To health!
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Sept. 27, 2019

The Honorable Seema Verma
Administrator
Center for Medicare and Medicaid Services
7500 Security BLVD
Baltimore, MD

***Submitted electronically***

**Re: CMS-1715-P, Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations**

Dear Administrator Verma:

On behalf of the New Jersey Hospital Association (NJHA) and its over 400 hospital, health system, PACE and post-acute members, thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Calendar Year 2020 Physician Fee Schedule proposed rule.

We support a number of proposed policy changes that ensure access to care, support public health efforts, improve quality and promote regulatory relief. Specifically, we strongly support CMS's proposed reversal of its previously finalized policies for evaluation and management (E/M) payments. Those policies would have resulted in a significant disconnect between the resource use and intensity of physician services and the compensation for those services, which could have threatened access to care for vulnerable populations. We also applaud CMS's commitment to addressing the opioid crisis by proposing to implement the statutorily required payments for opioid treatment programs (OTPs), and proposing a new bundled payment model for certain substance use disorders. We also appreciate that the agency again proposes mostly gradual, flexible increases to requirements under the Quality Payment Program (QPP) for the CY 2020 performance period. We also welcome the agency's willingness to review the current Advisory Opinion regulations for the physician self-referral law.

However, other proposed policies could prove highly problematic for the field. CMS's proposed criteria for therapy assistant services are far too restrictive and administratively burdensome. The resulting payment cut would reduce resources for medically necessary services, including those needed to ensure patient safety. In addition, while we support the agency's proposed OTP model, we are alarmed by the proposal to price the Part B injectable and implantable drugs used in the bundle using the average sales price (ASP) without the legally mandated 6% add-on. Lastly, some of CMS's proposed changes to the QPP's Merit-based Incentive Payment System (MIPS) – especially the increase in the number and weight of cost measures, and the proposed MIPS Value Pathways (MVP) framework – require considerable revisions to ensure they assess providers fairly and accurately.

**PAYMENT FOR EVALUATION AND MANAGEMENT (E/M) VISITS**

In the CY 2019 PFS final rule, CMS adopted a policy to pay a blended rate for Levels 2 through 4 E/M visits and to require providers to meet only those documentation requirements associated with a Level 2 E/M visit. This policy was scheduled to go into effect for CY 2021. We expressed serious concerns with the blended payment rate, as we believe it would have resulted in a significant disconnect between the resource use and intensity of physician services and the compensation for those services, which could have threatened access to care for vulnerable populations. **As such, we strongly support CMS's proposed reversal of its prior methodology and adoption of an alternative framework developed by the Joint AMA CPT Workgroup on E/M.** Under this alternative, CMS would assign separate payment rates to all E/M visit levels for new and established patients.

However, as CMS develops the specific valuations and payments for the E/M visit codes and any other add-on codes it finalizes, as well as the budget neutrality impact of these changes on other areas of the PFS, we urge the agency to consider the degree of redistribution among specialties that this proposal could create. We further urge CMS to ensure that providers caring for the sickest and most vulnerable patients are not unfairly penalized.

**PROPOSED PAYMENT REDUCTION FOR SPECIFIC CODE GROUPS FOR CY 2020**

In the rule, CMS proposes significant reductions to the relative value units (RVUs) of certain CPT code groups – a move that could potentially limit patients' access to these vital services. For example, CMS's proposed valuations for the code set that describes long-term EEG monitoring with video recording – which is key to the care of patients with epilepsy – would result in a nearly 50% reduction in payment for these services. The RVUs that CMS proposes are even lower than the Relative Value Scale Update Committee (RUC)-recommended values, and, as such, do not reflect the level of time and expertise required to perform this specialized service. CMS similarly disagrees with the RUC-recommended values for the code set that describes myocardial PET scans and instead proposes RVUs that would result in a payment cut for these services. Decreases of this magnitude over a short time period will negatively impact physicians and hospitals that care for patients for whom these services are critical.

We have previously urged the agency to phase in substantial fluctuations in payment rates in order to promote predictability and reliability for providers. We urge CMS to consider such an approach in this situation or when the RVUs for any CPT code set are drastically reduced in a given year.

**COINSURANCE FOR COLORECTAL CANCER SCREENING TESTS**

In general, beneficiaries are not required to pay Medicare Part B coinsurance for colorectal cancer screening tests. However, colonoscopies and sigmoidoscopies that begin as a screening service, but have a polyp or other growth removed as part of the procedure, are no longer considered "screening" tests, and carry coinsurance requirements for beneficiaries. We appreciate CMS's recognition of beneficiaries' and providers' concerns about the coinsurance when beneficiaries expected to receive a colorectal screening procedure, but instead received what Medicare considers to be a diagnostic procedure.

In this rule, CMS requests comment on whether it should introduce a notification requirement under which physicians or their staff would be required to inform beneficiaries before a colorectal cancer screening that they may incur a coinsurance payment if the physician discovers and removes polyps. We strongly recommend that CMS use its existing resources to inform beneficiaries of their possible coinsurance requirement, rather than providers. Medicare already provides notifications to beneficiaries through the annual Medicare and You beneficiary handbook and medicare.gov, both of which are resources to which Medicare beneficiaries turn for information about their coverage. Given that the imposition of coinsurance for a colorectal cancer screening in which polyps were discovered and removed is a coverage decision made by Medicare, CMS is the appropriate entity to notify beneficiaries of their coinsurance requirements. Requiring physicians or their staff to provide this notification would introduce an additional, unnecessary regulatory burden, which could force them to divert important resources away from patient care. It also could create distrust among beneficiaries if providers begin their routine colorectal cancer screening with a warning about possible unexpected payment, rather than focusing on the care they are providing.

**MEDICARE PART B BENEFIT FOR OPIOID TREATMENT PROGRAMS (OTPS)**

OTPs are health care entities that focus on providing medication-assisted treatment (MAT) for people diagnosed with opioid use disorder (OUD). Previously, OTPs were not able to bill and receive payment from Medicare for the services they furnish. In addition, Medicare has historically not covered methadone, a common MAT therapy, because it is not administered by a physician and thus is not covered like other MAT drugs under Part B or Part D.

Enacted October 2018, Section 2005 of the Substance Use-disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act established a new Part B benefit category for OUD services furnished by an OTP beginning on or after Jan. 1, 2020. In this rule, CMS proposes several definitions, requirements, payment methodologies and other programmatic aspects to implement this statutory requirement. Many of the proposals would codify in the Code of Federal Regulations (CFR) what was established in the statute.

We appreciate CMS's commitment to addressing the opioid crisis, and attempt to strike a balance between the flexibility of the benefit (e.g. with partial and non-drug episodes) and appropriate oversight (e.g., certification by the Substance Abuse and Mental Health Services Administration and Medicare enrollment requirements). This benefit would fill a gap in care for individuals seeking treatment for OUD. However, OTPs often have limited long-term effectiveness due to the nature of their services: it is difficult for the average person suffering from OUD to keep up with weekly interactions, as helpful as they may be. In addition, the focus of OTPs on OUD may make these programs less effective for the majority of OUD patients who are addicted to multiple substances including alcohol and other illicit or prescription drugs. In other words, it is the minority of OUD patients who are addicted to opioids only.

To be clear, we believe this Medicare benefit and its proposed provisions should have a positive impact on certain patients. However, we think CMS and its partners at the Center for Medicare and Medicaid Innovation should use the significant amount of work and research they have undertaken to inform this benefit to also investigate more comprehensive payment models that address a wider range of substance use disorders and focus on long-term recovery. One example of this is the Addiction Recovery Medical Home model, a bold, new alternative payment model developed and currently being piloted by members of the Alliance for Addiction Payment Reform, which includes the AHA. This model uses a multi-faceted, team-based approach that addresses three different, but often overlapping, phases of recovery: pre-recovery and stabilization; recovery initiation and active treatment; and community-based recovery management. The Alliance has also partnered with the National Committee for Quality Assurance (NCQA) to ensure the development of quality measures that more accurately reflect patient outcomes and performance.

**Drug Component Pricing**

We are concerned about the proposal to price the Part B injectable and implantable drugs used in the bundle using the average sales price (ASP) without the standard 6% add-on. This add-on is a required part of the payment for Part B drugs, and accounts for, among other things, overhead costs and additional mark-ups accrued in traditional drug distribution channels. However, CMS states that it believes "many OTPs purchase the drugs from manufacturers," thus limiting these extra costs. The agency has a legal obligation to include a factor for overhead and adequately justify any add-on less than the standard 6% with data. That obligation is not met by an unsupported assertion of belief.

## BUNDLED PAYMENTS FOR SUBSTANCE USE DISORDERS UNDER THE PFS

In addition to the newly established Part B benefit for OUD treatment in OTPs, CMS proposes to establish bundled payments for the overall treatment of OUD for physicians outside of OTPs. The bundle would include management, care coordination, psychotherapy and counseling activities. The bundle would not include any medication used for MAT (as billing and payments for these drugs would remain under Medicare Parts B and D) or toxicology testing (which would continue to be billed separately under the clinical lab fee schedule).

We appreciate CMS's proposals on this bundle, and believes that the specific provisions will allow for flexibility in care that will improve access. For example, adding the three new codes associated

with the bundle to the list of services eligible for payment when furnished via telehealth will help extend the reach of providers who treat patients with OUD. In addition, not limiting the use of the codes to any particular specialty and allowing general supervision of non-face-to-face portions of services will result in more types of clinical staff to provide services.

Similar to our concerns about the OTP benefit, however, we worry that the scope of these services is unnecessarily limited to OUD. While opioids are currently the main driver of drug overdose deaths according to the Centers for Disease Control and Prevention, more than a third of drug overdose deaths that occurred in 2017 were associated with other substances. As CMS and the Department of Health and Human Services undertake laudable and vitally important work to address the opioid crisis, we encourage the agencies to employ a broader strategy that will not leave others suffering from addiction to other substances behind. Thus, we urge CMS to consider amending the bundle's definition to include office-based treatment for substance use disorder rather than solely OUD.

We understand this is a larger undertaking than what is proposed in the rule, but believe that for this bundle – which would pay for professional services rather than drugs and equipment – it would be feasible and highly beneficial to expand the population of patients for whom providers can offer comprehensive treatment.

**CRITERIA FOR REVOCATION AND DENIAL OF MEDICARE BILLING PRIVILEGES**

CMS proposes to broaden the criteria it would consider to revoke or deny the billing privileges of Medicare-participating clinicians to include instances of patient harm. Specifically, the agency would assess whether clinicians had "been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of healthcare with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm." The agency would consider a number of factors: the nature and frequency of harm events; whether state licensing agencies took specific actions (e.g., licensure restrictions, required participation in mental health programs, mandatory abstinence from drugs or alcohol); and any other information CMS deems relevant. CMS believes these criteria are appropriate given its responsibility to protect Medicare beneficiaries from harm. We share in CMS's desire to ensure Medicare beneficiaries are safeguarded from harm. As such, we have several cautions that we urge the agency to consider to ensure that its criteria are applied fairly and appropriately. For example, the regulation does not indicate whether the agency would consider only those licensure actions that have been fully adjudicated, or also those that are in process. We believe action should be taken only once the state licensure's board process is complete. Furthermore, CMS's proposal to include "any other information deemed relevant" is very broad, and could, in theory, mean that minor actions against professionals could lead to the revocation of billing privileges. Such revocations have the potential to lead to care access issues. For these reasons, we recommend that the agency further consult state licensure boards, medical professional groups and hospitals before finalizing its criteria to ensure they are applied in a fair, consistent fashion.

**PAYMENT FOR THERAPY ASSISTANT SERVICES**

We ask CMS to make less restrictive the proposed calculation for determining which cases involving therapy assistants would be subject to a statutorily-mandated 15% cut. The proposed methodology is too restrictive and the resulting cut would reduce resources for medically necessary services, including those needed to ensure patient safety. Further, the resulting administrative burden would divert resources from patient care and conflict with the agency's "Patients over Paperwork" initiative.

This rule builds upon last year's rulemaking to implement the Bipartisan Budget Act of 2018 requirement that outpatient physical and occupational therapy services furnished in whole or in part by a therapy assistant be paid at 85% of the PFS amount, beginning in CY 2022. Last year's rule also finalized a threshold for therapy assistant services – 10% of total minutes – that would trigger the payment cut.

Under this rule, CMS would assess a claim's status relative to the 10% threshold using a calculation of total service time, therapist minutes and therapist assistant minutes, rounded to the nearest whole minute, following these guidelines:

- Total Service Time: Total minutes by the therapist (whether independent or concurrent) plus any additional minutes independently provided by the assistant.
- Therapist and Therapist Assistant Minutes:
    - Concurrent therapy. If concurrent (therapist and assistant providing overlapping services) minutes plus assistant minutes are greater than 10% of therapist-only minutes, the payment cut would apply to all minutes provided by both the therapist and assistant.
    - Same service furnished separately. If therapist and assistant separately furnish portions of the same service and the assistant's minutes are greater than 10% of total minutes, the payment cut would apply to total service time.

To align with congressional intent, we ask CMS to restructure the calculation to only count independent therapy assistant minutes in the 10% threshold. This approach would avoid penalizing providers for providing two sets of professionals when they are needed to ensure safety and effective outcomes. Therapists and assistants furnish concurrent care for higher-skilled procedures; for example, stroke patients who are relearning how to walk typically require assistance from two professionals. To help stroke patients take multiple steps, the physical therapist may provide neuromuscular re-education by assisting with foot placement and verbal cues as well as preventing the knee from buckling when weight is put on the weak leg, while the assistant helps the patient maintain an upright position and perform weight shifting. If during this stroke patient's 60-minute visit, the therapist provided 50 minutes of independent therapy and the therapist and assistant jointly provided 10 minutes of concurrent therapy, the entire hour of service would be subject to the 15% cut. Thus, this example illustrates how the proposed calculation would inappropriately reduce payments for patient-centered therapy using the safety precautions needed to ensure a high-quality outcome.

**Proposed Additional Administrative Burden**
The rule's proposed new documentation requirements associated with the new therapy assistant claims modifiers are overly burdensome. Specifically, the proposed rule would require treatment notes to explain, via a short phrase or statement, the application or non-application of the therapy assistant modifier for each service furnished that day. In other words, in addition to existing documentation requirements, CMS would require a statement in the medical record for each line of every claim to explain why the therapy assistant modifier was or was not used. Doing so would necessitate detail that is redundant to the application of the modifier itself and not statutorily required. Further, the rule does not explain how the proposed documentation would add new insights beyond those already provided under the existing extensive documentation requirements of the Medicare Claims Process Manual Chapter 15. Therefore, we urge CMS not to finalize this requirement. However, if CMS proceeds with this new documentation requirement, we ask the agency to allow providers using no assistants to easily indicate so to bypass this duty.

## ADVISORY OPINIONS ON THE APPLICATION OF PHYSICIAN SELF-REFERRAL LAW

We welcome the agency's willingness to review the current Advisory Opinion regulations "in an effort to identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process."

We strongly share with CMS the view that tethering the process for issuing advisory opinions for a strict liability payment statute too closely to the process used for issuing advisory opinions under the Anti-Kickback criminal statute is having unintended consequences. Timely responses to reasonable provider requests for advice on the application of the physician self-referral regulations are pivotal when the ability to bill for services rendered depends on numerous general conditions subject to interpretation. Confidence as to whether claims are properly payable in the agency's view can be key to avoiding extraordinary potential exposure given the increasing use of the False Claims Act to allege physician self-referral noncompliance.

We support the changes proposed by the agency with respect to shortening the time CMS has to respond to a request, simplifying the certification requirement and expanding the universe of parties that can utilize an advisory opinion. Depending on how they are implemented, the changes could have a significant impact in improving both the advisory opinion process and levels of compliance among providers. We believe the agency can and should go further, however, to expand the type of requests evaluated by CMS and to address the ramifications if the agency does not issue an opinion within the specified timeframe.

**"General Questions of Interpretation"**
By continuing to limit the types of questions or situations it will consider, CMS will make it more difficult for providers to comply. Given the resources and time required to draft and formalize proposed arrangements, CMS should not decline requests on the characterization that a request poses only a "general question of interpretation" (especially not after the allotted timeframe for review has passed and the provider has no opportunity for rebuttal). The proposed rule already

includes the safeguard necessary to allow meaningful application of the physician self-referral law and to avoid waste of agency resources – all requests need to describe arrangements with a sufficient level of detail. With this basic requirement in place, the distinction between planned arrangements and general matters of interpretation is abstract and unnecessarily favors the form of a request over its substance. To the extent CMS has a need to limit or qualify its response, it can do so and explain its reasoning. But to dismiss or disregard such inquiries up front with no explanation undermines the effectiveness of the regulations. The regulated community is entitled to know what it must do to comply. The "general question of interpretation" restriction should be deleted.

**Requests Pending Beyond the Allotted Timeframe**
Historically advisory opinion requests have not received prompt attention from CMS – even to acknowledge requests, or, if needed, pose additional factual questions regarding the arrangement at issue. The lack of a response or decision should have consequences. If an opinion is not issued within the required 60 days of the completed request (subject to the tolling periods identified in existing regulations), the requester should be deemed to have received a favorable determination and may rely on it until such time as CMS formally issues an opinion. Hospitals and health systems need to know what requirements they must meet to get paid. When the regulations are unclear or vague, the regulator has a duty to clarify those requirements.

**Matters under Investigation**
The agency's proposal does not address the problems created by its current refusal to accept requests concerning "courses of action substantially similar" to those that may be under investigation. This is especially the case when the request is from parties not involved in an investigation. CMS reiterates in the proposed rule that the agency can only advise on whether a financial relationship exists and whether that arrangement qualifies for an exception in a particular set of circumstances. Given that limited scope, CMS's decision on a particular request is by definition totally independent of any other arrangement between other parties. The discretion to decline a request or delay issuing a clarifying opinion due to pending litigation should be limited to only those circumstances the agency finds will directly impact the investigation. Investigations and litigation of alleged physician self-referral violations extend over many years. Providers should not be effectively required to act at risk simply because another federal agency is reviewing another arrangement that CMS is also obliged to review, including in response to a False Claims Act *qui tam* filing.

## MEDICARE SHARED SAVINGS PROGRAM (MSSP) QUALITY MEASUREMENT

CMS proposes a number of changes to the measure set used to determine whether accountable care organizations (ACOs) meet the quality performance standard in MSSP. ACO quality performance helps determine whether ACOs are eligible to earn shared savings, or determines the magnitude of losses for which an ACO may be liable in downside risk models.

**Measure Proposals for CY 2020**
We do not support the removal of ACO-14 (Preventive care and screening: Influenza vaccination) as we do not believe its proposed replacement – ACO-47 (Adult Immunization Status) – is

appropriate for the MSSP at this time. We acknowledge that the use of ACO-47 would allow the agency to assess whether ACOs are providing a wider range of important preventive vaccinations. Indeed, ACO-47 would assesses the percentage of patients 19 and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); Herpes zoster virus; and pneumonia.

However, two issues would make ACO-47 measure performance inappropriately dependent on factors beyond the ACO's control. First, not all of the vaccinations included in the measure are covered under Medicare Part B. While influenza and pneumococcal vaccinations are covered, the tetanus shot is covered only if it is received as a treatment for an illness or injury (e.g., a patient steps on a rusty nail). Medicare Part B does not cover the other vaccinations included in the measure, though they often are as a part of the Medicare Part D prescription drug program, or as part of Medicare Advantage plans. As a result, measure performance could depend on the extent to which the included patient population participates in the optional Part D or Medicare Advantage benefits, or can afford to pay out of pocket for the vaccinations. Second, as noted by the Centers for Disease Control and Prevention (CDC), there remain shortages of the zoster vaccination that make its availability uncertain. As noted on the CDC website, "due to high levels of demand for GSK's Shingrix vaccine, GSK has implemented order limits and providers have experienced shipping delays."

If Medicare Part B coverage for the vaccinations was to expand, and if the supply of zoster vaccinations was to stabilize, we believe ACO-47 could be an appropriate replacement for ACO-14 in a future MSSP program. However, unless and until the coverage and availability issues are fully addressed, we urge CMS not to adopt ACO-47 for the MSSP program.

**Updates to Existing MSSP Measures**

We support CMS's proposal to make ACO-43 (Ambulatory Sensitive Condition Acute Composite) a pay-for-reporting measure for two years (2020 and 2021). The agency anticipates making significant measure specification changes during 2020, and as a result, CMS will need the 2020 and 2021 performance periods to allow ACOs to gain experience with the new measure and establish an appropriate performance baseline.

We urge CMS to make ACO-17 (Smoking Cessation) a pay-for-reporting measure again for CY 2019. Appropriately, CMS made ACO-17 pay-for-reporting in 2018 in light of significant measure specification changes during the performance period to address data collection issues. Those changes are proposed formally in this rule, and CMS notes they are effective for 2019. In practical terms, this means ACOs have not had significant experience with the measure, and the benchmarks they would be expected to achieve have changed. For this reason, it would be appropriate to keep the measure as pay-for-reporting again for CY 2019.

**Request for Comment on Aligning the MSSP Quality Scoring with the MIPS Quality Category**

In the proposed rule, CMS solicits input on whether and how to align the MSSP quality scoring approach with the MIPS quality category, and how the MIPS quality category score could be used to adjust shared savings and losses under the program.

We appreciate CMS's goal of achieving better alignment of scoring methodologies across its pay-for-performance programs. Indeed, we have long noted that the uncoordinated scoring approaches across CMS programs can result in added administrative burden and confusion for providers. However, at a time when the MSSP is undergoing significant change with the implementation of the New Pathways approach, we believe it is premature to implement drastic changes to the MSSP quality scoring approach. Furthermore, we have significant concerns about the potential revised scoring approaches that are outlined in the RFI; we urge CMS not to pursue them.

Specifically, we do not support requiring ACOs to achieve a quality score at or above the 4th decile of MIPS quality performance to be eligible for shared savings. CMS scores MIPS quality measures using deciles, assigning between one and 10 points to each measure. The deciles are set based on the performance of all providers nationally. In the rule, CMS asserts that the current minimum attainment threshold in MSSP to be eligible for shared savings – the 30th percentile – is equivalent to the 4th decile of performance in the MIPS. Yet, CMS provides inadequate data on national performance on the measures in the ACO program to back this assertion. Furthermore, this approach raises significant concerns about fairness. If the goal is to align MSSP and MIPS quality scoring approaches, it makes little sense to hold the ACOs to a higher attainment standard than other MIPS clinicians. A more appropriate policy would set the minimum attainment standard at the 3rd MIPS decile.

In addition, we strongly urge CMS to retain pay-for-reporting in the first year of MSSP participation, as well as pay-for-reporting for newly added or significantly revised measures. For first-time participants in the MSSP, it takes significant resources to learn measure specifications, assess baseline performance and implement workflow changes – IT and otherwise – necessary for accurately capturing and improving quality performance. Furthermore, when CMS makes significant changes to existing measure specifications, providers must make several of these same adaptations. Given that CMS now scores MSSP ACOs on improvement over time, it is essential for CMS to establish an accurate performance baseline. Pay-for-reporting periods give ACOs the opportunity to ramp up their measurement and improvement capabilities in a sustainable fashion before their shared savings or losses are tied to quality performance.

**QUALITY PAYMENT PROGRAM – MERIT-BASED INCENTIVE PAYMENT SYSTEM**

Mandated by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the QPP began on Jan. 1, 2017, and includes two tracks – the default MIPS, and a track for clinicians with a sufficient level of participation in certain advanced alternative payment models (APMs). The rule proposes quality measurement changes for the CY 2020 performance period, which would affect payment in CY 2022.

We have urged that the MIPS be implemented in a way that measures providers accurately and fairly; minimizes unnecessary data collection and reporting burden; focuses on high-priority quality issues; and fosters collaboration across the silos of the health care delivery system. To achieve this desired state, we have recommended that CMS prioritize the following policy approaches:

- Adopt gradual, flexible changes in MIPS reporting requirements in the initial years of the program to allow the field sufficient time to plan and adapt;
- Streamline and focus the MIPS quality and cost measures to reflect the measures that matter the most to improving outcomes;
- Allow facility-based clinicians the option to use their facility's CMS quality reporting and pay-for-performance results in the MIPS;
- Employ risk adjustment rigorously – including sociodemographic adjustment, where appropriate – to ensure providers do not perform poorly in the MIPS simply because of differences in clinical severity and communities served; and
- Align the requirements for eligible clinicians in the Promoting Interoperability (formerly known as Advancing Care Information) performance category with the requirements for eligible hospitals and critical access hospitals.

.CMS has made progress in addressing nearly all of the above priorities. In the first three MIPS performance years (CYs 2017-2019), CMS adopted gradual increases to the length of reporting periods, data standards and the performance threshold for receiving positive or negative payment adjustments. The agency also implemented a facility-based measurement approach in 2019, has removed some outmoded quality measures and has taken steps to better align the promoting interoperability category's requirements with the hospital Promoting Interoperability Program. In general, we are pleased that the CY 2020 proposed rule would continue many of these approaches.

However, CMS proposes to take the MIPS program in a dramatically new direction by beginning to implement MIPS Value Pathways (MVPs) starting in the CY 2021 performance period. While the MVP approach has some potential improvements over the existing approach to the MIPS, there remain far too many unanswered questions about it for it to be ready to implement starting in the CY 2021 performance period. We strongly urge CMS to conduct further analysis and obtain further stakeholder input before proceeding with the MVP approach to the MIPS.

Furthermore, CMS proposes to add 10 more episode-based cost measures to the MIPS cost category, and to make significant revisions to the two overall cost measures it uses. It also would continue to raise the weight of the cost category by 5% each year until it reaches 30% for CY 2024 payment. We remain very concerned by the rapid increase in the number and weight of cost measures in the MIPS category, and urges CMS not to finalize either the new cost measures, or the increase to the cost category weight. Below we offer our comments on these two issues, as well as several other smaller scale proposed changes to the MIPS program.

**MIPS Value Pathways**

As we understand it, CMS believes its proposed MVP approach could align and reduce reporting requirements across the four MIPS performance categories. The rule does not propose any specific MVPs, but proposes a general framework, provides some examples and includes a request for information on how CMS could structure MVPs in future rulemaking. Built over time, the MVPs would organize the reporting requirements for each MIPS category around specific specialties (e.g., ophthalmology), treatments (e.g., major surgery) or other priorities (e.g., preventive health). CMS suggests that it likely would assign clinicians to particular MVPs, and that the MVP approach would replace the current construct of the MIPS program over time. CMS indicates it would reduce

reporting burden for those participating in MVPs by using a smaller number of quality and cost measures, and is exploring mechanisms of enhancing its mechanisms of sharing data with providers.

We thank CMS for considering ways of improving the MIPS program within the statutory boundaries set by the MACRA. In concept, we agree with most of the guiding principles CMS has articulated for the MVP approach. We especially appreciate the agency's stated interest in streamlining the number of measures that eligible clinicians must report, and in greater focus of all of the MIPS performance categories on high priority areas.

However, we strongly believe that any sweeping change to the construct of MIPS policy must be firmly rooted in data, experience and input from the field. While it is true that shortcomings of the MIPS are emerging, broadly representative data and experience on the strengths and weaknesses of the MIPS are still fairly limited. The MIPS is still a "young" policy in relative terms; indeed, the proposals in this year's rule update the program for only its fourth performance year. Furthermore, the field saw the first set of overall performance results on the MIPS was in early 2019.

There have been a number of frustrations with the current configuration of the MIPS program. Some have suggested that the quality measures and improvement activities are not as well-aligned with high priority areas as they could be, and that they do not connect across the silos of the delivery system as well as they could. Furthermore, reporting data across the four categories entails significant resources and sometimes burden. That is why we have advocated for CMS to adopt facility-based measurement, which allows for clinicians who spend most of their time working in hospitals to use their hospital's CMS hospital value-based purchasing results in the MIPS. Furthermore, many believe the MIPS measures do not have sufficient risk adjustment. CMS's "complex patient bonus" was a step in the right direction, but a more sophisticated approach is needed. Many of those responsible for large multi-specialty group practices have expressed frustration that the measures they use for the entire practice do not apply to as broad a cross-section of their practices as they could.

However, for the field to support the MVP approach, CMS must provide evidence that the benefits of the MVP approach outweigh its drawbacks. Unfortunately, the RFI simply does not provide sufficient information to fully evaluate whether this is the case, and raises a host of other practical and conceptual concerns. For these reasons, we strongly urge CMS not to set a date certain for implementing the MVP approach and instead conduct further analysis and obtain additional stakeholder feedback. We would be pleased to help the agency engage hospitals in such work. Indeed, we believe there are at least three issues that CMS must examine further using data modeling.

First, CMS would need to ensure there are enough measures available to create MVPs applicable to the over 1 million eligible clinicians that currently participate in the MIPS program. Given the wide range of specialty types participating in the MIPS, this is a daunting task. Furthermore, given CMS's correct focus on implementing "Meaningful Measures" in its programs, adding measures simply for the sake of having enough to create an MVP likely would not be the best approach.

However, if CMS's concept is to assign clinicians to particular MVPs, it would need to ensure it has measures that meaningfully apply to their clinical practice. We suggest that CMS attempt to construct several more "prototype" MVPs, determine how many clinicians it could potentially assign to each, and obtain clinician input on whether the measures in those MVPs actually do align with their clinical practice.

Second, CMS must ensure that using an MVP approach would provide a fair, equitable comparison of performance across clinician and group types and specialties. If CMS's intention is to assign clinicians to particular MVPs, then their goal should be that clinicians have comparable opportunities to perform well. Stated differently, CMS would need to ensure that some MVPs are not inherently "easier" to score well on than others. This, too, is a profoundly challenging issue to address. However, we suggest that CMS use the "prototype" MVP analysis articulated above to look at the performance distributions across MVP models to determine whether any specialty types or group types score any worse than others.

Lastly, we are concerned about the feasibility of an MVP approach for a multi-specialty group practices. We have previously urged the agency to consider approaches that let multi-specialty practices that operate under a single tax ID number (TIN) identify sub-groupings within their practices that could measure and report separately under the MIPS (i.e., "decomposing" the TIN). We believe such an approach would be necessary to implement MVPs. However, the key distinction between the current MIPS and the MVP approach is that decomposing a TIN may be compulsory rather than voluntary. As a result, multi-specialty groups may actually face an increase in their reporting burden, which would contradict CMS's stated goal of reducing provider burden.
MIPS Quality Category. For CY 2020 quality reporting, CMS would mostly carry over CY 2019 reporting requirements and scoring approaches. However, among other changes, CMS proposes to increase the data completeness thresholds, and asks for feedback on collecting new types of data using the Consumer Assessment of Providers and Health Systems (CAHPS) for MIPS survey.
We support CMS's proposal to increase the data completeness thresholds for four of the six MIPS data collection types from 60% to 70% of the clinician or group's patients that meet measure denominator criteria. This increase would apply to measure data reported using Medicare Part B claims, MIPS clinical quality measures (CQMs) (formerly known as clinical registry measures), Qualified Clinical Data Registries (QCDRs) and electronic CQMs (eCQMs). The reporting of complete data is an important step to ensuring that MIPS performance is assessed accurately. Furthermore, we appreciate CMS using data from the field to inform its decision to increase the threshold. CMS found that the average MIPS data completeness across clinicians and groups was 74% or better. We would encourage CMS to continue using a data-driven approach to increasing thresholds in the future.

CMS also solicits input on whether it should collect patient narratives as a part of the CAHPS for MIPS survey and display those narratives publicly, and whether it should collect CAHPS data at the individual clinician level. We appreciate the potential value of both kinds of data for quality improvement purposes. However, we seriously question whether the data would be meaningful for either a public reporting or accountability purpose. On patient narratives, many clinicians, hospitals and health systems already work with their CAHPS survey vendors to collect patient

narrative information. Often these stories help shed light on underlying data trends. At the same time, we would be troubled by any attempt for CMS to "score" clinicians or groups on open-ended narrative questions as a part of the MIPS. It is very likely that any such score would be based on an arbitrary determination of what constitutes a "good" or "bad" experience.

With respect to collecting CAHPS for MIPS data at the individual clinician level, many clinicians find value in understanding how patients perceive their own individual performance. However, we foresee a number of significant challenges both with publicly reporting the measure results, and with scoring such results in the MIPS program. We also are concerned about the potential cost of implementing individual clinician-level reporting. In order to generate reliable, accurate performance data that one would need for either public reporting or for scoring in the MIPS program, clinicians would need to collect a robust sample of patient experience surveys. Yet, members have reported that obtaining enough clinician-level CAHPS data entails enormous expense, especially for large and/or multi-specialty group practices. At a time when survey response rates are falling – both for the entire CAHPS family of surveys and other national surveys outside of health care – a requirement to collect individual clinician-level data may not be sustainable or may provide further inducement for clinicians to give up their solo or small group practice in favor of working in a large group or for a hospital. While we believe there are many benefits for physicians who work in hospitals, we understood CMS to have concerns about the perception that it was piling on sufficient burden that its regulations are a reason for physicians to seek employment rather than maintain their independent practices.

In addition, we continue to urge CMS to take other steps to modernize the CAHPS for MIPS survey, as well as all members of the CAHPS survey family. In collaboration with the other major national hospital associations, the AHA recently released a report outlining recommendations for modernizing the HCAHPS survey. Many of the recommendations in that report would apply to the CAHPS for MIPS survey. Specifically, we continue to urge CMS to develop an electronic survey option that allows for clinicians and groups to provide the survey via email, on a website or integrated within an application. The only two survey modes currently permitted by CMS are mailed and telephonic surveys (or a mixed mode of both survey modes). The use of an electronic mode not only aligns with how many patients prefer to provide feedback, but also may allow for increasing sample sizes and the timeliness of survey receipt in a more economical way. In addition, CMS should consider shortening the survey. The CAHPS for MIPS survey currently contains 58 questions, and we are concerned that a survey of that length may harm survey response rates.

MIPS Cost Category. Using its statutory discretion under the Bipartisan Budget Act of 2018, CMS proposes to continue gradually increasing the weight of the MIPS cost category (currently 15%) by five percentage points each year through CY 2024 payments. As a result, for CY 2022, the weight of the cost category would be 20%. Furthermore, CMS proposes to add 10 additional episode-based cost measures to the cost category. Lastly, CMS proposes methodology updates to its two overall cost measures – Medicare Spending per Beneficiary (MSPB), and Total Per Capita Costs. Clinicians and groups would be scored on the measures for which they have a sufficient number of attributed cases.

Hospitals and clinicians alike are focused on improving the value of care, and need well-designed measures of cost and resource use to help inform their efforts. However, we remain very concerned

by the rapid increase in the number and weight of cost measures in the MIPS category. We urge CMS not to finalize either the new cost measures, or the increase to the cost category weight.

Serious questions remain about the reliability, accuracy and meaningfulness of all of the measures in the cost category, making it problematic to increase the weight beyond where it already is. The new episode-based cost measures – as well as the proposed methodology changes to the overall cost measures – have not yet been endorsed by the National Quality Forum (NQF). We believe that all measures used in public reporting and pay-for-performance programs should be NQF-endorsed because the process gives important insights into the reliability, validity and usability of measures.

We believe an NQF endorsement review is essential to examine several fundamental measure design issues, especially with the two overall cost measures. For example, the MSPB measure once had a minimum case threshold of 125 cases because CMS's analyses suggested that many cases were necessary to get a statistically reliable result. Yet, in the CY 2017 QPP final rule, CMS lowered the MSPB minimum volume threshold from 125 cases to just 20 cases. We do not believe the measure has changed in such a way that it achieves reliable results without the higher case threshold, and worry that with the lowered threshold, physicians will be rewarded or penalized based on random variation, not real performance differences. Further, these measures are calculated solely on the basis of Medicare Fee for Service (FFS) patients. In some parts of the United States, such as California, many communities are dominated by Medicare Advantage plans and the number of Medicare FFS patients is so small a portion of the population that many practices would have insufficient numbers of patients, and the patients that choose to stay in FFS may have more medical conditions or more expensive conditions than those who find Medicare Advantage to be their best option. Thus, these measures may provide a very skewed portrait of the physicians' practice pattern.

In addition, the MSPB measure once included specialty adjustment to account for differences in specialty mix that can affect the costs of care. CMS removed this adjustment several years ago by simply suggesting it was "unclear" whether the adjustment helps to account for cost differences by specialty. The agency did not provide a complete analysis to demonstrate this finding. In this year's rule, CMS proposes to calculate medical and surgical episodes of care differently using slightly different attribution rules for each type of episode. Conceptually, this may help to address the longstanding concern that a lack of specialty adjustment could lead to inferior performance for more expensive specialties. But the information provided in the proposed rule and on CMS's website are insufficient to make this judgment. CMS needs to be more transparent about the nature and impact of this change.

We also remain concerned that the basic performance attribution approach for the MSPB and total per capita cost measures in the MIPS lacks a "line of sight" from clinician actions to measure performance. The measures do not reflect the performance of just the clinician or group practice. Rather, the measures attribute all of the Medicare Parts A and B costs for a beneficiary during a defined episode (three days prior to 30 days after an inpatient admission for MSPB, and a full year for total cost per capita). Yet these costs reflect the actions of a multitude of health care entities – hospitals, physicians, post-acute providers, etc. The ability for any clinician or group to influence

overall measure performance will vary significantly depending on local market factors, including the prevalence of clinically integrated networks.

Furthermore, while we appreciate the concept behind the episode-based measures, we are concerned that clinicians have had limited time to understand their baseline performance and implement changes to improve performance. In contrast to the two total cost measures, the episode-based measures include only the items and services related to the episode of care for a particular treatment or condition. This measurement approach can result in a more clinically coherent set of information about cost. However, this approach also necessitates the use of algorithms for identifying costs relevant to an episode, and a multi-step approach for attributing measure performance. This methodology adds necessary rigor, but also adds enormous complexity. Yet, clinicians only have information from previews that CMS conducted using data from 2016 and 2017.

Lastly, before increasing the weight of the cost category further, we urge CMS to assess the extent to which sociodemographic factors impact cost measure performance. Sociodemographic adjustment should be incorporated as needed. The evidence showing the link between sociodemographic factors and patient outcomes continues to grow. Most recently, this connection is clearly evident in a report to Congress from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and in the National Academy of Medicine's (NAM) series of reports on accounting for social risk factors in Medicare programs. Both reports provide evidence-based confirmation of what hospitals and other providers have long known – patients' sociodemographic and other social risk factors matter greatly when trying to assess the performance of health care providers.

The NAM reports show that performance on a variety of outcomes – readmissions, cost and patient experiences – is affected by social risk factors. The ASPE report demonstrates that clinicians, hospitals and post-acute providers alike are more likely to score worse on CMS pay-for-performance programs when they care for large numbers of poor patients. CMS took an important step towards recognizing the impact of these factors by implementing a MIPS "complex patient bonus," but we believe that bonus should be viewed as an interim step while more sophisticated approaches to accounting for social risk factors are developed.

**MIPS – Improvement Activity Category**

The MACRA requires that CMS establish a MIPS performance category that rewards participation in activities that improve clinical practice, such as care coordination, beneficiary engagement and patient safety.

We support CMS's proposal to establish seven factors that it would consider in whether to remove particular improvement activities from its inventory. We believe the criteria are well aligned with the agency's Meaningful Measures framework, and would help promote the inclusion of activities that have a meaningful link to better care.

However, we urge CMS to reconsider its proposal to increase the requirement for how many clinicians within the group must participate in the activity. Rather than requiring that only one

clinician from the group complete an activity, CMS would require that at least 50% of the group's national provider identifiers (NPIs) perform the activity for the same continuous 90-day performance period. We question whether this threshold is achievable, especially for multi-specialty group practices operating under a single TIN. Furthermore, groups generally are expected to participate in more than one activity to receive full credit in this category. As a result, it would be possible – and desirable – for groups to select a range of activities that apply to varying proportions of the clinicians in their groups. A requirement that every improvement activity has participation from 50% of clinicians may result in less – rather than more – engagement in the activity. We recommend that CMS leave the improvement activity participation threshold unchanged for now.

**MIPS – Promoting Interoperability Category**
CMS proposes changes to the promoting interoperability category that affect performance in CYs 2019 and 2020.

*CY 2019 Reporting Changes*
We support CMS's proposed modifications to promoting interoperability measures for the current performance year. Specifically, we support CMS's proposal to change the Query of Prescription Drug Monitoring Program (PDMP) bonus measure to a Yes/No attestation, rather than requiring the reporting of a numerator and denominator. As we noted in our comments last year, PDMP integration with certified electronic health records (EHRs) is not widespread and many eligible clinicians likely need to enter data manually into the certified EHR to document the completion of the query and conduct manual calculation of the measure. We understand that laws in several states do not permit PDMP data to be brought into and stored within a certified EHR, thereby extending the need for manual data entry and manual calculation of the measure indefinitely. We believe moving to a "yes/no" attestation will significantly lessen administrative burden.

We also support CMS's proposed changes to the Support Electronic Referral Loops measures. CMS clarifies that to qualify for the measure exception, an eligible clinician must receive fewer than 100 summaries of care for referrals, transitions of care and new patients combined. Second, CMS would modify the point redistribution for the two Referral Loop measures. If an eligible clinician claims an exclusion for the first Referral Loop measure, the 20 points will be redistributed to the Provide Patients Access measure. If exclusions are claimed for both measures, then 40 points will be redistributed to the Provide Patients Access measure.

*CY 2020 Reporting Changes*
We strongly support CMS's proposal to maintain a reporting period of any continuous 90-day period through the CY 2021 performance year. In addition, we support CMS's proposal to remove the Verify Opioid Treatment Agreement measure. As noted in our 2018 comments, this measure lacks a standard that specifies the data to be included in the agreement. Without such standards and accompanying certification requirements, it is unclear how a provider's certified EHR technology could support this activity.

We also support CMS's proposal to retain the Query of PDMP measure as a bonus measure for CY 2020 reporting. We agree with the agency's assessment that additional time is needed to make

the PDMP measure part of eligible clinician workflows. The measure would continue to be reported as a Yes/No attestation rather than a numerator/denominator measure.

We support CMS's proposed revision of the hospital-based clinician exclusion. Under current policy, groups and virtual groups are considered hospital-based only if 100% of their clinicians meet the definition of "hospital based". However, stakeholders have reported difficulty with meeting the 100% standard, especially given the turnover of staff in some physician groups. Thus, for CY 2020 reporting, CMS proposes that a group or virtual group would be considered hospital-based if more than 75% of the NPIs billing under the group's TIN or virtual group's TINs meet the definition of hospital-based. We believe this is reasonable and aligns with the 75% threshold that CMS uses to determine performance in the facility-based measurement approach in the MIPS cost and quality categories.

Lastly, we support CMS's proposal to continue allowing non-physician clinician types (e.g., NPs, PAs, CRNAs) to reweight their scoring from Promoting Interoperability by not reporting any measures. We agree with CMS's analysis that most of these eligible clinicians are not reporting the Promoting Interoperability measures. Consequently, CMS believes that it does not have enough data to make this category required for these clinician types at this time.

**Medicaid Promoting Interoperability**
We support CMS's proposed changes to the Medicaid Promoting Interoperability Program. We believe it is reasonable for CMS to align the Medicaid eCQMs that eligible professionals (EPs) must report with those in the MIPS. We would urge that the reporting period for the Medicaid Promoting Interoperability program align with that of the MIPS program by allowing clinicians to report data from any 90-day continuous period during 2020.

We also support CMS's proposal to allow EPs to attest to completing a security risk assessment in October 2021, and subsequently submitting evidence that the analysis was complete. The Medicaid Promoting Interoperability program ends in 2021, and the deadline for reporting data would be in October 2021 to ensure states have adequate time to issue payments before the end of that year. Because eligible professionals tend to perform the analysis by the end of the year, they may not have sufficient time to complete the security risk analysis that is required to attest. We believe CMS's proposal to modify the attestation for CY 2021 so that Medicaid EPs could attest that they will have it completed prior to the end of 2021 – and subsequently submit evidence that it was completed – is a reasonable approach.

## QUALITY PAYMENT PROGRAM – ADVANCED ALTERNATIVE PAYMENT MODELS

The MACRA provides incentives for physicians who participate in advanced APMs. These include a lump-sum bonus payment of 5% of payments for professional services in 2019 through 2024; exemption from MIPS reporting requirements and payment adjustments; and higher base payment updates beginning in 2026. For the most part, advanced APM criteria and processes carry over from the CY 2018 QPP final rule.

**General Principles for Advanced APMs**

We support accelerating the development and use of alternative payment and delivery models to reward better, more efficient, coordinated and seamless care for patients. Many hospitals, health systems and payers are adopting such initiatives with the goal of better aligning provider incentives to achieve the Triple Aim of improving the patient experience of care (including quality and satisfaction), improving the health of populations and reducing the per capita cost of health care. These initiatives include forming ACOs, bundling services and payments for episodes of care, developing new incentives to engage physicians in improving quality and efficiency, and testing payment alternatives for vulnerable populations and underpaid services.

Despite the progress made to date, the field as a whole is still learning how to effectively transform care delivery. There have been a limited number of Medicare APMs introduced thus far, and existing models have not provided participation opportunities evenly across physician specialties. Therefore, many physicians are still exploring APMs for the first time or at only the early stages of transforming care under APM arrangements. As a general principle, we believe the APM provisions of MACRA should be implemented in a broad manner that provides the greatest opportunity for physicians who so choose to become qualifying APM participants. CMS should take an expansive approach that encourages and rewards physicians who demonstrate movement toward APMs. The agency also should ensure that it designs APMs with a fair balance of risk and reward, standardized and targeted quality measures and risk adjustment methodologies, physician engagement strategies, and readily available data and feedback loops between CMS and participants.

While we acknowledge and appreciate CMS's development and implementation of more APMs that qualify as advanced APMs, we continue to be concerned that these existing and announced APMs offer too few opportunities for certain types of providers that serve more dispersed and vulnerable populations. For example, rural providers often lack the access or ability to make investments needed to participate in new models, among the many other challenges they face given their geographic location, low patient volumes, aging infrastructure, workforce shortages and other factors. High-risk APMs are not accessible to these providers, even those that wish to participate in them. Similarly, post-acute and behavioral health providers serve particularly challenging and unique populations and thus are in need of APM options tailored to the degree of risk they can manage given their patient populations. CMS should consider these and other providers when designing APMs and expand opportunities for them to participate in advanced APMs that offer targeted resources and a manageable amount of risk.

**CY 2020 Proposals**

We support CMS's proposal to expand its definition of medical homes to include medical homes operated by another payer that is formally collaborating in a CMS multi-payer model through a written agreement. The emergence of such models makes it important for CMS to have a mechanism to capture them and give participating professionals an opportunity to be rewarded under the advanced APM track.

We also support CMS's revised approach to calculating marginal risk rates for other payer advanced APMs. CMS believes its current marginal risk standard of 30% sometimes prevents it

from approving other payer models that have otherwise strong financial risk requirements. Some of these models use marginal risk rates lower than 30% only when participants are at risk for much higher levels of losses. The agency believes this is to protect participants from potentially catastrophic losses and undue financial burden. As a result, CMS proposes to provide that, in the event the marginal risk rate varies depending on the amount by which actual expenditures exceeds expected expenditures, it would use the average marginal risk rate across all possible levels of actual expenditures to determine whether the payment arrangement has a marginal risk rate of at least 30%.

We thank you for the opportunity to provide these comments on this proposed rule and look forward to working with you in the future to find solutions to benefit hospitals, providers and patients. Should you have any questions, please do not hesitate to contact Jonathan Chebra, Senior Director of Federal Affairs, at jchebra@njha.com or 609-275-4100.