Federation of American Hospitals®

Charles N. Kahn III
President and CEO

January 26, 2021

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–5528–IFC, Most Favored Nation Model

Dear Ms. Richter:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care across settings in both urban and rural areas. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services. The FAH appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Interim Final Rule with Comment (IFC) titled "Most Favored Nation (MFN) Model."

On December 23, 2020, the United States District Court for Maryland issued a temporary restraining order preventing CMS from implementing this IFC.[1] On December 28, 2020, the United States District Court for the Northern District of California issued a preliminary injunction vacating the MFN rule pending completion of notice and comment rulemaking.[2] As a result of these Court decisions, it is unclear whether the public comment period on the MFN IFC remains relevant. We urge the new Administration and CMS to review the procedural deficiencies of the IFC and, if CMS determines that any similar

[1] Order, Assoc. Comm. Cancer Ctrs. v. Azar, No. 20-cv-03531 (D. Md. 23 Dec. 2020).
[2] Order Granting Motion for Preliminary Injunction, Cal. Life Sciences Ass'n v. Azar, No. 20-cv-08603-VC (N.D. Cal. Dec. 28, 2020)

rulemaking is warranted, CMS should remedy these deficiencies and go back to the drawing board with a proposed rule that allows substantive and meaningful notice and comment. If CMS were to move forward with such a rulemaking, the FAH offers our comments during the public comment period that ends on January 26, 2021 for CMS's consideration in developing future policy for Part B drugs.

Under current law, Medicare pays hospitals and physicians for Part B drugs based on average sales price (ASP) plus six percent. In the IFC, CMS intended to adopt a new model for paying for Part B drugs that will substitute the lowest price in one of 22 Organization for Economic Cooperation and Development (OECD) countries with per capita gross domestic product (GDP) of at least 60 percent of the U.S. per capita GDP for ASP plus six percent. The MFN Model price would be GDP adjusted to make it comparable to purchasing power in the U.S. In addition, CMS would make a flat add-on payment ($148.75 for the first calendar quarter of the model, to be updated quarterly) per drug administration. The model would apply nationwide to the 50 Part B drugs with the highest expenditures, and participation would be mandatory for Medicare participating providers and suppliers that submit a claim for a separately payable drug that is an MFN Model furnished to an MFN beneficiary, unless otherwise excluded.[3]

The MFN Model differs from an Advanced Notice of Proposed Rulemaking (ANPRM) that CMS published on October 25, 2018. In that ANPRM, CMS solicited public comments on potential options for testing changes to payment for Part B drugs and biologicals through a revised distribution system. Under the model, CMS would have contracted with private vendors to purchase Part B drugs on behalf of hospitals and physicians. The private vendor would purchase drugs from manufacturers at privately negotiated prices that would be limited by an index of prices paid for these drugs in selected European countries. Physicians and hospitals would continue to receive an add-on payment based on the plus 6 percent of ASP revenue that model participants would have garnered outside the model.

The FAH supports CMS's goals of reducing Part B drug costs for Medicare beneficiaries, maintaining financial stability and reducing burden for physicians and hospitals, and addressing the disparity in drug prices between the U.S. and other countries. However, we were very concerned that the system CMS planned to implement in the ANPRM would have been highly disruptive to the current Part B drug distribution system and would have been more burdensome, rather than less burdensome, to the hospitals and physicians mandated to participate in the model. The MFN Model, as currently conceived by CMS, is an improvement over the ANPRM model previously contemplated as it eliminates the revised and burdensome distribution system where hospitals and physicians would no longer obtain drugs directly from a manufacturer or distributor and would instead obtain them from a vendor that would negotiate prices on their behalf.

Nevertheless, the FAH remains concerned that the MFN Model continues to suffer from some of the same deficiencies that we raised to CMS's attention about the ANPRM, and

[3] CMS would exclude: Children's hospitals, Inpatient Prospective Payment System exempt cancer hospitals and Extended Neoplastic Disease Care Hospitals, Critical Access Hospitals, Indian Health Services Facilities, Rural Health Clinics and Federally Qualified Health Centers, hospitals in the U.S. territories, drugs administered through an item of durable medical equipment, drugs administered inpatient but paid under Medicare Part B and, drugs paid under the End Stage Renal Disease Prospective Payment System

should be withdrawn. Of most concern is that the model may increase international prices rather than lower U.S. drug prices. Further, CMS raises the specter that severe access problems may result from hospitals and physicians being unable to obtain drugs at the prices paid by Medicare.

Below we provide more detail on the specific concerns we have with the MFN Model IFC.

I. CMS Model is Inconsistent with its Own Guiding Principals

In the IFC, CMS indicates that model participation would be mandatory nationwide for any provider or supplier that submits a claim to a Medicare beneficiary for any of the 50 highest expenditure Part B drugs. However, such mandatory participation is inconsistent with guiding principles established for the Centers for Medicare and Medicaid Innovation Center (CMMI) in a September 2017 Request for Information (RFI). In that RFI, CMS established guiding principle #2:

> (2) Provider Choice and Incentives – *Focus on voluntary models*, with defined and reasonable control groups or comparison populations, to the extent possible, and reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality healthcare to their patients. Give beneficiaries and healthcare providers the tools and information they need to make decisions that work best for them. (Italics added).[4]

In addition to being inconsistent with CMS's own guiding principles for CMMI, the FAH reiterates our earlier comments challenging whether CMS has authority under §1115A of the Social Security Act (the Act) to mandate participation from hospitals, physicians, and other providers in the MFN Model. We have attached our prior comments on this topic from our letter responding to CMS's RFI re: new directions for CMMI and have made similar comments in a number of submissions to CMS including in our May 9, 2016 letter on the Part B Drug Payment Model.

In summary, the FAH believes CMS has incorrectly concluded that the statute provides it with authority to mandate provider participation in a CMMI demonstration. The FAH does not believe that §1115A of the Act provides CMS with this authority. Such mandatory provider and supplier participation is inconsistent with both the letter and spirit of the law that established CMMI, as well as the scope of CMMI's authority to test models under 1115A and make recommendations to Congress for permanent or mandatory changes to the Medicare program.

II. Scope of the Model

CMS indicates that the model would be nationwide for the 50 drugs accounting for the highest amount of Part B drug expenditures. The FAH's calculations show that Table 2 totals to $29.8 billion in 2019 allowed charges for Part B drugs. The Part B Drug Dashboard[5] shows

[4] Centers for Medicare & Medicaid Services: Innovation Center New Direction: https://innovation.cms.gov/Files/x/newdirection-rfi.pdf, page 1.
[5] Medicare Part B Drug Spending Dashboard | CMS

Medicare expenditures totaling to $37.2 billion in 2019. Therefore the 50 drugs included in the MFN Model account for approximately 80 percent of Medicare spending for Part B drugs.

However, in the September 2017 RFI, CMS established CMMI guiding principle #6 that states:

> 6) Small Scale Testing – *Test smaller scale models* that may be scaled if they meet the requirements for expansion under 1115 A(c) of the Affordable Care Act (the Act). (Italics added).[6]

Testing a model nationwide on the 50 highest expenditure Part B drugs accounting for approximately 80 percent of total Part B drug spending is not small-scale testing. The opportunity to compare a model's results with the status quo is the minimum standard by which models should be designed. Without meeting the standard, CMS will be unable to measure the model results against the statutory standard.

The MFN Model is not a test at all. It is the adoption of a nationwide policy for the highest expenditure drugs that will affect pricing and payment for the 20 percent of Part B drug spending that is not in the model. As CMS notes, the impacts of the model could be broad and lead hospitals and physicians looking outside the model for substitute products to meet their patients' needs. The increase in demand for alternative products could actually result in the price of non-model drugs increasing. The IFC acknowledges this possibility in the impact section where the Assistant Secretary for Planning and Evaluation (ASPE) analysis "assumed that manufacturers will increase prices for non-MFN Model drugs."[7] If demand for non-model drugs is affected by the model—as seems a certainty and is acknowledged in the impact section—there is no control group that will be unaffected by the model's impact in order to make any conclusion as to whether the intervention was successful as would occur in a conventional demonstration model.

Again, CMS is planning to adopt a model that is directly in conflict with guiding principles it established in 2017. Despite what was clear direction from Congress that CMMI authority be used to test models before broader expansion, CMS is again planning to undertake a national, mandatory model that runs 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.

Finally, 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. Under its CMMI waiver authority, models are required to reduce spending without reducing quality or increase quality without increasing spending. Given the potential for Part B drug prices to increase outside of the model, CMS must consider the impact on spending both inside and outside of the model to determine whether it is compliant with the CMMI statute.

[6] Innovation Center New Direction, page 1.
[7] 85 FR 76240.

III. Schedule for Implementation

Perhaps it is an academic consideration now that two Federal District Courts have precluded CMS from implementing the MFN Model without first going through notice and comment rulemaking, but CMS announced the MFN Model on November 20, 2020 with an implementation date of January 1, 2021 with no prior notice nearly 18 months after the rule first arrived at the Office of Management and Budget for review and clearance. It was only then that CMS released the rule as an IFC claiming that waiver of notice and comment rulemaking was in the public interest. The courts rightfully rejected this analysis of a perceived emergency that CMS could have addressed at any point before late November 2020.

With that said, we stress that a delay of 42 days between the IFC and implementation of the new model would have provided woefully insufficient time for model participants to adjust contracts and other planning to be able to comply with such a drastic change in payment frameworks. Indeed, it is precisely for this reason why notice and comment on a proposed rulemaking is required by the law. Notice and comment rulemaking allows the affected public to bring concerns to the agency that it may not have considered in developing a proposed rule. The agency then may include those considerations in developing a final rule. At minimum, a major rule (as this would be as it affects more than $100 million in annual spending) requires a 60-day delay between being finalized and its effective date under the Congressional Review Act (5 U.S.C. 801(a)(3)). CMS may provide for a longer delay than 60 days if the regulatory provision is of particular complexity or will impose sufficient burden on the regulated party such that a longer period of time is needed between the rule being finalized and its effective date.

We note that the Medicare Prescription Drug, Improvement and Modernization Act of 2003 established section 1847A of the Act, which changed the pricing methodology for Part B drugs from 95 percent of average wholesale price (AWP) to ASP plus six percent, was signed into law on December 8, 2003, but did not go into effect until January 1, 2005, or more than 1 year after its enactment. This period of time was necessary for undergoing notice and comment rulemaking and establishing procedures for drug manufacturers to report Part B drug sales prices to CMS. At the same time, it also provided an open and transparent system for hospitals and physicians to be informed and prepared for a major change in how they would be paid for Part B drugs. This transition provides a suitable model for CMS to consider if it again plans to develop a model to test changes in Medicare payment for Part B.

At a minimum, if CMS were to issue a final rule after notice and comment on a newly proposed rule, as discussed above, the FAH requests that CMS provide at least a six month delay between publication of the final rule affecting Part B drug prices and its implementation date. Further, as we stated in response to the ANPRM, we further request that CMS not implement any model affecting Part B drug prices mid-year and consider that contracts are more likely to be negotiated on the basis of a calendar year consistent with the outpatient prospective payment system payment cycle. As noted above, going through notice and comment rulemaking as occurred with the transition from AWP pricing to ASP pricing also provided a longer lead time for the physician and hospital community to accommodate its contracts and systems to changes in Part B drug pricing.

IV. Add-On Payment

CMS calculated a "per dose" add-on payment for January 1, through March 31, 2021 of $148.73. This add-on payment is intended to approximate the total add-on to ASP encompassed by the plus six percent to ASP. There will be no beneficiary coinsurance on the add-on payment. The add-on payment will not vary by drug administered nor will it be paid more than once per drug administered. A "dose" is the number of units on a claim for a particular drug.

The FAH concurs with CMS's calculation of the add-on payment and supports the agency not making the add-on payment subject to beneficiary coinsurance. The FAH suggests that CMS clarify whether "per dose" allows the add-on payment to be made only once per encounter or whether it may be made once for each drug, administered in a single encounter. As written, we believe the add-on payment is made once per each drug administered in a single encounter.

V. Potential for the Model to Increase Prices Abroad and Not Reduce Prices in the United States

Among the goals of the MFN Model is for Medicare to offer comparable pricing relative to international markets. However, the model would not necessarily reduce international prices. These target prices could be achieved either through reducing U.S. prices or raising international prices. The IFC itself acknowledges the potential for international prices to rise. In the impact section of the IFC, the ASPE analysis indicates that "published literature suggests that when a large country establishes an international reference price, smaller reference countries experience price increases and longer launch delays for new products."[8]

CMS should consider that drug pricing abroad may be subject to many different variables that do not apply in the U.S., as most countries have some kind of national health insurance. These countries may not pay at all for a particular drug if its cost is too high whereas Medicare has a requirement to pay for every Part B drug that is reasonable and necessary for treatment of illness or injury. Other countries have more access to biosimilar products as a result of their earlier introduction to European markets and may already be using cost containing strategies, such as indication-specific pricing and step therapy. In addition, as noted in a ASPE issue brief,[9] there are limitations in comparing drug prices between the U.S. and other countries including differences in package sizes with various amounts of unused drug and the potential for rebates and other off-invoice discounts that vary in availability by country. ASPE also acknowledges that many of the drugs are administered through the "hospital" sector in other countries; strict budget caps for hospital spending can impact hospital use of these drugs and also influence rebates from drug manufacturers to keep hospital spending within the required budgets.

[8] 85 FR 76240 referencing Patricia M. Danzon, ''The Economics of the Biopharmaceutical Industry'', in Sherry Glied and Peter C. Smith (eds.), The Oxford Handbook of Health Economics, Oxford University Press 2011, pp. 520–554.

[9] https://aspe.hhs.gov/system/files/pdf/264421/Part-B%20Drugs-International-Issue-Brief.pdf

No public policy would be served by achieving comparability via rising international prices. CMS indicates that it may terminate the MFN Model in accordance with section 115A(b)(3)(B) of the Act. This provision allows CMMI models to be terminated if the Secretary or CMS's Chief Actuary determines that the model does not improve the quality of care or reduce spending or both. The FAH suggests that CMS include provisions for immediately terminating the model if the evidence suggests that the chief outcome of the model is an increase in the prices that are paid for Part B drugs in international markets. Further, CMS should consider that there could be unintended consequences for U.S. markets both inside and outside of the model, such as reduced prices in the model being offset by increases in Part B drug prices outside of the model for Medicare and non-Medicare payers, as reasons to terminate the model.

VI. Potential for the Model to Create Access Issues

In the IFC, CMS presents three impact analysis scenarios from the Office of the Actuary (OACT) and additional analyses from ASPE. In one of the scenarios, OACT considers that separately payable Part B drugs represent approximately five percent of the overall U.S. prescription drug market. According to OACT, this fact could "cause strong resistance to the model."[10] OACT raises the prospect that manufacturers may not lower their Part B drug prices in the U.S. market. Lower Medicare reimbursement may reduce beneficiary access to essential Part B drugs as hospitals and physicians may no longer be able to obtain Part B drugs at the prices paid by Medicare.

The analyses from OACT and ASPE are clear that there is significant uncertainty regarding reactions to the model explaining why so many impact scenarios are presented. One OACT scenario is labeled "Extreme Disruption Illustration" where physicians and hospitals become unable to offer the top 50 drugs within the model and nearly one-half of $286.3 billion in model savings results from lost utilization. Such a scenario would be a catastrophic loss of access to medically necessary drugs for Medicare beneficiaries. In other scenarios, as noted above, manufacturers raise international prices rather than lower domestic prices and anticipated savings from the model are not realized.

VII. Conclusion

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. Unfortunately, the FAH is highly skeptical that this model will address the fundamental issues driving these price increases and believes it could result in unintended consequences such as higher international prices or reduced access to Part B drugs in the U.S. The FAH continues to support other actions the Department of Health and Humans Services is taking to help reduce Part B drug prices, such as prioritizing action on drug approvals in both the brand and generic spaces where no competitor drug exists, and scrutinizing activities taken to extend the exclusivity period of high-cost drugs through the gaming of the current regulatory process and approving new biosimilar products.

[10] 85 FR 76237.

We appreciate your consideration of our comments regarding the MFN Model and hope you will take them into consideration when taking further action to address rising prices for Part B drugs through notice and comment rulemaking. If you have questions about our comments or need further information, please contact me or my staff at (202) 624-1534.

Sincerely,

Attachment

Attachment

Federation of American Hospitals®

Charles N. Kahn III
President and CEO

December 21, 2018

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., Room 445-G
Washington, DC 20201

Re: CMS–5528–ANPRM, Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural parts of America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Advanced Notice of Proposed Rulemaking (ANPRM) titled "Medicare Program; International Pricing Index Model for Medicare Part B Drugs" (the IPI Model).

In this ANPRM, CMS solicits public comments on potential options for testing changes to payment for certain separately payable Part B drugs and biologicals (drugs). Specifically, CMS intends to test a revised distribution system which would have private vendors purchase Part B drugs on behalf of hospitals and physicians. Rather than pay average sales price (ASP) plus 6 percent to the physician or hospital administering the Part B drug, the model would pay the private vendor based on prices more closely aligned with international prices in selected European countries. The private vendor would purchase drugs from manufacturers at privately negotiated prices. Physicians and hospitals would continue to receive an add-on payment based on the +6 percent of ASP revenue that model participants would have garnered outside the model and without sequestration in the most recent year of claims data.

FAH supports CMS's goals of reducing Part B drug costs for Medicare beneficiaries, maintaining financial stability and reducing burden for physicians and hospitals, and addressing the disparity in drug prices between the U.S. and other countries. However, we are very concerned that the system CMS is planning to implement will be highly disruptive to the current Part B drug distribution system and will be more burdensome, rather than less burdensome, to the hospitals and physicians that will be mandated to participate in the model. Further, FAH is concerned that the model may increase international prices rather than lower U.S. drug prices and potentially increase US prices for physicians and hospitals not within the bundle.

FAH recognizes that CMS is soliciting comments on the concept and has not yet specified many of the model's details. Nevertheless, absent more specificity, there is insufficient information available for FAH to be in a position to support the model. This letter will detail our concerns about the information that is currently known about the model.

I. CMS Model is Inconsistent with its Own Guiding Principals

In the ANPRM, CMS indicates that model participation would be mandatory for physician practices, hospital outpatient departments, and potentially other providers and suppliers in each of the selected geographic areas. However, such mandatory participation is inconsistent with guiding principles established for the Centers for Medicare and Medicaid Innovation Center (CMMI) in a September 2017 Request for Information (RFI). In that RFI, CMS established guiding principal #2:

> (2) Provider Choice and Incentives – *Focus on voluntary models*, with defined and reasonable control groups or comparison populations, to the extent possible, and reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality healthcare to their patients. Give beneficiaries and healthcare providers the tools and information they need to make decisions that work best for them. (Italics added).[1]

In addition to being inconsistent with CMS's own guiding principles for CMMI, FAH reiterates our earlier comments about whether CMS has authority under §1115A of the Social Security Act (the Act) to mandate participation from hospitals, physicians and other providers in the IPI model.

We have attached our prior comments on this topic from our letter responding to CMS's RFI re: new directions for CMMI and have made similar comments in a number of submissions to CMS including in our May 9, 2016 letter on the Part B Drug Payment Model.

In summary, FAH believes CMS has incorrectly concluded that the statute provides it with authority to mandate provider participation in a CMMI demonstration. The FAH does not believe that §1115A of the Act provides CMS with this authority. Such mandatory provider and supplier participation are inconsistent with both the letter and spirit of the law that established CMMI, as well as the scope of CMMI's authority to test models under 1115A and make recommendations to Congress for permanent or mandatory changes to the Medicare program.

[1] Centers for Medicare & Medicaid Services: Innovation Center New Direction: https://innovation.cms.gov/Files/x/newdirection-rfi.pdf, page 1.

II. The Current Distribution System is Appropriate and Working

In the ANPRM, CMS describes the current purchasing and distribution system for Part B drugs.

Under this system, referred to in the ANPRM as "buy and bill," Part B drugs administered in the outpatient setting:

> Flow from the manufacturer through drug wholesalers (or specialty distributors) to the provider or supplier. At each step of the process, the drugs are sold to the next entity in the supply chain and that entity takes title to the drug. Distribution management systems are employed to order drugs, track sales and shipments, manage price and customer lists, record financial transactions, and support other industry processes.
>
> The role of the health care provider within the buy-and-bill system is to seek out low cost drug suppliers and purchasing mechanisms (for example, by joining a group purchasing organization (GPO)), order, buy (or use financing), receive, and store drugs, administer drugs to patients, file claims to bill insurers for payment, and collect patient cost-sharing.[2]

CMS's ANPRM accurately describes current systems in place for the purchasing and distribution of drugs administered in hospitals. This purchasing and distribution system is currently working well and provides appropriate market incentives for physicians and hospitals purchasing and administering drugs to seek the best possible prices for Part B drugs. Hospitals and physicians obtain these prices by working through GPOs, other group purchasing arrangements, wholesaler/distributor price lists, and directly negotiated agreements with manufacturers as described in the ANPRM.

These pricing arrangements between drug purchasers and drug manufacturers then factor into the ASP calculation. Section 1847A of the Act appropriately recognizes that the acquisition cost for the drug is not the only cost physicians and hospitals have for the drug. The additional 6 percent of ASP compensates physicians and hospitals for the costs associated with shipping, storage and handling, inventory, and maintaining an in-house pharmacy among other costs associated with administering Part B drugs to patients.

The purchasing and distribution systems in place today are not responsible for escalating drug prices. Even though the current distribution system for Part B drugs is not problematic, CMS anticipates proposing a model that will be highly disruptive to this system. Among the most consequential aspects of the IPI Model is CMS's plan to require hospitals and physicians in the model to obtain drugs through a "model vendor" rather than through their current distribution networks. While CMS indicates that it seeks to minimize disruption, the FAH believes that requiring physicians and hospitals to acquire drugs through a model vendor will be highly disruptive without providing the burden-reduction savings that CMS purports would be realized from removing physicians and hospitals from the "buy and bill" process.

CMS indicates that the most significant benefit to hospitals and physicians of the IPI Model would be that the model vendor, rather than the health care providers, would take on the financial risk of acquiring the drugs and billing Medicare. Unlike the current system,

[2] 83 FR 54548.

physicians and hospitals would not take title to the drugs that they are administering. Rather, the vendor would purchase the drugs but not necessarily take possession of them. Vendors would be required to arrange for distribution of the drugs to physicians and hospitals. Unlike the competitive acquisition program (CAP) that was administered from 2006 through 2008, the model vendor would not have to provide a patient-specific prescription but could purchase drugs in bulk much as is currently done under the "buy and bill" system. Model vendors would have flexibility to offer innovative delivery mechanisms to encourage physicians and hospitals to obtain drugs through the vendor's distribution arrangements, such as electronic ordering, frequent delivery, onsite stock replacement programs, and other technologies.

CMS appears to believe the model would allow physicians and hospitals to maintain their current distribution system – including in-house pharmacies and inventories of Part B drugs – while being relieved of the burden of negotiating prices and purchasing of the drugs. However, the model would only apply to Medicare Part B drugs in the model. It would not apply to Part B drugs not included in the model or drugs that are purchased for patients outside of the model (e.g., Medicare Advantage patients; Medicare fee-for-service patients not in the model; non-Medicare patients). Thus, hospitals would need to continue to maintain their current purchasing and distribution arrangements for non-model drugs and drugs administered to patients outside of the model.

Rather than unburdening hospitals, the model would increase burden on hospitals by adding another administrative mechanism for purchasing drugs administered in hospitals solely for Medicare Part B drugs included in the model. Under the current distribution system, hospitals do not need to distinguish between patient insurers when purchasing Part B drugs administered in the hospital. Hospitals, working through GPOs and wholesalers, purchase drugs and maintain them in pharmacy inventory without needing to account for whether the patient has Medicare or another insurance until the drugs are administered. Once the drug is administered, hospitals will bill the patient's insurer based on the drug and quantity administered. Under the system anticipated in the model, hospitals would need to track inventory separately for Part B drugs administered to patients in the model—a task they do not do currently.[3]

Further, many of FAH's hospital members are multi-hospital systems where purchasing and acquisition is handled system-wide. If some hospitals within a multi-hospital system are included in the model and others are not, this will be a further burden in that the hospital will have to maintain two administrative purchasing systems; one for those member hospitals in the model and another for those hospitals not in the model where purchasing and distribution systems would be left unchanged.

CMS would require all hospitals to enroll with at least one vendor but would allow enrollment with more than one vendor. Given the administrative difficulties described above, the FAH believes it is highly unlikely there would be hospital interest in enrolling with more than one vendor as that would merely increase administrative challenges. The FAH believes

[3] The FAH understands that hospitals eligible for the 340B drug discount program track drugs administered to patients eligible for 340B discounts and obtain 340B discounts when replenishing drug inventory. The 340B program is limited by statute to non-profit hospitals making FAH members ineligible for the program despite providing similar levels of uncompensated care as those hospitals eligible for the 340B program, and serving a percentage of low-income patients far greater than the statutory eligibility threshold. In the 340B program, the additional burden to hospitals is offset by discounted drug prices hospitals receive. In the model, CMS would be imposing an additional burden on hospitals for no apparent benefit and at potentially a higher cost.

hospitals would select the model vendor that best meets their needs for the majority of drugs included in the model rather than enrolling in separate model vendors for different drugs.

CMS anticipates requiring model vendors to serve all of the selected model geographic areas and supply all drugs included in the model.[4] Although the FAH does not recommend proceeding with the model as it is described in the ANPRM, if CMS decides to proceed with this model, the FAH believes it is critical that CMS retain these requirements to avoid the potential for hospitals to have to enroll with more than one vendor to obtain all of the Part B drugs included in the model.

In addition to the administrative burden of maintaining two purchasing and distribution systems for Medicare and non-Medicare payers, this system would have additional costs to hospitals as CMS indicates that "physicians and hospitals would pay the model vendor for distribution costs."[5] Essentially, CMS would not just be requiring hospitals to duplicate its purchasing systems for drugs administered in the hospital, it would also be imposing an additional administrative cost on hospitals to pay the model vendor for the services it would be providing. Again, the FAH reiterates that these additional burdens and costs would disrupt a system that is currently working.

The FAH further notes the guiding principle from above that "to the extent possible, [CMMI models will] reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality healthcare to their patients." Given the enormous burden that would be imposed on hospitals in the model of maintaining two systems for purchasing, distribution, and inventory of Part B drugs, the FAH believes that significant disruption of administrative systems for Part B drugs is inconsistent with this CMS guiding principle for CMMI.

III. Other Administrative Burden Issues

Several other aspects of the anticipated model also raise administrative burden concerns for hospitals. Under the current "buy and bill" system, hospitals bill Medicare for the drug and the Medicare beneficiary (or the beneficiary's supplemental insurer) for Part B coinsurance. As the hospital would no longer buy and own the drug, ostensibly, the responsibility for billing Medicare and collecting coinsurance would be with the model vendor. However, learning from the experience with CAP (where the CAP vendor had difficulty collecting coinsurance), CMS indicates that the hospital would collect beneficiary coinsurance and provide it to the model vendor. Further, even though the hospital would not be paid by Medicare for the drug, it would still have to submit "informational drug claims to the Medicare Administrative Contractor (MAC)."[6]

This system would require the hospital to maintain all of its current administrative functions plus add an additional administrative mechanism to furnish the model vendor with beneficiary coinsurance. Further, the model vendor would be billing Medicare for the Part B drug. Therefore, the hospital and the model vendor would also need an administrative mechanism to communicate information about the beneficiary (e.g., the beneficiary's medical condition and indications for the drug, which would raise concerns about violations of patient confidentiality under the Health Insurance Portability and Accountability Act), the drug

[4] 83 FR 54551.
[5] 83 FR 54551
[6] 83 FR 54551

furnished, and its quantity in order for the model vendor to be able to bill Medicare for the Part B drug. Currently, there are only three parties to the transaction: the hospital, the MAC and the beneficiary. The anticipated model would add a fourth party to the transaction—the model vendor. An administrative apparatus would be needed for communications between the hospital and vendor as well as the vendor and the MAC. There would be no savings of administrative burden to the hospital as it would still be required to submit an information only claim for the Part B drug for which it is no longer being paid as well as put in the place the additional systems needed for distribution of drugs included in the model.

One potential alternative to this system would be to use the information only claim submitted by the hospital to the MAC to pay the model vendor for the Part B drug. However, such a system would place the onus for accurate claim submission on the hospital making a claim for payment on behalf of another party for which it is receiving no benefit. The FAH would strenuously object to any system where a hospital would be responsible for accurate claims submission for payment that goes to another party. Further, hospitals will already be in possession of valuable Part B drugs that it does not own—a situation which may be of concern to both hospitals and model vendors as to who has responsibility when drugs are lost, mishandled, spoiled, or otherwise not administered.

IV. Potential Add-On Payment

CMS recognizes that hospitals have costs associated with drugs beyond those of just acquiring the drug. CMS indicates that the additional 6 percent add-on payment "can help to cover the costs of the drug ordering, storage and handling born by physicians and hospitals, payments to join group purchasing organizations or other entities with similar purchasing arrangements."[7] Recognizing these costs, CMS seeks to structure the model such that it will continue to pay for "certain distribution costs…the goals for the model add-on payments would be to hold heath care providers harmless to current revenues to the greatest extent possible." Thus, CMS anticipates proposing to continue to make an add-on payment but divorce the add-on payment from the price of the drug. That is, the add-on payment will be a fixed amount and will no longer be a function of the price of the drug.

It is unclear from the ANPRM how the add-on payment would be determined other than "the alternative compensation would approximate the expected add-on amount for included drugs in the absence of the model before sequestration."[8] Sequestration refers to the 2 percent reduction that is applied to the portion of the Part B drug payment paid by Medicare exclusive of beneficiary coinsurance. Effectively, the hospital receives 104.3 percent of ASP rather 106 percent of ASP, including the effect of the 2 percent sequester (Medicare's 80 percent share reduced by 2 percent plus the beneficiary's 20 percent share equal 104.3 percent of ASP). CMS anticipates that the add-on payment will be the full 6 percent excluding the effect of the sequester. However, CMS is required to apply the sequester to any payment it makes from the Medicare Trust Fund so it is unclear how CMS can ensure that the add-on payment will equal 6 percent other than raising it above 6 percent such that applying the 2 percent sequester results in a 6 percent add-on payment. It is not clear whether CMS intends the add-on payment to be for each drug administered, or as described further below, how CMS intends to calculate and distribute the add-on payment. FAH suggests that CMS address all of these issues in the proposed rule.

[7] 83 FR 54553

[8] 83 FR 54553

The add-on payment is construed as a percentage add-on but it is not clear to what the percentage is applied. As indicated above, CMS says the expected add-on amount for included drugs would approximate the revenues the hospital received in the absence of the model. This does not seem possible, however, because the 6 percent add-on in the current system is a function of the price of the drug (e.g., $100 drug means a $6 add-on), and CMS indicates that the add-on payment will no longer be a function of the price of the drug under the new model. The FAH believes that CMS is intending to fix the add-on payment based on historical data such that, if drug prices decline under the model, the add-on payment would remain unchanged. In other words, CMS intends to make the 6 percent add-on revenue neutral to the 6 percent add-on that hospitals would have received in the absence of the model *before* the model was in effect. FAH requests that CMS indicate whether this understanding is correct during the rulemaking process.

Further confusing this issue is that CMS says the add-on payment will be a set payment per administered drug that would be based on: 1) the class of drug; 2) the physician's specialty; or 3) the physician's practice. These are not variables in the determination of the current add-on payment so it does not seem possible that hospitals can be held revenue neutral to the current system in the absence of the model if the add-on payments are being distributed on a different basis than they are currently. Given this confusion, the FAH believes it is critical that CMS provide more details in the proposed rule as to how this add-on payment will be determined and, as discussed above, how the expected add-on amount for included drugs would approximate the revenues the hospital received in the absence of the model.

The FAH further notes that CMS indicates "beneficiary cost-sharing would apply to the model specific alternative compensation"[9] which could raise further confusion from Medicare beneficiaries about what this coinsurance is for. Under the current system, beneficiaries pay 20 percent coinsurance for the drug and an additional 20 percent coinsurance for the drug administration. These two payments would become three coinsurance payments: 20 percent for the drug (which would be collected by the hospital but paid to the model vendor), 20 percent for the drug administration, and 20 percent for the add-on payment.

The add-on payment is intended to compensate hospitals for administrative costs associated with furnishing drugs. However, the FAH believes it is unprecedented for Medicare to pay separately for an administrative cost outside of the item or service to which it is associated. Indeed, CMS intends to include drugs that are administered "incident to" a physician service in either a physician office or hospital outpatient department in the model. While CMS will pay separately for drugs and biologicals under the "incident to" provisions, it also pays for other costs under the "incident to" provisions that "are commonly either rendered without charge or included in the physicians' bills"e.g., administrative costs for which Medicare provides no separate payment.[10] Beneficiaries may find it very confusing as to why they are being charged 20 percent coinsurance for an "add-on" that can only be described as an administrative cost.

[9] 83 FR 54553

[10] Section 1861(s)(2)(A) and (B) of the Social Security Act (the Act) describe the "incident to" provisions. Section 1861(s)(2)(A) of the Act applies to drugs not usually self-administered in the physician's office while section 1861(s)(2)(B) applies to drugs not usually self-administered in hospital outpatient departments. While the quoted language is from section 1861(s)(2)(A) of the Act that applies in physicians' offices, the same principle applies to "incident to" services in the hospital outpatient department.

V. Scope of the Model and Schedule for Implementation

CMS indicates that the model would cover a portion of the country that accounts for 50 percent of Medicare Part B drug spending.[11] In the September 2017 RFI, CMS established CMMI guiding principle #6 that states:

> 6) Small Scale Testing – *Test smaller scale models* that may be scaled if they meet the requirements for expansion under 1115 A(c) of the Affordable Care Act (the Act). (Italics added).[12]

Testing a model in 50 percent of the country is not small-scale testing. Further, CMS indicates that prices paid in the IPI model would go into the determination of ASP.[13] That means there would be no control group that is unaffected by what is being tested in the model, and thus no ability to accurately evaluate the model's effects. The opportunity to compare a model's results with the status quo is the minimum standard by which models should be designed. Without meeting the standard, CMS will be unable to measure the model results against the statutory standard. In other words, this is not a test at all. It is the adoption of a policy in 50 percent of the country – that by design will also impact the other 50 percent of the country – absent statutory authority.

Again, CMS is planning to adopt a model that is directly in conflict with guiding principles it established just over one year ago. Despite what was clear direction from Congress that CMMI authority be used to test models before broader expansion, CMS is again planning to undertake a national, mandatory model that runs 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.

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. Under its CMMI waiver authority, models are required to reduce spending without reducing quality or increase quality without increasing spending. Given the potential for Part B drug prices to increase outside of the model, and that prices in the model will go into the determination of ASP, CMS must consider the impact on spending both inside and outside of the model areas to determine whether it is compliance with the CMMI statute.

CMS further plans to issue a proposed rule in the Spring of 2019 with the potential for the model to start in the Spring of 2020. This schedule for implementation is unrealistic. Even if CMS could address the multitude of issues that FAH is raising and additional issues that will surely be raised by other commenters for a proposed rule in the Spring of 2019, CMS must allow at least 60 days for public comment and sufficient time beyond the end of the comment period for CMS to address the public comments and publish a final rule. At the earliest, a final rule will not be complete until sometime during the summer of 2019.

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[11] 83 FR 54553

[12] Innovation Center New Direction, page 2.

[13] 83 FR 54556

Once the final rule is complete, only then can CMS begin the process to solicit model vendors. CMS indicates that model vendor selection factors may include eight different factors; all of which must be met within 6 months.[14] Not specified is what date that 6 months is from, but presumably it would be from the date of selection. If the program were to start on April 1, 2020, selection must be completed by November 1, 2019. Thus, CMS is anticipating a maximum of 3 to 4 months for it to complete a solicitation and selection process for model vendors; a timeframe which is unrealistic given the requirements of the federal government contracting process, including developing and agreeing upon contracts.

CMS is then providing a period of 6 months from the date of selection for the vendors, hospitals and physicians to be ready for implementation. The ANPRM lists 13 different tasks for the model vendors that would occur in these 6 months, including negotiating prices with drug manufacturers and enrolling hospitals and physicians.[15] This is a very short time period for all of these tasks to occur, and it does not consider that physicians and hospitals may already have contractual commitments to purchase Part B drugs through existing suppliers and distribution networks; all of which would need to be changed to accommodate the model. Again, CMS is imposing an extraordinary burden on physicians and hospitals inconsistent with the CMMI guiding principle to "reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality healthcare to their patients."

At a minimum, the FAH requests that CMS not implement the model mid-year and consider that contracts are more likely to be negotiated on the basis of a calendar year consistent with the OPPS payment cycle. While the FAH opposes the model being considered, CMS should at least implement on the basis of a calendar year so it is consistent with the timing of when changes occur under the physician fee schedule and the outpatient prospective payment system.

VI. Potential for the Model to Increase Prices Abroad and Not Reduce Prices in the United States

Among the goals of the IPI model is to offer comparable pricing relative to international markets. Model vendors would negotiate prices with the goal of limiting prices in the U.S. to an index that is based on international pricing. CMS indicates that on average, Medicare currently pays 180 percent of what other wealthy countries pay for the mostly costly physician-administered drugs. The target price for the model is 126 percent of the average price other countries pay for the drug.[16] However, the model would not necessarily reduce international prices. These target prices could be achieved either through reducing U.S. prices or raising international prices. CMS itself acknowledges the potential for international prices to rise but dismisses this concern: "manufacturers may seek to raise prices or limit foreign sales. However, existing, multiyear pricing relationships in foreign markets may minimize this response.[17]

CMS should consider that drug pricing abroad may be subject to many different variables that do not apply in the U.S., as most countries have some kind of national health

[14] 83 FR 54442
[15] 83 FR 54551
[16] "What You Need to Know about President Trump Cutting Down on Foreign Freeloading," US Department of Health and Human Services. https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html
[17] 83 FR 54557

insurance. These countries may not pay at all for a particular drug if its cost is too high whereas Medicare has a requirement to pay for every Part B drug that is reasonable and necessary for treatment of illness or injury. Other countries have more access to biosimilar products as a result of their earlier introduction to European markets and may already be using cost containing strategies, such as indication-specific pricing and step therapy.

No public policy would be served by achieving comparability via rising international prices. The FAH suggests that CMS include provisions for immediately terminating the model if the evidence suggests that the chief outcome of the model is an increase in the prices that are paid for Part B drugs in international markets. Further, CMS should consider that there could be unintended consequences for U.S. markets both inside and outside of the model, such as reduced prices in the model being offset by increases in Part B drug prices outside of the model for Medicare and non-Medicare payers.

VII. Potential for the Model to Create Access Issues

Under the IPI Model, model participants in the selected geographic areas would have to enroll with at least one model vendor and obtain included drugs from a model vendor for administration to included Medicare FFS beneficiaries.[18] This raises the question as to what would occur if no model vendors participate or if a vendor does not have access to all of the drugs a provider needs to serve their patients. Would hospitals be able to obtain drugs as they do now or would access to Part B drugs potentially be compromised?
It is unclear to us whether there is a business case for model vendors to participate based on information in the ANPRM. The responsibilities for potential vendors are significant. The ANPRM lists 13 different responsibilities that would have to be fulfilled by model vendors in order to qualify for participation. In addition, CMS indicates that model vendors would be required to serve all of the selected model geographic areas and supply all of the included drugs to physicians and hospitals that enroll with the vendor.[19] For the CAP program, these requirements were significant barriers to participation, as CMS outlined in the 2010 Physician Fee Schedule Final Rule published on November 25, 2009.[20] Ultimately, CAP failed because there was not a vendor willing to participate in the program.

For a vendor to participate, it would need to have a sufficient volume of participants to enable it to obtain drugs at a cost less than the price CMS will pay under the IPI. CMS says Part B drug ASPs are 180 percent of international prices and the IPI is intended to produce an average reduction of 30 percent from today's prices. Thus, a model vendor would have to believe it can negotiate a Part B drug price of no more than 130 percent of the international price once the model is fully implemented. If the potential model vendor cannot obtain drugs at less than the price CMS will pay, there will be no incentive to participate at a financial loss. CMS indicates that physicians and hospitals would pay the model vendor for distribution costs. In addition to the concerns raised above – that this imposes an additional administrative cost on hospitals to essentially duplicate their current purchasing systems – the payment of distribution costs alone would be insufficient to induce vendor participation. At this point, there is no evidence of interest in being model participant. According to Modern Healthcare, the most likely commercial entities qualified to participate in the Part B Drug IPI Model would need more information before expressing any interest in participating.[21]

[18] 83 FR 54551
[19] 83 FR 54551
[20] 74 FR 61907, 61912
[21] Cohrs, Rachel, "Potential Vendors Cautious On Trump Admin's Medicare Part B Demo," Modern Healthcare,

Another potential concern would be vendor participation at the outset of the model but the vendor not being able to meet its commitment to stay in the program. If there is only one model vendor, and it can no longer supply all the drugs included in the model and/or drops out of the program, would Part B drugs in the model then be obtained through "buy and bill?" If there are multiple model vendors, would hospitals be required to switch mid-year to using a different model vendor than the one with whom they were initially enrolled or would they be able to purchase drugs through "buy and bill?" The implications of these questions for beneficiary access to Part B drugs are significant and are questions that must be answered if CMS proceeds to the proposed rule stage for the IPI model.

VIII. Conclusion

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. Unfortunately, the FAH is highly skeptical that this model will address the fundamental issues driving these price increases and believes it could result in unintended consequences. Meanwhile, it will create enormous disruption to current hospital purchasing acquisition, inventory, and distribution systems even though these systems have no role in the price inflation that is of concern to CMS. The FAH continues to support other actions the Department of Health and Humans Services is taking to help reduce Part B drug prices, such as prioritizing action on drug approvals in both the brand and generic spaces where no competitor drug exists and scrutinizing activities taken to extend the exclusivity period of high cost drugs through the gaming of the current regulatory process and approving new biosimilar products.

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We appreciate your consideration of our recommendations regarding the ANPRM on the IPI Model. If you have questions about our comments or need further information, please contact me or my staff at (202) 624-1500.

Sincerely,

Attachments

ATTACHMENT

Federation of American Hospitals®

Charles N. Kahn III
President and CEO

November 20, 2017

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 Humans 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 Center[8] and the Center on Aging at American Institutes for Research[9] 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 Evalutation & 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.

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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