Federation of American Hospitals®

Charles N. Kahn III
President and CEO

November 19, 2018

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

Re: CMS-3346-P; Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; 83 Fed. Reg. 47686 (Sep. 20, 2018)

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 hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction Proposed Rule* (Proposed Rule).

The FAH commends CMS' efforts to reduce regulatory burdens shouldered by providers and suppliers that participate in the Medicare and Medicaid programs, while at the same preserving quality and safety. The approach taken by CMS in the Proposed Rule would afford hospitals increased operational flexibility for satisfying regulatory obligations, enable efficiencies in multi-provider systems, and eliminate duplicative and unnecessarily onerous requirements. These types of reforms are always welcome, particularly when they enable hospitals to devote more resources to providing quality health care to patients. The FAH offers

its overall support for the provisions set forth in the Proposed Rule, while providing the recommendations detailed below.

OVERALL SUPPORT FOR THE PROPOSED RULE

In general, the FAH is pleased that CMS is proposing changes that would allow increased flexibility and eliminate or reduce unnecessary requirements governing ambulatory surgery centers (ASCs), hospitals, psychiatric hospitals, critical access hospitals (CAHs), portable x-ray services, and emergency preparedness obligations for providers and suppliers. The FAH strongly supports many of the key provisions, including:

- Removing the requirement that ASCs have a written transfer agreement with a hospital that meets certain requirements or ensuring that all physicians performing surgeries at the ASC have admitting privileges in a hospital that meets certain Medicare requirements.

- Adding new standards that would enable the legally-responsible governing body of a multi-hospital system to elect to have a unified and integrated Quality Assessment and Performance Improvement (QAPI) Program and a unified and integrated program for infection control, respectively, for all member hospitals.

- Removing the requirement that a hospital's medical staff attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest and instead deferring to applicable State law concerning the medical-legal obligations for when autopsies should be sought.

- Removing cross-references to certain long-term care requirements that are unnecessary and unduly burdensome for hospitals and CAHs that furnish swing-bed services.

- Allowing non-physician practitioners or MD/DOs to document progress notes (in accordance with State laws and scope of practice requirements) for patients receiving services in psychiatric hospitals.

- Removing the requirement that CAHs disclose to CMS its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a five (5) percent or more ownership interest, because the requirement is duplicative of what is already mandated by the provider agreement and enrollment rules.

- Allowing CAHs to conduct a biennial review of patient care policies and procedures, rather than requiring such a review be completed on an annual basis.

- Simplifying the training and education requirements for portable x-ray technologists to require them to have successfully completed: (i) appropriate and formal training in x-ray technology and demonstrated competence in the use of equipment and administration of portable x-ray procedures; OR (ii) 24 months of training and

experience under the direct supervision of a physician certified in radiology or who possesses other equivalent qualifications.

- Permitting orders for portable x-ray orders to be in writing, by phone, or by electronic means.

- Allowing facilities to review their emergency programs, and provide emergency preparedness training, every two years rather than every year.

- Eliminating the requirement that facilities document a process for collaboration with local, tribal, regional, state, and federal officials, but retaining the requirement that the collaboration occur.

- Improving flexibility for emergency preparedness testing exercise requirements for inpatient and outpatient facilities.

RECOMMENDATION CONCERNING HOSPITAL CONDITIONS OF PARTICIPATION (CoPs) AND ASC CONDITIONS FOR COVERAGE (CfC)

CMS is proposing to allow hospitals and ASCs to determine through patient care policies when practitioners must furnish a comprehensive history and physical (H&P). Specifically, CMS' proposals would:

- Replace the ASC CfC requirement that every patient to have a comprehensive H&P within 30 days prior to surgery in an ASC with a requirement that allows the operating physician and ASC to determine which patients would require the more extensive testing and assessment prior to surgery; and

- Add a provision to the hospital medical staff, medical records services and surgical services CoPs allowing the medical staff the option to develop and maintain a policy that identifies specific patients that may have a simplified assessment in place of a comprehensive H&P (or any update to such assessment) prior to specific outpatient surgical or procedural services.

The FAH generally believes that affording providers greater flexibility in meeting CfCs and COPs is a better approach to regulatory oversight so long as the Joint Commission standards can be satisfied, and patient safety and quality can be maintained. While the proposals outlined above could result in additional flexibility, it is important to note that a consequence of the changes could be variation and potential misalignment across facilities of the standards used to determine when a comprehensive H&P will be required. This could create confusion and patient safety concerns in the event that physicians and practitioners have privileges at facilities that adopt varying standards. If CMS finalizes these proposals, the FAH recommends that CMS monitor the degree to which patient assessment standards vary across facilities and, if so, whether those variations have an impact on patient safety.

RESPONSE TO REQUEST FOR ADDITIONAL BURDEN REDUCTION PROPOSALS

The FAH appreciates CMS' ongoing solicitation for comments on additional regulatory reforms that would further reduce burdens on hospitals and create cost savings, while at the same time preserving quality of care and patient health and safety. As we have detailed in prior submissions to the agency, many opportunities exist to repeal or revise regulations that are outdated, ineffective, or otherwise overly burdensome without impacting the quality and safety of care that our members provide. For example:

- CMS should eliminate duplicative documentation requirements for physicians under the CoPs when the information is already present in the medical record. This would align with the CY19 Physician Fee Schedule Final Rule in which CMS eliminated duplicative notation requirements for teaching physicians related to evaluation and management (E/M) visits when that information has already been put into the medical record by another physician, resident, or nurse.

- CMS should work with providers and clinicians to re-evaluate the plan of care requirements to determine their current utility and whether modifying and streamlining the documentation requirements would increase their usage among clinicians as a care tool rather than simply meeting a documentation requirement. Requiring nurses (and in some cases, multiple clinicians) to document every issue/condition the patient has – even if those conditions are not relevant to the patient encounter and/or are found elsewhere in the medical record – is time consuming and/or duplicative.

Additionally, the FAH resubmits the attached recommendations for administrative actions that would result in regulatory relief for hospitals (Attachment A).[1] We note and appreciate that some of these recommendations have been achieved since our initial submission.

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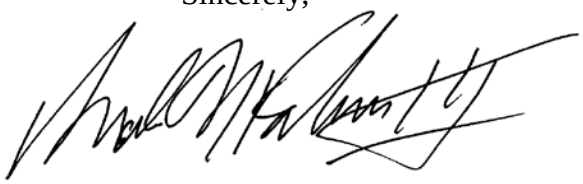
The FAH appreciates your consideration of our comments and recommendations on the continuing efforts CMS is undertaking to reduce the regulatory burdens faced by providers and suppliers. We remain ready to work with CMS on this important initiative. Should you have any questions, please contact me or my staff at (202) 624-1500.

Sincerely,



[1] See attached letter to Administrator Verma dated November 7, 2017. The FAH also made recommendations in comments submitted to CMS in response to the agency's proposed FY and CY 2018 Proposed Rules.

Attachment A

Charles N. Kahn III
President & CEO

November 7, 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

Dear Administrator Verma:

The Federation of American Hospitals (FAH) appreciates your commitment to undertake regulatory reform and reduce the regulatory burden on health care providers, as evidenced by your recently launched "Patients Over Paperwork" initiative. 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. As CMS evaluates new and existing regulations, the FAH recommends examining the policies through the lens of benefit to beneficiaries balanced against the time, effort, and resources required by providers to determine whether the policies will result in meaningful improvements in quality, efficiency, or beneficiary experience.

The attached document recommends actions the Centers for Medicare & Medicaid Services (CMS), as well as other agencies within 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. The FAH submitted these comprehensive recommendations to the HHS Secretary in May and responded to the Requests for Information in the 2018 CMS payment rules.

Among those recommendations, for example, HHS should ensure that the Center for Medicare & Medicaid Innovation (CMMI) acts only within its designated authority to voluntarily *test* innovative payment and care delivery models, not make permanent or mandatory changes to the Medicare program. The FAH does not believe that section 1115A authorizes the CMS to mandate provider participation in CMMI models, such as the Episode Payment Model (EPM) or the Comprehensive Care for Joint Replacement (CJR) models. The law 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 also 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. This is a view shared by many stakeholders, and we appreciate CMS's acknowledging this in the recent EPM-related proposed rule.

Given the statutory limitation on CMMI making mandatory changes to the Medicare program, the FAH supports CMS's proposal to cancel the EPM. The CJR model, however, remains mandatory under current CMS regulations. The FAH urges CMS to comply with the statute and fully eliminate the mandatory nature of this model while ensuring that it – and any other future CMMI models – is solely voluntary. 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 BPCI 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 and is the proper and appropriate use of legislatively granted demonstration authority.

Thus, the FAH applauds the commitment CMS made in January 2017 and August 2017 to build on the BPCI model to design a new voluntary bundled payment model that would meet the criteria to be an Advanced Alternative Payment Model (APM) and encourages CMS to implement this new voluntary bundled payment model as soon as possible. As we approach CY2018, this new model is not yet available to clinicians, and CMS has not released a timeline for its development. It is important that CMS act soon on its intention, as there are more than 1200 participants in Phase 2 of BPCI awaiting guidance from CMS on the new framework. BPCI participants and prospective participants will require substantial lead time to do the advance work required prior to participate in any new CMS model. Providing prospective participants with information now will likely lead to greater success of the model in the future.

Another recommended action includes indefinitely suspending the troubled Hospital Star Ratings. The FAH appreciates that CMS did not publish updated Ratings in October and acknowledged stakeholder concerns regarding the accuracy of the measure. The FAH urges CMS to suspend the system for as long as needed while the Agency collaborates with stakeholders and quality experts to ensure that any future system includes appropriate risk adjustment and accurately distinguishes among providers. The currently flawed Ratings system

does not provide accurate information on which beneficiaries, their families, and their providers can rely to make decisions about their care.

Also, as of January 1, 2017, non-grandfathered off-campus provider-based departments are no longer reimbursed under the Outpatient Prospective Payment System (OPPS) under section 603 of the *Bipartisan Budget Act of* 2015. In implementing this provision, the FAH recommends that CMS provide hospitals with broad flexibility to relocate their provider-based departments to meet community needs and still 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. 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 able 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.

Thank you again for your attention to these critically important policies. Please see the attached document for additional details on these and other recommended actions. We appreciated the opportunity to participate in the October 26th provider listening session and look forward to working with you as you continue these efforts. The FAH representatives listed below would be happy to meet with you and your staff to discuss any of the recommendations.

FAH Representatives:

Katie Tenoever (KTenoever@FAH.org)
Steve Speil (SSpeil@FAH.org)
Erin Richardson (ERichardson@FAH.org)
Paul Kidwell (PKidwell@FAH.org)

Sincerely,

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.

- **<u>Recalibrate Bundling Programs</u> – *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.

- **<u>Implement Prospective Beneficiary Assignment to Medicare ACOs</u>** – ***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.

- **<u>Increase Flexibility in Developing Preferred Provider Networks for APMs</u> – *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.

- **<u>Create Single Bundled Payment Program Stark and Medicare Anti-Kickback Waiver</u> – *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 eCQMs** – ***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.

- **<u>Clarify Flexible Timing of a Physician's Admission Order</u> – *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

- **<u>Retain Flexibility for Private Sector Accreditation Standards</u>** – ***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.

- **<u>Promptly Issue Flexible Guidance for Hospital Co-Location Arrangements</u> – *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

- **<u>Increase Transparency in the LCD Process</u> – *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.