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President and CEO

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

Dear Administrator Verma,

The Federation of American Hospitals (FAH) appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on the Innovation Center New Direction Request for Information (RFI). 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 members are diverse, including 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.

As CMS considers the Center for Medicare and Medicaid Innovation's (CMMI) next direction, the patient must be at the center of that evaluation. Improving quality, retaining and improving access, and addressing cost for patients should be at the core of any innovation strategy CMS seeks to implement. Evidenced by the RFI, we know that CMS shares this vision.

CMS has laid out several important principles in the RFI that the FAH strongly supports, and we appreciate the opportunity to provide comments on those and other issues in greater detail below. Among the issues we discuss below, we would like to emphasize a few key priorities. The FAH has long held that CMS only has the authority to test models on a voluntary basis. As such, we appreciate CMS's emphasis and focus on testing voluntary models. We believe CMS should go further and commit to only test models on a voluntary basis. We also appreciate CMS's emphasis on pursuing models on a small-scale. The past use of Innovation Center authority has been overly broad in its reach and rather than testing a new payment design or delivery concept, it effectively imposed new Medicare payment policy throughout most of the

country, and without Congressional consideration. We appreciate that CMS is reconsidering this approach and scaling models appropriately. While not addressed in the RFI, as discussed further below, CMS does not have the authority to implement permanent or mandatory changes to Medicare stemming from results of a CMMI model without Congressional approval.

Guiding Principles

1. Voluntary Models

The FAH strongly believes that all CMMI models should only be implemented on a voluntary basis as the **statute does not authorize CMS to mandate provider participation in any CMMI models**. This is a view shared by many stakeholders, and we appreciate CMS acknowledging such in the recent Proposed Rule to cancel the Episode Payment Model (EPM) and scale back the Comprehensive Care for Joint Replacement (CJR) model. As we discussed in our comments to that Proposed Rule, the FAH supports CMS's proposal to cancel the EPM, but we continue to have strong concerns about the mandatory nature of the CJR, or any other similar model.

The FAH has repeatedly expressed significant legal and policy concerns over any proposal to implement a CMMI model under which provider and supplier participation would be mandatory. We believe that CMS has incorrectly interpreted that it may require mandatory participation of providers in a CMMI demonstration, as first evidenced by the CJR demonstration as well as the EPM demonstration. The FAH disagrees that §1115A of the Social Security Act (SSA) provides CMS with the authority to mandate provider and supplier participation in CMMI models. Such mandatory provider and supplier participation runs counter to both the letter and spirit of the law that established the CMMI and the scope of its authority to test models under section 1115A and make recommendations to Congress for permanent or mandatory changes to the Medicare program.

The purpose of the CMMI is to test innovative payment and service delivery models to maintain or reduce program expenditures while preserving or enhancing quality of care, with an emphasis on models that improve coordination, quality, and efficiency of health care furnished to Medicare and Medicaid beneficiaries (§1115A(a)(1) of the SSA). The statute directs the Secretary to select "from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures" (§1115A(b)(1)(A) of the SSA). The law further directs CMS to evaluate each Phase I CMMI model, and only after taking into account this evaluation, if appropriate, the model may continue to be tested in Phase II to expand "the scope and duration," provided certain requirements are met (§1115A(c) of the SSA), including a requirement for a separate notice and comment rulemaking for any expansion. CMS is required to report periodically to Congress on CMMI models and make proposals for legislative action on models it deems appropriate (§1115A(g) of the SSA).

The language, structure, and requirements of section 1115A of the SSA clearly indicate that Congress did not delegate its lawmaking authority to CMS. Under section

1115A, any permanent or mandatory changes to Medicare payment systems must be enacted by Congress after taking into account results of models that have been tested. Congress is the branch of the Federal government responsible for enacting changes to Medicare payment systems through legislation; CMS is granted limited authority under specific provisions of law to make specific changes to those payment systems or to test new models. There is no language in the statute or any legislative history that supports the interpretation that Congress delegated its authority to make permanent changes to the program to the Secretary through the CMMI. In fact, the limited legislative history on this provision indicates the exact opposite. Notably, nowhere does the law expressly state that CMS can make models mandatory.

Because delegations of lawmaking authority to the agencies may be constitutionally suspect, Congress would have had to include specific statements in the legislation indicating that it both intended to and actually was delegating its lawmaking role to the Agency. Any such delegation would have had to include clear standards for the administration of duties to limit the scope of Agency discretion as well as procedural safeguards from arbitrariness or abuses. In other words, Congress would have had to specifically permit CMS to require participation of providers of services and suppliers in a model tested by the CMMI in the language of the authorizing statute. CMS may not impute that Congress granted the Agency this authority.

Any Agency interpretation that the statute permits mandatory models raises issues of impermissible delegation of lawmaking authority where none was intended. This is especially true because Congress precluded administrative or judicial review of a substantial number of matters of CMMI demonstration authority under section 1115A(d)(2) of the SSA to permit the testing of models. The waivers of administrative or judicial review require that the scope of delegation to the Agency be read in the narrowest terms, meaning that the Agency may not infer additional grants of authority absent specific language in the statute. An Agency determination allowing mandatory participation of providers of services and/or suppliers is an overreach in interpretation that contradicts the statutory mandate and raises concerns about impermissible delegation of lawmaking authority to the executive branch. **Absent specific language in section 1115A authorizing the mandatory participation of providers of suppliers, we do not believe CMS may implement a policy that requires such mandatory participation. We urge CMS to ensure that all CMMS models are voluntary, including the CJR model.**

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 was the intent of Congress in enacting section 1115A and is the proper and appropriate use of legislatively granted demonstration authority. It was the manner in which previous demonstrations were conducted pursuant to section 402(a) of the Social Security Amendments of 1967 (P.L. 90-248), as amended by section 222(a) of the Social Security Amendments of 1972 (P.L. 92-603).

2. Small-scale Models

Despite what was clear direction from Congress that CMMI authority be used to test models before broader expansion, CMS has undertaken national, mandatory models that run afoul of the intent of the law. Such models deprive Congress of its authority to review the results of CMMI models and make decisions about whether those results warrant a broader expansion.

In advancing the CJR model and EPM model, CMS made a clear departure from legislative intent and implemented a national model that changed Medicare payment policy for more than a thousand hospitals and their patients. Advancing Medicare payment policy on such a wide-scale, without the benefit of understanding patient and provider impact through testing on a smaller-scale, puts Medicare beneficiaries and providers at risk.

Given that CMMI is tasked with testing payment models that are considerably different than Medicare's current payment structure, it is imperative that CMS understand the impacts of those changes prior to seeking to advance them more broadly. **We appreciate that the RFI reflects this policy and endorse CMS's new principle that CMMI models be tested on a small-scale basis.**

3. Transparent Model Design

We agree with CMS that models are best created through early collaboration with stakeholders. Working with providers and payers, hospitals have independently engaged in models of care that not only involve payment changes but also changes in how patients are provided care. In developing models, CMS has the opportunity to learn from existing innovations to ensure that the Agency is avoiding models that test already disproven concepts but also build on positive results from existing delivery system changes.

As such, CMS should solicit robust public input prior to and during model development. Additionally, where appropriate, CMS should engage in formal public notice and comment rulemaking. The changes being tested and advanced by CMS impact the way care is delivered and paid for and as such, it is important that CMS avail itself of all available, relevant information while developing its models. Due diligence up front will have the consequence of a better designed model and more robust results.

4. No Model Expansion Without Congressional Input and Approval

As noted above, the statute lays out the steps CMS must take to expand the "scope and duration of a model," including first evaluating each Phase I CMMI model. Only after taking into account this evaluation, if appropriate, may CMS continue to test the model in Phase II, provided certain requirements are met (§1115A(c) of the SSA). The statute also requires CMS to periodically report to Congress on CMMI models and make proposals for legislative action on models the Congress determines to be appropriate using its lawmaking authority (SSA §1115A(g)). **These provisions, and indeed the entire structure of section 1115A, reinforces that any permanent or mandatory changes to Medicare payment systems must be enacted by Congress.**

Unfortunately, CMS bypassed the phased testing process in addition to impermissibly delegating itself lawmaking authority with regard to the CJR and EPM models. There was no Phase I or Phase II testing of these models. Instead, CMS immediately mandated participation despite the lack of statutory authority. **The FAH is very concerned with this approach to Medicare payment policymaking. Imposing mandated models on providers and suppliers without any testing and Congressional action is contrary to both the language and intent of section 1115A authority. Under this approach, the Agency grants to itself broad lawmaking authority; and that authority was never granted to the Agency.**

5. Appropriate Program Waivers

The *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) and subsequent implementation of the Quality Payment Program (QPP), as well as this RFI on the new direction for the Innovation Center, signal to the provider community the value and importance of APMs in fundamentally reshaping our health care payment and delivery system. Yet, the current health care program integrity regime has not kept pace and is designed to keep hospitals and physicians and other providers in silos, rather than working in alignment as a team, which is necessary for success in an APM.

To truly effectuate change, the hospital community must be afforded the flexibility to align physicians' (as well as other providers') otherwise divergent financial interests, while promoting incentives to reduce costs and improve quality. While APMs offer the chance to change this paradigm, the Stark physician self-referral law (Stark law), anti-kickback statute (AKS), and certain civil monetary penalties (CMPs) stand as an impediment. A legal safe zone is needed that cuts across these laws.

We urge CMS to put aside its current piecemeal approach to bundled payment fraud and abuse waivers and work with the Office of Inspector General to develop a single, overarching waiver for CMS-led bundled payment programs applicable to the Stark physician self-referral law, anti-kickback statute, and relevant CMPs. In the alternative, CMS should consider a new, bundled payment program exception to the Stark law, or revisit and modify current Stark law exceptions to specifically address and explicitly permit gainsharing or other compensation arrangements in CMS-led bundled payment programs. This would encourage financial relationships that incentivize collaboration in delivering health care, while rewarding efficiencies and improving care.

6. Timely Availability of Accurate Data Needed to Properly Manage Care and Monitor Performance

Many of the alternative payment models advanced thus far require acute care hospitals to be the ultimate bearers of financial risk. As such, hospitals must be given the tools needed to manage patient care and achieve program goals. **Specifically, it is critical that hospitals receive relevant and timely data, be permitted enough time to analyze the data, and take appropriate action with participant partners on a timely basis. The data must be provided prior to the start of any new model, and at regular intervals (e.g., monthly) throughout the model.**

To successfully manage risk, hospitals must have sufficient time and data to analyze and understand the composition, characteristics, and needs of their patient population, as well as the quality of local providers. As indicated by experience with the BPCI models and our members' experience with CJR, comprehensive management and analysis of data is the foundation for hospitals to redesign and coordinate care, select and form networks with the right partners, and establish the necessary organizational and technological infrastructure.

Given our member hospital experience in receiving data from CMS under current models, we have concerns about the timeliness of the data received and its quality. For example, the CJR Final Rule was announced in November of 2015, however, participant hospitals did not receive their performance year claims experience until September 2016. In many cases, our members did not find the data helpful, as it was produced in a "raw" format that was difficult for our smaller hospitals to analyze. Those hospitals that could analyze the data found the data to be incomplete in many cases and not consistent with the hospital's own data. The FAH urges CMS to work more closely with hospitals to better define the data parameters and the format(s) of data that would be most helpful to hospitals and its collaborators. This would allow them to more effectively examine their own cost and quality data and act on these data to improve the care provided to beneficiaries in a cost-effective manner.

7. Appropriate Quality Measurement

Measuring quality is an integral part of all CMMI models and is a key component of a potential expansion of a successful model. **It therefore is imperative that CMS carefully evaluate the quality measures proposed and used in each model to ensure that the measures selected fit the purpose of the demonstration.** In addition, the measures must appropriately capture accurate and relevant timely data directly related to the care provided to the patient. Any quality measurement program should recognize pre-established goals as well as quality improvement from one measurement period to the next.

The FAH recommends that the data collection methods used in any CMMI model minimize data collection burden and incorporate data collection methods that can be pulled directly from patient records. In addition, the quality measurement results must be shared with clinicians and providers in a timely manner to inform and facilitate improvement in patient care.

The use of tools such as frequently asked questions (FAQs) are very helpful for informing patient care and improving quality. These types of tools enable clinicians and administrators to ask detailed questions as they arise rather than trying to interpret general rulemaking guidance. The FAH strongly encourages CMS to incorporate such tools in the development of any new CMMI projects. However, FAQs must be updated frequently and provided in a forum where providers have easy access at all hours of the day. These types of tools are essentially for launching an effective new program of quality measurement.

Further, as the FAH has commented in regulatory relief submissions to CMS, the Agency should step back and focus on measures that really matter and can drive care improvement aligned across care settings. Unfortunately, the proliferation of measures has continued unabated

in both the government and commercial payer space. The extensive number of quality measures, which often are not relevant to the program's purpose, incorporates multiple different definitions, inclusions, exclusions, and reporting periods for each measure, adding significant administrative costs to the reporting process and hindering the ability of individual providers to succeed under a complex array of differing quality measures. CMS should consider whether CMMI, through the development of its models, can serve as a catalyst for rationalizing and streamlining quality measurement.

Potential Models

1. Expanded Opportunities for Participation in Advanced APMs

The FAH applauds the commitment CMS made in January 2017 and August 2017 to build on the BPCI model to “design a new voluntary bundled payment model that would “meet the criteria to be an Advanced APM.”¹ However, as we approach CY2018, this new model is not yet available to clinicians, and CMS has not released a timeline for its development.

It is important that CMS act soon on its intention. There are more than 1200 participants in Phase 2 of BPCI awaiting guidance from CMS on the new framework. As CMS is aware, current BPCI participants and new participants alike will require substantial lead time to do the advance work required prior to participate in any new CMS model. Providing prospective participants with information now will likely lead to greater success of the model in the future.

As noted in the FAH comments on the CY2018 QPP Proposed Rule, CMS has identified a limited number of models that merit designations as Advanced APMs and whose participating clinicians could reach Qualifying APM Participant (QP) status. While the success of APMs rests on allowing different payment models to compete on value and efficiency and allowing the marketplace to determine success among the models, under the statute, the Advanced APM incentive bonus lasts for only six years (2019-2024). As we move into Quality Payment Program performance year two, limited availability of Advanced APMs leaves a narrow window for CMS to use the MACRA-established incentive payments to encourage providers to shift into these models. The FAH is concerned that clinicians and their hospital partners ultimately may be unlikely to join together in APMs, and clinicians will instead choose the predictability of remaining in Merit-Based Incentive Payment System. The net result will be that Medicare's movement from volume to value will be considerably slower and much less robust than CMS desires for its beneficiaries. **To improve participation in**

¹ 82 Fed. Reg. 215 (January 3, 2017). “However, building on the BPCI initiative, the Innovation Center intends to implement [a] new bundled payment model for CY 2018 where the model(s) would be designed to meet the criteria to be an Advanced APM.” And, in response to stakeholder comments, “We appreciate these considerations as we design a new voluntary bundled payment model.” See also 82 Fed Reg. 39313 (August 17, 2017). “...providers interested in participating in bundled payment models may still have an opportunity to do so during calendar year (CY) 2018 via new voluntary bundled payment models. Building on the BPCI initiative, the Innovation Center expects to develop new voluntary bundled payment model(s) during CY 2018 that would be designed to meet the criteria to be an Advanced APM.”

Advanced APMs, the FAH encourages CMS to implement the new voluntary bundled payment model as soon as possible.

2. Consumer-Directed Care & Market-Based Innovation Models

The FAH appreciates CMS's commitment to the patient's role in the health care delivery system. The patient, at the heart of the system, has a direct connection to all aspects of the care continuum. As such, patients offer key information on how the care delivery system can be improved. Their involvement in care redesign is essential, and we appreciate CMS's commitment to their involvement in their roles as both patient and consumer.

While the concepts described here may hold promise for the improvement of patient care and patient involvement, they deserve to be set forth with additional detail before stakeholders can comment appropriately. **That said, any innovation in this area must be faithful to all Medicare and Medicaid beneficiaries, ensuring that their access to and choice of provider is preserved.**

3. Prescription Drug Models

The FAH appreciates the urgent need to address soaring drug price increases. It is an issue that hospitals are attempting to manage on a daily basis. Hospitals bear a heavy financial burden when the cost of drugs increases. They are not only major purchasers of drugs, but patients often end up in the hospital when they cannot afford to take their medications as prescribed.

When the cost of drugs increases, hospitals must make tough choices about how to allocate scarce resources. Fortunately, there are several actions the Department of Health and Human Services could take to help address the source of the problem. The Campaign for Sustainable Rx Pricing has released a number of proposals that will bring additional transparency, competition, and value to the market place.² For example, Federal programs like Medicare and Medicaid purchase prescription drugs for their beneficiaries, but most are not structured to accommodate value-based payment models. **Steps should be taken to ensure these programs can best take advantage of recent developments in value-based purchasing to ensure all parts of the U.S. health care system can benefit from market-based negotiating efforts to lower drug prices.**

4. Medicare Advantage (MA) Innovation Models

Medicare Advantage Participation and QP Determinations for Advanced APMs

The FAH continues to urge CMS to proceed cautiously in considering whether to provide a pathway for Medicare Advantage (MA) plans and their clinicians to count their participation in MA toward QP determinations under the Medicare Option for Advanced APMs. The legislative text of MACRA specifically *excluded* MA from the Medicare Option for

² <http://www.csrxp.org/wp-content/uploads/2016/04/CSRxP-Policy-Platform-Summary.pdf>.

Advanced APMs and specifically included MA under the All-Payer Combination Option. CMS expressly noted this statutory construction in the CY2018 QPP Proposed Rule:

“The Medicare Option for QP determinations under sections 1833(z)(2)(A), (2)(B)(i), and (2)(C)(i) of the Act, is based only on the percentage of Part B payments for covered professional services, or patients, that is attributable to payments through an Advanced APM. As such, payment amounts or patient counts under Medicare Health Plans, including Medicare Advantage...cannot be included in the QP determination calculations under the Medicare option. Instead, eligible clinicians who participate in Other Payer Advanced APMs, including those with Medicare Advantage as a payer, could begin receiving credit for that participation through the All-Payer Combination Option in 2021 based on the performance in the 2019 All-Payer QP Performance Period.”³

As the FAH commented in response to the CY2018 QPP Proposed Rule, and reiterates here, while CMS might have flexibility through its waiver and demonstration authorities, the FAH would caution against use of that flexibility, if it exists, in the face of such a clear statutory directive from Congress. In the CY 2018 QPP Final Rule, CMS notes that developing such a demonstration will allow the Agency “to test whether giving clinicians incentives for participation in Advanced APMs with Medicare Advantage alone (without having to concurrently participate in an Advanced APM with Medicare fee-for-service) encourages more clinicians to move to the Advanced APM path under the Quality Payment Program.”⁴ This test, however, is clearly against Congressional intent, and CMS ultimately agrees in that same Final Rule, stating that under the statute, “eligible clinicians who participate in Other Payer Advanced APMs with Medicare Advantage as the payer can only achieve QP status if they also participate in an Advanced APM with Medicare fee-for-service.”⁵

Medicare Advantage plans have developed a myriad of contractual models that can distribute a range of risk to providers and clinicians – from minimal to substantial – with little evidence to providers, beneficiaries, or even CMS as to how care incentives are being driven. Should CMS move forward with its stated intent in the CY 2018 QPP Final Rule of creating a pathway for MA participation to count towards the Medicare Option,⁶ the variety of incentives and relationships between plans, providers, and members under MA make it difficult to differentiate between those health care providers and clinicians taking on sufficient levels of risk and those being paid under a fee-for-service-like paradigm. The FAH believes Congress recognized these difficulties and delayed the counting of MA participation until the 2019 performance period in order to allow CMS to fully examine these considerations.

The FAH encourages CMS to focus CMMI on creating Medicare fee-for-service Advanced APMs, as Congress envisions in the statute. Medicare fee-for-service providers are eager for the availability of additional Advance APM-eligible models, such as the new voluntary bundled payment model that builds upon the current BPCI model. Per CMS’s statements in regulations published this year, this new model was originally slated to be “implemented” in

³ 82 Fed. Reg. 30190 (June 30, 2017) and 81 FR 77473 (November 4, 2016).

⁴ 82 Fed. Reg. 53865 (November 16, 2017).

⁵ 82 Fed. Reg. 53864 (November 16, 2017).

⁶ 82 Fed. Reg. 53864-53866 (November 16, 2017).

2018 but will now be “developed” in 2018, with no clear timeline from CMS. **Given limited CMMI resources and the statutory separation of MA counting toward QP determination, the FAH recommends that CMMI apply its resources to developing Advanced APMs under Medicare fee-for-service.**

New Medicare Advantage Models and Models Outside of Fee-For-Service or Medicare Advantage

In the RFI, CMS notes the Agency is potentially interested in a demonstration in MA that incentivizes plans to compete for beneficiaries, including those beneficiaries currently in Medicare fee-for-service. CMS also seeks comments on options for paying for care delivery that incorporate price sensitivity and a consumer driven or directed focus and might be tested as alternatives to FFS and MA.

The FAH urges CMMI to move cautiously when exploring such options, as they have the potential to increase rather than decrease beneficiary costs and confusion. Medicare fee-for-service and MA provide beneficiaries with a plethora of options for their health care coverage, and MA plans are already quite successful in competing for fee-for-service beneficiaries. Recent data released by CMS touted lower MA average monthly premiums and record-breaking MA enrollment in 2018, with more than one-third of Medicare enrollees (34 percent) expected to be in an MA plan in 2018. CMS also noted continued strong access to MA, with 99 percent of Medicare enrollees with access to an MA plan, and more than 85 percent of Medicare enrollees with access to ten or more MA plans.⁷ Additionally MA plans can and do compete for beneficiaries by offering supplemental benefits, including dental and vision, as well as limits on out-of-pocket costs.

Reports from the Medicare Rights Center⁸ and the Center on Aging at American Institutes for Research⁹ note that the existing options within the Medicare program are often overwhelming for beneficiaries. Adding new options within MA or outside of both fee-for-service and MA is likely to increase beneficiary confusion – and potentially beneficiary costs if they end up with plans that are not as comprehensive or have more limited networks. There is also the potential for increased provider confusion, which would come at a time when providers are already struggling to keep up with significant delivery system reforms in Medicare fee-for-service, including accountable care organizations (ACOs) and bundled payments, as well as contracting with a myriad of MA plans. The FAH strongly urges CMMI to evaluate the potential

⁷ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-09-29.html>.

⁸ Medicare Rights Center, *Medicare Trends and Recommendations: An Analysis of 2015 Call Data from the Medicare Rights Center's National Helpline* (March 2017) <https://www.medicarerights.org/2015-medicare-trends>. The analysis found that 23 percent of calls to the Medicare Rights Center's helpline in 2015 were regarding Medicare enrollment or disenrollment.

⁹ Center on Aging at American Institutes for Research, *Medicare Complexity Taxes Counseling Resources Available to Beneficiaries* (October 2016) <http://www.air.org/system/files/downloads/report/Medicare-Complexity-Taxes-Counseling-Resources-October-2016-rev.pdf>. The brief cites research from 2011 and 2014 stating that, “Many beneficiaries do not choose the highest value plans – those offering the highest quality with the lowest cost – and they avoid switching plans because they fear that care may be disrupted, costs may be higher, or that they will need to learn a whole new set of rules and requirements.”

costs and benefits of such options – and provide ample opportunity for stakeholder input and comment – before moving forward with any demonstrations in this area.

5. Mental and Behavioral Health Models

Medicaid currently prohibits, in most instances, federal Medicaid funding to be used to reimburse for inpatient psychiatric care provided in an Institution for Mental Disease (IMD) with more than sixteen beds. Under current Medicaid managed care rules, at state direction, federal funds can be used to reimburse for short-stays (15 days or less per month) by a Medicaid beneficiary in an IMD. Additionally, through its 1115 Medicaid waiver authority, CMS has allowed certain states greater flexibility in providing services to Medicaid beneficiaries in an IMD.

As the nation seeks solutions to the ongoing and growing opioid crisis, the need for acute, inpatient psychiatric and substance use disorder services grows. IMDs can and should be part of addressing the crisis and the FAH believes that CMS should consider its CMMI authority for use in expanding the availability of IMD services. By expanding the use of services provided in an IMD, we can help assure that availability of appropriate resources meets the national need.

6. Other Areas Where CMS Should Consider Voluntary Models

a. Post-Acute Care

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 (PAC) services. **As CMS continues to develop and implement bundled payment programs, which place financial risk on acute care hospitals for PAC spending, it is important to provide payment flexibility to PAC hospitals to allow them to achieve efficiencies and better coordinate care with acute care hospitals that are at financial risk under these bundled payment models.** This is an issue that the FAH has brought to the attention of CMS in our comments related to the EPM model and which we reiterate here.

Optimal efficiencies for PAC utilization requires involvement of PAC providers in bundling arrangements. For example, inpatient rehabilitation facilities (IRFs) could test a CMMI bundling program that would not be derived from the IRF prospective payment system (PPS), but instead would permit IRFs to assume the risk of caring for certain patients over a defined period of time and with sufficient regulatory relief, such as rescinding the 60 percent rule and three-hour rule.

Options for acute care hospitals to reduce PAC spending are currently limited to encouraging patients to receive PAC in settings that receive lower Medicare payments or encouraging PAC providers that have the ability to reduce payments through efficiencies to do so. Thus, providing payment flexibility to PAC hospitals is important to allow them to effectively compete in a changing environment and to continue to provide beneficiaries with

PAC options that best meet their needs.

In this environment, PAC providers such as skilled nursing facilities (SNF) or home health agencies (HHA) have the ability under existing regulations to modify their practice or utilization patterns in a manner that produces lower Medicare payments for patient care. SNFs can reduce their Medicare payments within the current prospective payment rules by simply providing fewer days of care. In addition, SNFs can also reduce the level of therapies provided, which would put patients into lower-paid Resource Utilization Group categories. Similarly, HHAs can reduce the number of therapy encounters during a home health episode with the result of receiving less Medicare payment.

The second-year evaluation of BPCI found that SNFs reduced the amount of Medicare spending for SNF services during an episode of care primarily through reduced length of stay (*i.e.*, reducing the number of days patients were in SNFs). The study found a statistically significant reduction in SNF length of stay both when the SNF was an episode initiator itself as well as when the SNF was a downstream PAC provider for a BPCI participating acute care hospital.¹⁰

Unlike SNFs and HHAs, there is no flexibility for IRFs to reduce their Medicare payments for the benefit of hospitals participating in the bundled payment models, regardless of the cost-efficiencies an IRF may generate. This is because episode target prices and performance period spending in Medicare's bundled payment programs are based on Medicare payments, and Medicare payments to IRFs are per-discharge (not per diem) and diagnosis based (not therapy based). Thus, IRFs need additional flexibility to participate in bundled payment programs in order to reduce Medicare spending for Medicare bundled payment patients, which is not available under the current Medicare IRF prospective payment system (IRF PPS).

A voluntary CMMI bundling program that would allow IRFs to assume the risk of caring for certain patients over a defined period of time and with sufficient regulatory relief would enable IRFs to more fully and robustly share in the potential risks and rewards of these bundled payment programs. It would also allow hospitals participating in the bundled payment program to benefit from savings achieved by IRFs under the alternative payment model, which is similar to how acute care hospitals now benefit from SNFs' reduced length of stay. Thus, this voluntary alternative payment model would permit greater accountability among and between acute care hospitals and IRFs. This approach directly aligns with CMS's recognition of the need for payment flexibility as Medicare reimbursement moves towards alternative payment models and away from fee-for-service.

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

¹⁰ Dummit et al., "CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 2 Evaluation & Monitoring Annual Report," August 2016.

needed to meet their patients' needs, focusing on what is best for the patient, not on whether a patient's diagnosis satisfies the 60 percent rule.

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.

The FAH urges CMMI to provide the opportunity for IRFs to carry more risk in bundling programs, while rescinding the 60 percent and three-hour rules.

Permitting greater shared accountability between hospitals and IRFs would strengthen their relationship, leading to improved patient care and reduced costs.

b. Medicare Population-Based Payment

Medicare has 57 million beneficiaries and spending in excess of \$600 billion a year. It is important that CMMI recognize the important opportunity it has to test bold innovations to care delivery and payment.

As such, CMMI should consider testing a voluntary Global Payment ACO model, which would add a prospective, capitated payment model to the Medicare ACO portfolio. To support affordable and accessible health care, it is critical that all components of the health care delivery system efficiently provide care to patients. Prospective, global payments could advance this concept and facilitate a payment model where all providers are accountable for providing better care for a patient's total health care needs. This innovative model would also introduce choice for patients who may want to access all of their health care needs under one accountable entity. For providers, this option would introduce flexibility, accountability, and the freedom to manage a population's health while driving efficiencies, and most importantly, better patient outcomes.

We urge CMMI to build on the evolution of ACO programs by allowing providers to take on higher levels of risk in order to better coordinate patient care and improve health outcomes across all care settings. The model would include:

- Prospective, capitated payments from CMS to participating entities consisting of provider organizations coming together to manage the total health needs of a defined population.
- CMS contracting directly with the participating providers to hold them accountable for high quality, efficient care under Medicare Part A and Medicare Part B, at a minimum.
- Allowing participating providers to fully accept both upside and downside risk associated with managing a Medicare population's total cost of care, not just sharing in the savings.
- Active beneficiary enrollment as an option, combined with the prospective attribution model currently used in the Next Generation ACO model.
- A sufficient number of participating beneficiaries in order to be scalable and sustainable from both a financial and clinical risk perspective.

- Robust performance measurement on quality and cost efficiency, as well as beneficiary protections with respect to access to providers, network adequacy, appeal rights, and out-of-pocket cost limits.

Such a test would allow providers the flexibility to provide patient care in a coordinated, seamless manner. The FAH believes that such a test has the potential to provide a voluntary, alternate approach to how CMS currently reimburses for Medicare services.

c. Telemedicine

The technology that makes telemedicine possible is advancing rapidly. The opportunities to provide greater access and quality care to people in the setting that they choose are growing constantly. Assessment, consultation, treatment management, and education between provider and patients are all now possible without the two being in the same room or even the same state.

Hospitals in both rural and urban settings are investing in telehealth technologies because they appreciate the benefit to patients, ultimately helping to address inequities in access to care, containment of health care cost growth and enhancement of quality. When appropriate, a provider visit via live video is just as effective as an in-person visit. This is especially helpful in rural areas where patients may live several hours away from practices or in portions of the country where there are shortages of specialty physicians, for example in the behavioral health field. Remote patient monitoring allows physicians to monitor patients once they are released from the hospital, potentially avoiding preventable readmissions and secondary conditions.

Telehealth is clinically proven, improves the convenience of and access to care for patients, and is vital to the clinical care integration that will improve quality and help curb cost growth. Unfortunately, patients are not able to take advantage of the full range of these technological advances because Medicare has not kept pace.

Fortunately, Medicare already has a great deal of authority to expand the use and availability of these important technologies. As we have noted in previous comments to the Agency, we encourage CMS to exercise its current authority to modernize and substantially expand the coverage and payment rules for telehealth and remote monitoring technologies, which would lead to improved access for beneficiaries in both rural and urban areas to primary as well as specialty and subspecialty care. **CMMI's authority offers additional opportunities to advance the use of telemedicine and demonstrate how it can increase access, reduce costs, and improve quality. We strongly encourage CMS to follow through and engage stakeholders in structuring a voluntary model focused on telemedicine.**

d. Rural Hospital Outpatient-Only Model

The challenges facing rural hospitals have been well documented. Declining inpatient volumes have put the viability of many of these hospitals at risk and threatens to leave many communities without the availability of hospital care. While there are a number of current, important Medicare programs like the low-volume hospital payment adjustment program that assist rural hospitals in sustaining community health services and which must be extended, CMMI should consider testing new models of care for rural communities. Among those concepts

that should be tested is an outpatient-only model of care for rural hospitals.

The idea is one that has been researched and further developed by the Medicare Payment Advisory Commission (MedPAC) and supported by Congress through the introduction of legislation. There are a number of ways to test such a concept, with MedPAC having outlined the most noted model.¹¹ The broad parameters, however, of such a model would allow certain rural hospitals to only offer outpatient services and, depending on the services offered, be paid a special, designated rate for these services.

Preserving beneficiary access to essential hospital services such as an emergency department and radiology in rural areas where the inpatient hospital model may no longer be viable is an imperative. A CMMI demonstration could test a new hospital payment and delivery model tailored for small, relatively isolated communities.

Thank you for the opportunity to comment on this RFI. Should you have any questions regarding these comments, please do not hesitate to reach out to me or my staff at (202) 624-1500.

Sincerely,



¹¹ <http://www.medpac.gov/docs/default-source/reports/chapter-7-improving-efficiency-and-preserving-access-to-emergency-care-in-rural-areas-june-2016-repo.pdf?sfvrsn=0>