in which Stage 3 is first implemented.* Hospitals currently are required to report electronic clinical quality measures (eCQMs) for purposes of Meaningful Use Stage 3 and also for the Inpatient Quality Reporting (IQR) program. However, the value of these measures for improving patient care is not clear. The requirements around reporting of eCQMs are extensive and require hospitals to expend significant resources re-tooling their EHR systems to capture and report the eCQMs solely for the purpose of meeting arbitrary standards and not for the purpose of improving patient care.
- **Streamline Hospital Quality Measures** – *HHS should step back and focus on measures that really matter and can drive care improvement aligned across care settings.* CMS requires an increasing number of quality measures be reported each year. While improvements in quality in hospitals and other health care facilities continue at a faster pace, the proliferation of measures results increasingly in conflict and overlap across programs. CMS should reassess current measures and review any new measures to focus on the most pressing clinical areas in need of improvement and ensure measures align across programs and care settings. In addition, CMS should consider expanding the programs for which quality data vendors are able to submit data on behalf of hospitals. In particular, it would be extremely helpful for vendors to submit data on the Perinatal Care and Behavioral Health measures just as they do for all other core measures. Allowing vendors to electronically submit the data would alleviate data entry burden for hospitals and improve the quality of the data submitted.

- **Postpone Implementation of PAC Quality Measures to Ensure Appropriate Alignment Across Care Settings** – *CMS should postpone all Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) Act quality measure implementation until the new cross-cutting measures have been tested and refined in the specific setting where they are being used.* The passage of the IMPACT Act reforming PAC payment and subsequent implementing regulations have placed significant burden on post-acute providers and the government quality reporting systems. Implementation time has been inadequate and requirements to report functional status data two different ways, such as for Inpatient Rehabilitation Facilities, causes enormous confusion in the field and does little to improve patient care. Harmonizing quality measures across settings requires significant testing in the actual setting to minimize or eliminate unintended consequences of measures not adequately capturing the patient care provided in the setting. The varying complexity of patients and their care needs across post-acute settings challenges measure developers to effectively capture the differences. Robust setting-specific testing and revision is needed prior to full deployment of the measures in consequential payment programs.
- **Expand PAC Provider Access to Patient-Level Information for Use in Analysis of Quality Reporting Programs for Inpatient Rehabilitation Facilities (IRFs)** – *The Administration should permit post-acute providers access to pre- and post-acute patient-level claims data beyond three days.* Under the current system, post-acute providers receive aggregated claims data, which does not fully inform the facility of the patient’s clinical condition and nuances that may be important for better understanding the facility’s performance on outcomes measures. Permitting access to more robust patient-level data, similar to what acute care providers receive, would better inform the understanding of the patient’s recovery and provide more specific information for the quality improvement work of the IRF. For example, CMS recently began publishing IRFs’ 30-day readmission rates on the “IRF Compare” website. IRFs should be provided with relevant data and information about the patients comprising these rates to facilitate improvement and better outcomes on this measure.
- **Ensure Appropriate Pre-Deployment Testing of all Federal Systems for Collecting and Reporting Hospital Quality Data Both at CMS and CDC** – *The Administration should ensure full testing of any changes to quality measures and the reporting structures to which the data is reported before the new/updated systems are deployed.* Hospitals are required to report a series of quality measures to CMS and Centers for Disease Control and Prevention (CDC). FAH members welcome the opportunity to improve patient care and value the feedback received from reporting data. However, inordinate resources are expended in reporting data to and retrieving data from faulty federal reporting systems. This year alone, CMS has had to recall preview reports, suspend reporting for several weeks, or change reporting deadlines three times in the first quarter due to problems with QualityNet reporting. Deploying systems that cannot either accurately receive the data or report data back to hospitals costs both the government and hospitals hundreds of thousands of dollars each year. Additionally, more robust testing of CDC National Healthcare Safety Network (NHSN) quality reporting systems prior to deployment of any new upgrade would avoid the challenges, downtime, and inability of

hospitals to effectively and efficiently retrieve their data to either check that it was recorded appropriately or inform improved patient care. Each time an upgrade is issued, hospitals experience significant challenges and down time in submitting and retrieving data at CDC.

- **Reform the Data Reporting Mechanisms for the NHSN at the CDC** – *The FAH recommends that CDC develop a vendor submission system similar to the CMS system of certified vendor reporting on behalf of multiple hospitals.* The NHSN was designed to facilitate public health reporting between local and federal health departments, but has been expanded to accept direct reporting of infection measures from 5,000 hospitals. The system is neither designed nor funded to efficiently handle the reporting load, nor can it efficiently generate reports that are needed for care improvement. By implementing a system whereby vendors could collect and report data on behalf of hospitals, the reporting of CDC data could be streamlined and more readily facilitate hospital quality improvement with the timely feedback of quality data to hospitals.

Health Information Technology

- **Delay Stage 3 Meaningful Use and Increase Flexibility** – *The Administration should delay the Stage 3 Meaningful Use Program and, at a minimum, allow a 90-day reporting period in any year in which Stage 3 is first implemented.* The current Meaningful Use Program is costly and burdensome for providers and has not resulted in the desired efficiencies and patient care improvements. Delaying Stage 3 would allow for a meaningful evaluation of whether the Program is meeting its goals and to further align the hospital Program with the Advancing Care Information (ACI) category of the MIPS for physicians, including eliminating the “all-or-nothing” standard. At a minimum, a 90-day reporting period in 2018 – and in any year in which Stage 3 is first implemented – with appropriate and timely notice to affected stakeholders is necessary to enable providers to implement system updates and train staff.
- **Modify MACRA Information Blocking Attestations** – *The Administration should modify the MACRA data-blocking attestations or provide clear guidance on how these requirements will be enforced so that providers understand what actions they need to take and/or avoid in order to be found in compliance.* Effective April 16, 2016, MACRA requires that EHR “meaningful users” demonstrate that they have not “knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.” CMS requires this be met through a three-part attestation that is so broad that providers could inadvertently be labeled as “data blockers” for taking reasonable actions regarding EHR functionality in response to requests for medical records.
- **Expand Coverage of and Establish Payment Parity for Telehealth Services** – *The CMS should take steps to remove Medicare’s restrictions and expand reimbursement of telehealth services. Medical and behavioral health services that can be appropriately delivered via telehealth technology should be reimbursed by Medicare, Medicaid, private insurance, and other payers at the same level as when those services are*

delivered in person. CMS currently engages in an outdated process for determining which services provided via telehealth are eligible for Medicare reimbursement. The process has resulted in Medicare beneficiaries not having access to appropriate telehealth services.

Hospital Payment Policies

- **Permit Hospital Provider-Based Departments to Relocate to Meet Community Health Needs** – *CMS should provide hospitals with broad flexibility to relocate provider-based departments, whether on- or off-campus, and retain hospital outpatient payments. At minimum, a number of exceptions, such as lease expiration and organic growth and community needs, are necessary for hospitals to deliver efficient, high quality care in a safe location.* In addition, this flexibility would enable hospitals to successfully renegotiate favorable lease terms, comply with local building codes, and preserve access to care in the aftermath of a natural disaster. Rural hospitals, for example, serve communities spread across larger geographic areas, making off-campus outpatient departments an important avenue to providing services needed by the community. As new employers arrive, expand, and contract or new housing developments are constructed, a rural community's needs can shift dramatically, and hospitals ought to be in a position to adapt to meet those needs. CMS regulations, however, unreasonably restrict a hospital's ability to do so by stipulating that under most circumstances an existing provider-based department that relocates would forfeit its ability to be paid as a hospital outpatient department.
- **Refrain from Enforcing CAH 96-Hour Rule** – *CMS should not enforce a condition of payment for Critical Access Hospitals (CAHs) requiring certification that a patient is likely to be discharged or transferred within 96 hours of inpatient admission.* As a Condition of Participation, CAHs are required to have an average length of stay of 96 hours or less per patient for acute care. There is also a separate condition of payment for CAHs that requires physician certification that a patient is expected to be discharged or transferred within 96 hours of admission. Some medical services offered by CAHs have standard lengths of stay greater than 96 hours and thus a physician would be unable to make the certification, which would result in non-payment to the CAH for those services. Enforcing this provision would prevent CAHs from offering necessary services that could extend beyond 96 hours.
- **Increase Flexibility and Simplify the MOON** – *CMS should simplify the Medicare Outpatient Observation Notice (MOON) form by making it an easy-to-understand, one-page form and removing open "free text" fields that are burdensome and unnecessary for patient understanding of their patient status.* The Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act), requires hospitals to provide notice to Medicare and Medicare Advantage patients informing them of their outpatient status. CMS has developed the MOON form that hospitals provide to patients informing them of their status. This form is needlessly complex and confusing for patients.

- **Clarify Flexible Timing of a Physician’s Admission Order** – *CMS should clarify that a physician’s order to admit a patient to a hospital need not be finalized (i.e., authenticated by a signature) prior to patient discharge for billing purposes.* CMS adopted a new admission order authentication timing standard (i.e., that the physician’s order must be finalized prior to patient discharge) when the Agency proposed a new physician order and certification scheme as part of its Two Midnight policy. While the Two Midnight policy was largely later modified, effective January 1, 2015, informal CMS policy suggests the new authentication standard for admission orders remains in effect. This is a completely different and unwarranted authentication standard for admission orders than applies to all other types of physician orders that support Medicare inpatient hospital services and also differs from the approach taken by every other payer. Physicians often authenticate (i.e., sign) all relevant orders (including admission orders) during regularly scheduled intervals, but that may occur after a patient’s discharge.

Accreditation

- **Retain Flexibility for Private Sector Accreditation Standards** – *The Administration should retain flexibility for private sector accreditors to innovate while still “meeting or exceeding” CMS survey standards.* HHS has historically deemed that providers meeting certain private sector accrediting body standards (e.g., the Joint Commission) meet or exceed the Medicare Conditions of Participation (COPs). Recently, the Agency has begun requiring these private sector bodies to use the same survey processes used by CMS. Such restrictions limit variation and innovation in the private sector.
- **Promptly Issue Flexible Guidance for Hospital Co-Location Arrangements** – *CMS should promptly issue flexible guidelines regarding co-location arrangements to allow greater access to care and enhance coordinated care for patients.* Hospitals often share medical space with other providers, which is called “co-location.” This allows them to furnish a broader range of services tailored toward the health needs of their patients, which is especially important for providing patients with greater access to care, including in rural areas where specialists can travel to a rural hospital to treat patients. Also, for PAC providers, the ability to co-locate with a hospital is becoming increasingly important as payment and care delivery models continue to be developed throughout the country. Recently, CMS has taken a more restrictive approach to shared medical space, which has caused confusion and infeasible surveyor requirements, such as imposing requirements that a shared space be separate from the hospital and provide, for example, independent entrance and waiting areas. This presents significant obstacles for patient access and quality of care, as well as moving toward more value-based care.

Local / National Coverage Determinations

- **Increase Transparency in the LCD Process** – *CMS should require a transparent process for Medicare Administrative Contractor (MACs) local coverage decision (LCD) determinations, including open meetings and publishing rationales.* LCDs determine whether millions of beneficiaries have access to new procedures and technological advances, but the current decision-making process lacks transparency. Enabling true

beneficiary and stakeholder input into the LCD process will help ensure beneficiaries have access to medically necessary care.

- **Issue National Coverage Decision and Establish an Appropriate Accreditation Timeline for Sleep Labs** – *CMS should develop and issue a National Coverage Decision (NCD) regarding accreditation of sleep labs to supersede several LCDs recently issued by MACs, and in the meantime, there should be a moratorium on the current LCDs.* While we support accreditation of sleep labs, the recent LCDs are inconsistent with prior CMS rulemaking and guidance and establish significant changes in the sleep lab accreditation process. Further, the LCDs lack notice and did not establish an appropriate timeline for accreditation to occur. The LCDs were finalized January 2017 and became effective in February 2017, despite a seven- to nine-month accreditation backlog and that the Joint Commission has not yet issued accreditation standards. This puts patient access to sleep labs at significant risk and thus a national coverage approach is needed.

HIPAA

- **Establish Cybersecurity Safe Harbors** – *The Administration should develop safe harbors for providers that demonstrate a minimum level of cyberattack readiness and mature information risk management programs.* The Health Information Portability and Accountability Act of 1996 (HIPAA) Security Rule requires “covered entities,” such as health care providers, to address and assess cybersecurity risks, so that they can safeguard the confidentiality and security of electronic protected health information (PHI). Providers also are audited to ensure compliance with these requirements. Failure to comply with HIPAA can result in substantial monetary penalties. The FAH recommends the establishment of safe harbors and positive incentives for providers meeting these safe harbors rather than a punitive approach for providers that are the victims of a cyber-attack despite investing in and practicing good cyber readiness and risk management.
- **Remove HIPAA Regulation Barriers to Sharing Patient Information for Clinically Integrated Care** – *The Administration should update the HIPAA regulations to remove the “patient relationship” requirement and permit the sharing and use of patient medical information among clinically integrated providers.* HIPAA limits the sharing of patient medical information for health care operations purposes, such as quality and improvement activities, only to those providers who have a “patient relationship” with the patient. This restriction, while originally well-intentioned, is outdated in today’s era of integrated, team-based care settings where the patient can benefit from care coordination and quality improvement efforts but may not have a “patient relationship” with all the providers in the group.
- **Allow Treating Providers to Access Their Patients’ Substance Use Disorder Records** – *The Administration should align the 42 CFR Part 2 requirements with the HIPAA requirements to allow the use and disclosure of substance use disorder records from a federally assisted program for “treatment, payment, and health care operations”*

without prior written authorization. Currently, 42 CFR Part 2 requires individual patient consent to share addiction records from federally funded substance use treatment programs. Using the HIPAA requirements would improve patient care by enabling providers with a patient relationship to access their patient's entire medical record.

- **Increase Flexibility and Clarity Regarding OCR Guidelines on Charges for Patient and Third Party Requests for PHI under HIPAA** – *The Office for Civil Rights (OCR) should be required to work with affected stakeholders to develop clear guidelines regarding “covered entity” fees and processes that may be charged for individuals’ PHI, and distinguish third party requests for PHI versus requests from individuals or their personal representative.* HIPAA permits a “covered entity” to impose a reasonable, cost-based fee to provide the individual (or the individual’s personal representative) with a copy of the individual’s PHI, or to direct the copy to a designated third party. There is substantial confusion, however, regarding these fees. While guidelines issued by OCR in February 2016 were intended to clarify matters, much confusion remains, especially regarding fees that may be charged for “third party” requests for this information, such as requests for massive amounts of medical records/PHI requested for litigation purposes.

Medicare Beneficiary Identification Numbers

- **Delay the Transition from SSNs to MBIs** – *The Administration should delay the transition in order to address numerous stakeholder timing, operational, and fraud concerns, with negative consequences for beneficiaries.* The transition from using Social Security Numbers (SSNs) to Medicare Beneficiary Identifiers (MBIs) is an enormous undertaking for the Medicare program, the states, beneficiaries, and the providers who serve them. Congress put forth an aggressive timeline for this transition in MACRA, requiring these changes by April 2019. However, given the current state of implementation planning, it is unlikely CMS can meet this deadline without severe consequences for stakeholders, including interruptions in beneficiary access to care. Thus far, stakeholders have raised concerns regarding state readiness; interactions with Medicare Advantage reporting; beneficiary and provider education; the vulnerability of the cards to fraud, especially as millions of new cards are mailed to beneficiaries; and the need for a longer transition period in which both SSNs and MBIs will be accepted. We commend CMS for setting up a mailbox for stakeholders to submit their questions; however, to date there have been no responses from the Agency to those questions, and stakeholders do not believe they have enough time to complete the necessary system changes and training.

Student Loan Repayment

- **Implement Parity for Student Loan Repayment Programs** – *The Administration should eliminate the distinction between non-profit and investor-owned organizations for determining student loan repayment program eligibility.* Registered nurses and advanced practice registered nurses working in a Health Resources & Services Administration (HRSA) defined Critical Shortage Facility (CSF) can receive relief for 60 percent of their unpaid qualifying nursing education loan balance in exchange for two

years of service through the Nursing Education Loan Repayment Program. However, a CSF is defined as a public or private non-profit health care facility located in, designated as, or serving in an area with shortages of primary care or mental health professionals. There is a similar limitation on loan repayment eligibility under the Public Service Loan Program. Thus, nurses and other clinicians who care for patients in investor-owned organizations are not eligible for either program, even if those organizations provide public health and safety services and/or are located in workforce shortage areas. These limitations exacerbate the already significant barriers in recruiting these important professionals to shortage areas, which adversely affects patient access to care. They also discriminate against health care clinicians at investor-owned institutions that provide the same critical services to patients in those areas as those services provided by clinicians at non-profit organizations. The FAH urges the Administration to eliminate barriers to, and propose funding for, loan repayment parity for the health care workforce.

Access to Medications

- **Maintain Timely Patient Access to Compounded Drugs** – *The Administration should drop the “one-mile” radius provision for hospital pharmaceutical compounding for its own patients.* The April 2016 Food and Drug Administration (FDA) draft guidance for hospitals and health systems compounding pharmaceuticals for use with their own patients included a provision that would limit to a one-mile radius the distribution of such compounded products. The FAH encourages FDA to drop this restriction prior to issuing a final guidance document. The one-mile limit is arbitrary and unworkable and does not consider the physical structure of some facilities. The current proposed restriction would significantly hamper appropriate patient care.

Select Financial and Operating Characteristics of Physician Owned Hospitals and Non-Physician Owned Hospitals

Dobson | DaVanzo

Dobson | DaVanzo

Al Dobson, Ph.D.

Kennan Murray, M.P.H.

Randall Haught

Sung Kim

March 30, 2016

Fact Sheet

Dobson | DaVanzo recently examined select operating and financial characteristics of hospitals in categories defined by hospital ownership¹. This fact sheet provides descriptive statistics for physician owned hospitals (POH) and non-physician owned hospitals, as shown in Exhibit 1 and Figures 1 through 7. Exhibit 1 provides these statistics in tabular form, while Figures 1 through 7 present the data graphically.

In this fact sheet, POH are defined as hospitals on the Physician Hospitals of America member hospital list as of March 30, 2016. Non-POH are defined as acute care hospitals that fall under the inpatient hospital prospective payment system (IPPS) defined under Section 1886(d) of the Social Security Act. We identified 68 POH and

3,116 non-POH to be included in the table using the FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File and FY 2014 Medicare Cost Reports.

The data were drawn from the FY 2014 Medicare Cost Reports, FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File, and 2014 CMS 100% Standard Analytic File Limited Data Set (LDS) for inpatient and outpatient services. Specific data sources for each variable are provided in the Appendix.

The statistics included in Exhibit 1 and Figures 1 through 7 represent select hospital financial and operating characteristics. They illustrate the differences between POH and non-POH on multiple dimensions.

Exhibit 1: Summary Statistics for Physician Owned Hospitals (POH) and All Other Medicare IPPS Hospitals (Non-POH)² from the 2014 Medicare Cost Reports, 2014 CMS 100% Standard Analytic File Limited Data Set, and 2016 Hospital IPPS Final Rule and Correction Notice Public Use File

	POH	Non-POH
Number of Hospitals	68	3,116
Hospital Operating Characteristics		
Medicaid Discharges as a Percent of Total	2.2%	12.4%
Percentage of Hospitals in Hospital Group with Medicare Maximum Readmission Penalty of 3%	10.3%	0.9%
Percentage of Medicare Inpatient Claims with Emergency Department Services	21.1%	72.4%
Percentage of Medicare Inpatient Claims for Patients with Dual Eligibility	12.2%	27.6%
Mean Number of CC/MCCs ³ per Medicare Claim	1.3	2.4
Hospital Financial Characteristics		
Total All-Payer Margin (Average)	21.0%	8.0%
Uncompensated Care Costs as Percent of Total Hospital Expense	1.6%	3.9%

¹ This study was commissioned by the Federation of American Hospitals and the American Hospital Association.

² Physician owned hospitals were identified using the Physician Hospital of America member hospital list as of March 30, 2016. We note that four hospitals on this list were not included in the analysis because Medicare provider numbers could not be found. Non-physician owned hospitals were identified using the FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File and FY 2014 Medicare Cost Reports.

³ CC is defined as complicating or comorbid condition. MCC is defined as a major complicating or comorbid condition.

Charts

Figure 1. Medicaid Discharges as Percent of Total Discharges for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

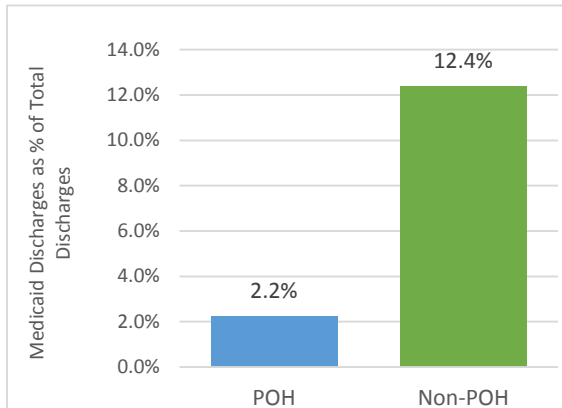


Figure 2. Percentage of Hospitals with Medicare Maximum Readmission Penalty of 3% for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

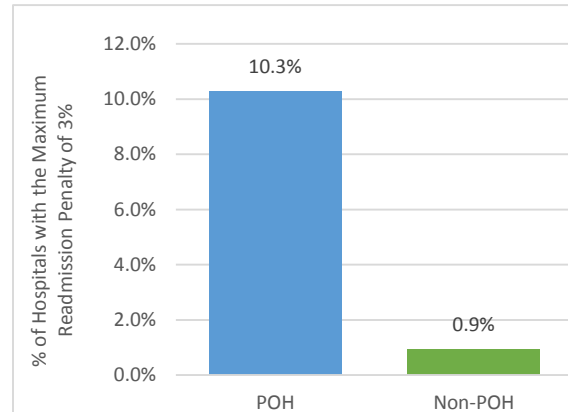


Figure 3. Percentage of Medicare Inpatient Claims with Emergency Department Services for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

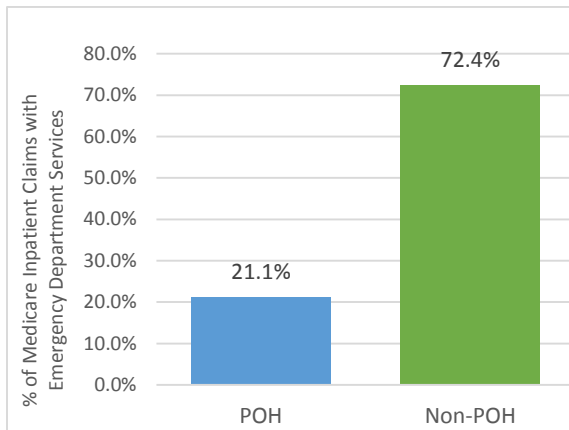
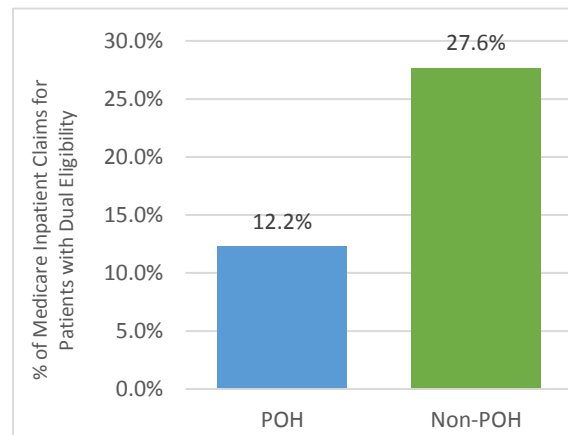


Figure 4. Percentage of Medicare Inpatient Claims for Patients with Dual Eligibility for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals



Note: Data were drawn from the FY 2014 Medicare Cost Reports, 2014 CMS 100% Standard Analytic File Limited Data Set for inpatient and outpatient services, and FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File. Physician owned hospitals were identified using the Physician Hospitals of America member hospital list as of March 30, 2016. Non-physician owned hospitals were identified using the FY2016 IPPS Final Rule and Correction Notice Impact Public Use File and FY2014 Medicare Cost Reports.

Charts

Figure 5. Mean Number of CC/MCCs per Medicare Claim for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

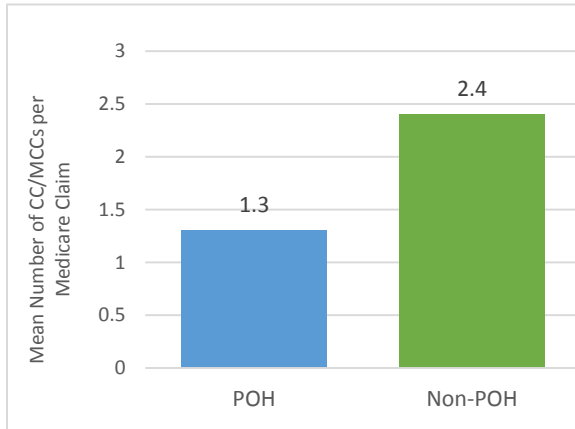


Figure 6. Average All-Payer Margin for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

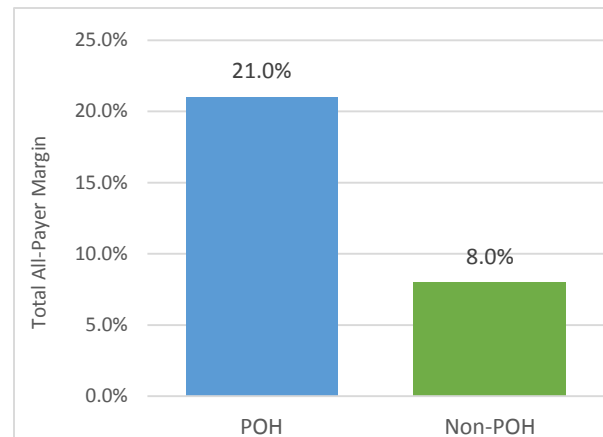
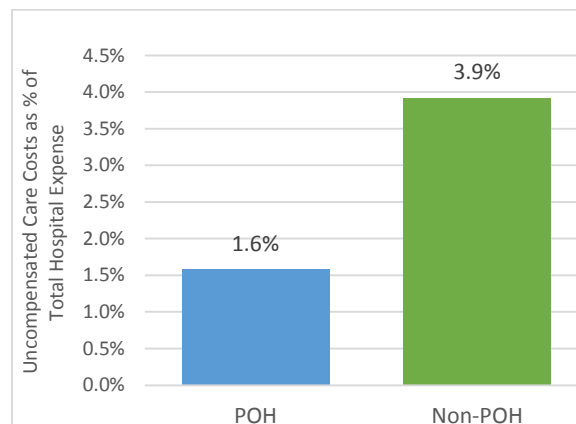


Figure 7. Uncompensated Care Costs⁴ as Percent of Total Hospital Expense for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals



Note: Data were drawn from the FY 2014 Medicare Cost Reports, 2014 CMS 100% Standard Analytic File Limited Data Set for inpatient and outpatient services, and FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File. Physician owned hospitals were identified using the Physician Hospitals of America member hospital list as of March 30, 2016. Non-physician owned hospitals were identified using the FY2016 IPPS Final Rule and Correction Notice Impact Public Use File and FY2014 Medicare Cost Reports.

⁴ Uncompensated care costs are defined as Line 30 from the S-10, which includes the cost of charity care plus the cost of non-Medicare and non-reimbursable Medicare bad debt expense.

Appendix

Appendix: Data Sources Used to Calculate Summary Statistics

Source: FY 2014 Medicare Cost Reports			
Data Point	Worksheet	Line	Column
Medicaid Discharges as a Percent of Total	S-3, part I	14	14
Total discharges	S-3, part I	14	15
Net patient revenue	G-3	3	1
Other revenue	G-3	25	1
Total revenue	Sum of Net patient and Other revenue		
Operating expense	G-3	4	1
Other expense	G-3	28	1
Total expense	Sum of Operating and Other expense		
Uncompensated care	S-10	30	1

Source: 2014 CMS 100% Standard Analytic File Limited Data Set		
Data Point	File	Variable(s)
Percentage of Medicare Inpatient Claims with Emergency Department Services	FY2014 Inpatient Claims File, FY2014 Inpatient Revenue File. ER claims were defined as having charges in revenue centers (0450-0459 or 0981).	REV_CNTR, REV_CNTR_TOT_CHRG_AMT
Mean Number of CC/MCCs per Medicare Claim	FY2014 Inpatient Claims File, FY2014 CC File, FY2014 MCC File	ICD_DGNS_CD1 - ICD_DGNS_CD25

Source: 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File	
Data Point	Variable(s)
Medicare readmission penalty	Readmission Adjustment Factor