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Mr. Eric D. Hargan  
Acting Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20001

***Re: Request for Information – Promoting Healthcare Choice and Competition Across the United States***

Dear Acting Secretary Hargan:

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 parts of the United States, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. We share the commitment of the President and the Department of Health and Human Services (HHS) to advancing competition and choice in the health care market. To that end, we appreciate the opportunity to respond to the Department's *Promoting Healthcare Choice and Competition Across the United States* Request for Information (RFI).

**Commitment to Competition and Choice**

The FAH is committed to a health care marketplace that offers patients the choice of qualified and able providers seeking to provide high quality patient care. FAH hospitals are vital to the communities they serve and invest heavily in offering the types of health services required by their patients. Whether it's maintaining access to the emergency department, investing in important lines of service like cardiac and cancer care, opening new urgent care access points, and serving as economic and jobs engines in their communities, local hospitals are engaged in providing value to both their patients and the broader communities they serve.

A critical part of offering value includes finding opportunities that improve efficiency and increase quality. To that end, many hospitals may explore various arrangements such as professional affiliations, mergers and acquisitions, and partnerships with other health care entities that allow them to reduce administrative cost and burden while focusing on improvements to clinical quality, access to care, and population health. A recent study by Charles River Associates, for example, found that hospital mergers can lead to important savings while providing opportunities for hospitals to invest in innovations and enhancements that improve quality.<sup>1</sup> In some instances, mergers allow for the expansion of service lines responsive to the needs of patients while in others, the preservation of services is the key goal. In both cases, patient choice is advanced and protected. Such mergers generally secure a stronger, more stable hospital and hospital system that spreads shared administrative risk across a broader array of providers while advancing the improvement of quality both through resource investment and shared experience.

We appreciate that the Department, through the RFI, has chosen to take an expansive look at all the factors that both encourage and discourage choice and competition in the health care market. In our view, and as the Department has noted, state and federal laws, regulations, guidance, requirements and policies are often at the core of what limits the full potential for patients and communities of a competitive marketplace – the guiding principle of FAH member hospitals.

#### Insufficient Hospital Payment Threatens Choice and Erodes Competition

An ongoing and increasing barrier to market entrance is the growing problem of inadequate Medicare and Medicaid reimbursement rates, specifically to the growing gap between payment and the cost of care. According to recent data prepared by the staff of the Medicare Payment Advisory Commission (MedPAC), hospital Medicare margins are in a downward spiral, expected to sink to -11 percent in 2018.<sup>2</sup> The impact of this negative margin is compounded by enrollment growth in the program, and the aging of those already enrolled. According to the most recent National Health Expenditures report, Medicare enrollment is expected to grow between 2.5 – 3.0 percent annually through 2025. As hospitals care for a greater number of aging Medicare beneficiaries, the economic pressure of negative margins will only grow, especially as permanent annual cuts to the hospital inflation update embedded in the Affordable Care Act (ACA) continue to take their toll at the same time that coverage expansion, which the cuts were intended to finance, falls further below the original estimates, accelerated, according to the Congressional Budget Office (CBO), by the repeal of the individual mandate. A report issued by the health economics consulting firm Dobson | DaVanzo in December 2016 found that from 2018-2026, hospitals will lose \$289.5 billion in inflation updates if the ACA cuts are not restored.<sup>3</sup> Cuts of that magnitude will constrain choice and competition.

Medicaid underpayments compound the financial impact of negative Medicare margins. While Medicaid payments vary greatly by state, research conducted by the Medicaid and CHIP Payment and Access Commission (MACPAC) shows that, in general, Medicaid base payment falls below Medicare

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<sup>1</sup> Charles River Associates, *Hospital Merger Benefits: Views from Hospital Leaders and Econometric Analysis*, January 2017.

<sup>2</sup> Medicare Payment Advisory Commission, *Assessing payment adequacy and updating payments: Hospital inpatient and outpatient services*, January 11, 2018.

<sup>3</sup> Dobson|DaVanzo, *Estimating the Impact of Repealing the Affordable Care Act on Hospitals*, December 6, 2016.

payment when compared against the same MS-DRG.<sup>4</sup> Hospital-financed supplemental payments assist in improving reimbursement rates, but are not universal or evenly distributed among hospitals. In addition, they are subject to multiple layers of review and approval by federal – most notably the Centers for Medicare & Medicaid Services (CMS) – state, and local authorities, making them an uncertain source of reimbursement. As with Medicare, growing Medicaid rolls aggravate the payment shortfall attributable to public financing, which is a growing share of overall hospital revenue, and now almost 50 percent on average.

The significant fiscal pressure these reimbursement rates have on providers has broad impacts on the system and is a root cause of why CBO recently concluded that as many as 60 percent of hospitals could experience negative overall margins in 2025.<sup>5</sup> Recent, rapidly-rising drug costs further pressure providers and threaten patient access to drug therapies. A study conducted by NORC at the University of Chicago found that inpatient drug spending increased on a per admission basis by 38.7 percent between fiscal year 2013 and fiscal year 2015 and that a number of drugs used in the hospital setting experienced unit price increases of more than 100 percent during the same time period.<sup>6</sup> The Campaign for Sustainable Rx Pricing has released a number of proposals that will bring additional transparency, competition and value to the market place, and we urge HHS to take action along those lines.<sup>7</sup>

Hospitals respond in a variety of ways to payment shortfalls. One is to reduce costs wherever possible, and in fact, MedPAC has reported sustained low case-mix adjusted annual cost growth. More broadly, however, the challenge of preserving services and hospital operations on fixed, below-cost public payer rates requires that hospitals pursue additional strategies. This includes negotiating competitive rates in the marketplace from private payers. While this helps compensate for inadequate Medicare and Medicaid rates, it is unclear whether and how long private payers will continue to sustain this silent subsidy. In addition, mergers with other hospitals and providers enable clinical and financial integration, as well as economies of scale that can help hospitals cope with lower payments, compete with other providers, and offer patients more choice in the care they seek.

Taken together, these and other necessary actions help preserve and enhance patient choice, and policymakers should refrain from taking actions that would limit the ability of hospitals to transform the delivery of care through mergers and other forms of collaboration. Moreover, to increase choice and competition, policymakers should address the public financing payment shortfall and close the gap. This is arguably the biggest roadblock to market entry, undermining competition and limiting choice.

### Medicaid Expansion and Preserving Provider Choice

Medicaid coverage expansion clearly benefits uninsured Americans through newly gained health insurance and the access to health care that insurance offers. Now there is growing evidence that hospitals in expansion states are generally in better financial condition than those in non-expansion

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<sup>4</sup> Medicaid and CHIP Payment and Access Commission, *Medicaid Hospital Payment: A Comparison across States and to Medicare*, April 2017.

<sup>5</sup> Congressional Budget Office, *Projecting Hospitals' Profit Margins Under Several Illustrative Scenarios*, September 2016.

<sup>6</sup> NORC, *Trends in Hospital Inpatient Drug Costs: Issues and Challenges*, October 2016.

<sup>7</sup> Campaign for Sustainable Rx Pricing, *Proposals for Change*.

states resulting in fewer hospital closures in expansion states and a preservation of services for not only Medicaid beneficiaries but also the community writ large.

This is the finding of a recent study published in Health Affairs, which concluded that the ACA's Medicaid expansion was associated with improved hospital financial strength and a substantially lower likelihood of closure.<sup>8</sup> Hospitals in expansion states were 84 percent less likely to close than facilities in non-expansion states. The benefit of expansion was especially evident in rural areas as the study found that rural hospital performance in Medicaid expansion states, as compared to their suburban and urban peers, was most positively impacted. The study finds that a reversion to pre-ACA eligibility levels would lead to a disproportionately large number of rural hospital closures.

In short, Medicaid expansion promotes patient choice and access to hospital services in many communities. To that end, policymakers should make every effort to encourage states that have not yet taken up expansion to do so, and for those that have, to retain it.

#### Network Adequacy and Consumer Information Supports Market Choice

CMS can promote choice for consumers in Medicare, Medicaid, and private insurance and competition among health plans by ensuring consumers have access to the providers and services to which they are entitled under their respective form of coverage. The FAH has long supported a three-part approach to ensuring network adequacy: 1) a federal floor of network adequacy requirements; 2) appropriate auditing to ensure such requirements are being met; and 3) timely, accurate information for consumers regarding health plan provider networks.

As discussed in our comment letter responding to the Proposed Notice of Benefit and Payment Parameters for 2019, we urge CMS to adopt the Medicare Advantage network adequacy standards as the federal floor, adapting them as necessary to meet the needs of other consumers, such as those participating in the Exchanges. In addition to the time and distance, these standards would include requirements relating to the minimum number of providers that must be included in a network.

Using the Medicare Advantage standards is the first step towards developing robust provider networks for consumers across the country. The second step is ensuring consumers are always able to access the identified network of providers after they have enrolled. Unfortunately, this is not always the case, even in the Medicare Advantage program. Our members have witnessed firsthand during the last several years the confusion that occurs when consumers are navigating provider networks and the challenges they can face when their access to care is restricted.

One such example of restricted consumer choice is when a Medicare Advantage Organization (MAO) uses downstream organizations to provide administrative and health care services to beneficiaries. These "networks within a network" are often far narrower than the provider network depicted in the provider directory or the Health Service Delivery (HSD) tables on which CMS based its approval of an MAO. This is unfair to enrollees who may have selected a particular MAO plan on the basis of its provider network, but then are discouraged from accessing particular providers. And this is especially problematic when a hospital is identified as in-network in the provider directory, but the physicians affiliated with the hospital, while in the main network, are not a part of the physician or

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<sup>8</sup> Health Affairs, *Understanding the Relationship Between Medicaid Expansions and Hospital Closures*, January 2018.

provider group to which the downstream organization directs enrollees. Another example is when post-acute providers are listed in the provider directory but are not actually available to receive patients who are discharged from the hospital. This results in patients staying longer than medically necessary in the hospital because there are no medically-appropriate post-acute care settings available.

To address these concerns and protect beneficiaries' choice of providers and access to care, CMS should audit MAOs' networks to ensure enrollees are able to access their providers and services, as well as adopt requirements that provider directories accurately depict the true scope of the provider network. In the post-acute care space, CMS should require MAOs to demonstrate meaningful access to providers and audits of plans' timely approvals of discharges to appropriate post-acute care settings. Additionally, CMS should ensure that IRF coverage is equally available to MOA enrollees as to Medicare fee-for-service beneficiaries and for MAOs to report denial rates by provider type. Once CMS implements the Medicare Advantage-based federal floor, it should undertake these audits for other health plans under its purview.

Finally, in order to appropriately utilize their networks, consumers must have accurate lists of the providers available to them both at the time they choose a plan and when they need to choose a provider. This includes adequate notification of any material changes to plans' network of providers during the plan year and appropriate updates to plans' provider directories. This information promotes consumer choice by ensuring they have the information necessary to choose the most appropriate plan for their health care needs.

### Efforts to Stabilize the Individual Insurance Market Critical to Choice and Access

The ability to shop for and purchase coverage through the marketplace continues to be an important option for millions of Americans. It is imperative that the marketplace, in which they purchase coverage, is well-functioning and stable with options that provide necessary services at an affordable price. Improvements to the consumer experience, including enhanced affordability, start with the stability of the marketplace. We believe there are a number of actions the Administration, working with Congress, can take that will make important improvements to the marketplace:

- Fund the cost-sharing reductions;
- Engage in and fund robust outreach and enrollment efforts;
- Ensure access to robust health benefits by preserving essential health benefits;
- Limit use of plans that do not meet ACA coverage standards and consumer protections

### Regulatory Burden Inhibits Choice, Competition, and Innovation

HHS can also increase choice and competition by reducing the regulatory burden on health care providers. As noted in a recent study, regulatory requirements result in a total of \$39 billion in annual costs for hospitals, health systems, and post-acute care providers – costs that are felt by the entire health care system. The study also notes that hospitals alone must comply with 341 mandatory regulatory requirements, while post-acute care providers must comply with an additional 288

requirements. In addition to money, providers expend considerable staff resources complying with these requirements, leaving less time for patient care and innovation.<sup>9</sup>

There are numerous steps the Department can take to alleviate this burden and enable providers to refocus their attention and reallocate their resources toward high-quality patient care. The FAH supports the efforts already undertaken by CMS through the “Patients Over Paperwork” initiative and encourages HHS to undertake such efforts across the Department. 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 the Department 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.

Detailed below are actions CMS and other agencies within the Department could take to implement regulatory reform across a variety of areas, such as alternative payment models (APMs) and hospital and post-acute payment policies. A more comprehensive set of recommendations to address regulatory burden is attached to this document, which we urge the Administration to review. These recommendations were also submitted to the HHS Secretary in May 2017 and responded to the Requests for Information in the 2018 CMS payment rules.

### *Delivery System Reform*

#### Voluntary Only Models from the Center for Medicare & Medicaid Innovation

The Center for Medicare & Medicaid Innovation (CMMI) is a powerful tool to promote health care choice, competition, quality, and efficiency. But this tool is most-effective – and in compliance with the statute – when the models and demonstrations are voluntary for health care providers. The FAH urges HHS to ensure that 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 CMS to mandate provider participation in CMMI models, such as the Comprehensive Care for Joint Replacement (CJR) model. 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 view in last year’s EPM-related rulemaking.

Given the statutory limitation on CMMI making mandatory changes to the Medicare program, the FAH strongly supported CMS’s cancellation of the EPM. The CJR model, however, remains mandatory under current CMS regulations. The FAH continues to urge CMS to comply with the statute and fully eliminate the mandatory nature of this model while ensuring that it – and any other

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<sup>9</sup> American Hospital Association, *Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals, and Post-Acute Care Providers*, October 2017.

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 Bundled Payments for Care Improvement (BPCI) Initiative shows a substantial number and range of providers and suppliers willing to participate in carefully crafted models. Encouraging voluntary participation by providers and suppliers appropriately recognizes the market-specific dynamics in a geographic area. It was the intent of Congress in enacting section 1115A and is the proper and appropriate use of legislatively-granted demonstration authority.

#### Preferred Provider Networks in Bundling Programs/Alternative Payment Models

In recent years, the value of preferred provider networks has emerged as a critical factor in facilitating care coordination and optimization of care in bundling arrangements/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. To address these concerns, the FAH urges CMS to use its authority to waive statutory and regulatory requirements for bundling arrangements/APMs, or adopt a more flexible interpretation of current law, that would permit hospitals to offer beneficiaries a “preferred provider list.” At a minimum, hospitals should be permitted to exclude from the list certain post-acute providers with objectively poor quality scores. Such action would still provide beneficiaries with choice among their post-acute care providers while promoting competition among those providers to promote better care and patient experience.

#### Single Bundled Payment Program Stark and Medicare Anti-Kickback Waiver

Outdated laws and regulations, such as the Stark physician self-referral law (Stark Law) and Medicare anti-kickback statute (AKS), undermine hospital efforts to achieve successful coordinated care arrangements and participate in new APMs. Gainsharing is a critical component of APMs, such as the CJR model, 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 and other similar financial arrangements between providers.

To address these concerns and facilitate participation in and competition among APMs, 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 Law and Medicare AKS, applicable to all gainsharing and other similar 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 these arrangements under CMS-led bundled payment programs.

## Guidance for Hospital Co-Location Arrangements

The FAH urges CMS to 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 post-acute care 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.

## IRF Risk in Bundling Programs and Rescinding the 60 Percent and Three-Hour Rules

The FAH urges CMS to allow Inpatient Rehabilitation Facilities (IRFs) to carry more risk in bundling programs, while rescinding the 60 percent and three-hour rules. Bundled payment programs should encourage high quality patient outcomes through incentivizing more collaborative and coordinated decision-making around the efficient utilization of care and services, including post-acute care services. Optimal efficiencies for post-acute care utilization requires involvement of post-acute care providers in bundling arrangements. For example, IRFs could test a CMMI bundling program that would not be derived from the IRF 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. 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 three-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. Alternatively, at a minimum, IRFs should have the flexibility to provide three hours of therapy through multiple modes, including group and concurrent therapies, without the risk of Medicare contractors denying the claim for an insufficient amount of “one-on-one” therapy.



## HIPAA Regulation Barriers to Sharing Patient Information

The Department 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.

### *Site Neutral Payments*

The past few years have seen a proliferation of site neutral payment rates in the Medicare program that can have deleterious consequences for patient access to care if providers can no longer afford to offer services in a geographic area. Implementation of these policies has ignored the standing costs hospitals must incur, particularly in certain geographies; been implemented with no research into the impacts on provider viability and patient access; and exacerbates the impact of negative hospital Medicare margins that are expected to sink to -11 percent in 2018, as noted above. While proffered as improving efficiencies, more often than not, site neutral policies simply become yet another payment reduction with which providers must grapple. The FAH’s recommendations regarding two of these policies are provided below.

## Relocation Flexibility for Off-Campus Provider-Based Departments

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*. To promote choice and competition among providers, the FAH recommends that CMS provide grandfathered hospitals with broad flexibility to relocate their provider-based departments to meet community needs and still retain hospital outpatient payments. Such flexibility recognizes that relocations may be necessary and appropriate in numerous situations that do not involve the acquisition of physician practices (which were the primary targets for lower payments under Section 603). At minimum, several 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 (exempted from lower payments under Section 603) that relocates would forfeit its ability to be paid as a hospital outpatient department.

### LTCH Site Neutral Payment Rate

The *Pathway for SGR Reform Act*, signed into law in December 2013, established patient and facility criteria governing payment for patients admitted to a long-term care hospital (LTCH). Beginning with cost reporting periods on or after October 1, 2015, payment for patients who do not qualify under the LTCH PPS are based on a “site neutral” rate, which is the lower of either the comparable inpatient PPS per diem rate, including outlier payments, or service costs. The site neutral payment rate is phased in so that, for cost reports beginning in FYs 2016 and 2017, cases are paid a blended rate of 50 percent of the comparable IPPS payment and 50 percent of the payment rate that would otherwise be in effect under the LTCH PPS. For FY 2018 and later, the blended payment rate ends, and payment is based fully on the site neutral payment rate. The FAH believes that the site neutral rate is inadequate in light of data indicating the medical complexity and higher acuity as well as the longer length of stays of these patients treated in an LTCH compared to similar patients cared for in a short-stay hospital. As a result, access to LTCH care for these medically complex patients could be compromised. To address these concerns, the FAH continues to urge CMS to revert to the blended payment rate rather than continue to implement the site neutral payment rate.

### *LTCH 25 Percent Rule*

The LTCH 25 Percent Rule serves, in effect, as a barrier to LTCH care and limits a patient’s choice of an appropriate post-acute care setting. It should never have been imposed, and the FAH appreciates and strongly supports CMS’s implementation of a regulatory moratorium on the 25 percent rule through FY 2018. However, the FAH urges CMS to go further and completely retire the 25 Percent Rule as it is no longer necessary in light of the new two-tiered payment system. The new 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 25 Percent Rule is obsolete.

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.

### *Accurate and Meaningful Provider Quality Information*

The FAH has a history of supporting public reporting in payment programs and recommending that the information reported to the public be accurate, meaningful 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 – to patients, their families, and the providers themselves. Our experience is that this has not always been the case. The current star ratings system on *Hospital Compare* does not include appropriate risk adjustment and does not accurately distinguish among providers. Additionally, the star ratings are overly simplified and thus

not able to assist patients in factoring into their choices issues such as proximity to home, post-acute services, transportation, and specific providers who have privileges at the facility. The current practice of consolidating multiple measures into a single star rating on *Hospital Compare* does a disservice to patients, their families, and providers by not providing accurate information on which to make decisions.

The FAH urges CMS to suspend indefinitely the star ratings system and work with the industry and quality experts to ensure that any future star rating system achieves our shared goal of providing accurate and actionable quality information.

### *Parity for Telehealth Services*

The FAH urges CMS to 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. Further, CMS currently engages in an outdated process for determining which services provided via telehealth are eligible for Medicare reimbursement, which has resulted in Medicare beneficiaries not having access to appropriate telehealth services. The FAH appreciates CMS's recent acknowledgement of these concerns. During an Open Door Forum earlier this month, Administrator Verma noted that telehealth can improve access to and choice of care in rural and urban communities and that the agency is closely examining its policies in this area. We encourage CMS to not only review its own policies but to also support efforts for providers to participate in multi-state telemedicine programs.

### Rural Hospitals and Access to Care

Rural hospitals, often the only choice of comprehensive care in their communities, face persistent and growing challenges to continue providing access to health services. Their locations create unique challenges, such as limited workforce options, physician shortages, an older, poorer patient mix and razor tight budgets. In many cases, as identified by researchers at the University of North Carolina's (UNC) North Carolina Rural Health Research and Policy Analysis Center, rural hospitals have found it impossible to remain open, and since 2010 eighty have closed.<sup>10</sup> The UNC research shows that patients in the impacted areas must travel between five and 30 miles (in some cases even more) to access inpatient care. Unfortunately, without action to improve the financial health of many rural hospitals, it is likely that additional closures will occur threatening access to hospital services for an even greater number of patients.

As previously stated, hospitals are feeling the negative impacts of unsustainably low Medicare and Medicaid reimbursement rates. Treating a high proportion of Medicare and Medicaid patients relative to overall patient volume, the research shows, is a leading factor in why rural hospitals have been forced to close. Additionally, caring for a large volume of uninsured patients is also a major factor in rural hospital closure – a symptom that could be treated in a number of states through the expansion of the Medicaid program. It is not surprising that the UNC research corroborates the findings of the research recently published in *Health Affairs* that most rural hospital closures occur in non-expansion states.

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<sup>10</sup> NC Rural Health Research Program, *Financial Distress and Closure of Rural Hospitals*, September 21, 2017.

While rural hospitals consider new models of care and delivery as a means for continuing to provide their patients with access to services, there are steps the federal government can take, in addition to those mentioned previously in this letter, to assist the financial health of these hospitals.

The Medicare Dependent Hospital (MDH) and the Low Volume Hospital (LVH) programs are vital to the health of rural hospitals. MDHs are hospitals that meet specific criteria that care for a larger portion of Medicare recipients (more than 60 percent) than their urban counterparts. Because the rural Medicare patient populations in these areas are older, suffer from higher rates of chronic illness, and have lower incomes, these rural hospitals struggle to stay financially stable under the Medicare fee schedule. In 1987, Congress recognized these challenges by providing MDH-designated hospitals payments that take into account their historical costs of providing care. The LVH program recognizes that certain hospitals are more isolated and simply do not have the patient volume for economies of scales. The sliding-scale payment adjustment created by the LVH program helps compensate for such a competitive disadvantage.

Both programs expired at the end of September and Congress has yet to extend them. They should be made permanent, and it is imperative that they be extended in their current form for at least five years. Continued delay is untenable as rural hospitals are now being forced to consider a reduction in services and staff and in worst case scenarios, may have to consider closure. Strong support by the Administration for the continuation of these two programs as they are currently authorized would be a significant step towards preserving patient access to services in rural communities.

#### Provider Shortages Threaten Choice

The shortage of physicians, nurses and other health care professionals is a well-documented issue confronting our delivery system. The need for a highly trained professional work force grows as both the technology used to deliver services continues to evolve while the services themselves are at a greater demand by an aging population. Critical to competition and choice in the health care marketplace is the availability of a work force that is able to deliver services in all settings. Unfortunately, current law and regulation have created barriers to this goal.

For example, 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 hospitals, which not infrequently are the sole source of care in rural communities, are ineligible for either program, even though those facilities 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 and choice of care. They also discriminate against health care clinicians at investor-owned health care facilities that provide the same critical services to patients in those areas as

those services provided by clinicians at non-profit organizations. The net result weakens competition and, ultimately, patient choice. The FAH urges the Administration to eliminate barriers to, and propose funding for, loan repayment parity for the health care workforce.

### Physician-Owned Hospitals: Conflict of Interest is Anti-Competitive

Almost eight years ago, after a decade of studies and congressional hearings showing the adverse impact of self-referral to physician-owned hospitals, 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. 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 behavior runs counter to a healthy, competitive marketplace, and the unlevel playing field ultimately erodes both competition and patient choice for the broader community full-service hospitals care for 24/7.

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 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.”

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.

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We appreciate the opportunity to provide you with these comments. Should you have further questions, please do not hesitate to reach out to me or my staff at (202) 624-1500.

Sincerely,



Enclosure

cc: Mr. John Graham, Acting Assistant Secretary for Planning and Evaluation  
The Honorable Seema Verma, Administrator, Centers for Medicare & Medicaid Services



**Enclosure**

**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 flourish extending to the right.

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.