June 27, 2016

Andrew Slavitt
Administrator
Center for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-5517-P Medicare Program; Notice of Proposed Rulemaking Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Administrator Slavitt:

I write to share the comments of the National Coalition on Health Care (NCHC) on the Notice of Proposed Rulemaking (NPRM) regarding implementation of the core Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

NCHC is a coalition of health care stakeholder organizations committed to promoting an affordable, high-quality health system in the United States. As the nation’s oldest and most diverse group working to achieve comprehensive health reform, we represent more than 85 member organizations, including health care providers, purchasers, payers, and consumers.

We applaud CMS for the extraordinary effort it has devoted to the implementation of MACRA and its commitment to stakeholder engagement throughout the process.

The fee-for-service (FFS) payment model, as it exists today, encourages volume and complexity in health care services and drives up health care costs. It provides little incentive for the robust care coordination and high quality care that patients, especially the most vulnerable, deserve. Enhancing the
affordability of health care will require both expanding alternatives to fee-for-service and improving existing payment systems like Medicare’s physician fee schedule.

For this reason, NCHC fully supports CMS’ goal for the Merit-Based Incentive Payment System (MIPS), evaluating clinicians in a way that supports the triple aim, as well as CMS’ goals for the Advanced APM Incentive:

- expand participation in APMs
- maximize participation in current and future Advanced APMs
- create clear and attainable standards for incentives
- promote the continued flexibility in the design of APMs
- support multi-payer initiatives across the health care market

In general, the NPRM offers thoughtful proposals to achieve those goals. In the pages below, we express NCHC’s support for a number of those proposals, along with suggestions for their refinement. NCHC particularly appreciates CMS’ efforts to promote greater use of outcome, EMR- and registry-based quality measures as well as its efforts to establish a glide path to broader participation in Advanced APMs and APMs in general. We also urge CMS to take steps to help more providers to meet its rigorous criteria for the Advanced APM Incentive. These steps include expanding proven primary care medical home models, enabling track one MSSP ACOs to move to two-sided risk after any performance year, adjusting existing models to conform to the proposed Advanced APM criteria and aggressively developing more specialty-focused models.

However, in a few limited but crucial respects, CMS’ proposals related to MIPS APMs and Advanced APMs would seriously undermine its own stated goals of expanding participation in APMs and Advanced APMs in particular. We are specifically concerned by:

- the exclusion of episodic bundling models other than the Oncology Care Model from both the MIPS APM and the Advanced APM categories;
- an approach to Medicare Advantage Advanced APMs which could slow providers’ embrace of some of the most sophisticated Alternative Payment Models
- a flawed framework for determination of Qualifying and Partially Qualifying Advanced APM Participants which discourages participation in Advanced APM models.

Finalization of these particular proposals could make MACRA’s regulatory structure substantially less effective. In the pages below we suggest alternative means of addressing these challenges.

**Detailed Comments on MIPS Submission:**

*NCHC strongly supports requiring health IT vendors, Qualified Clinical Data Registries (QCDRs) and qualified registries to allow for submission of all performance categories as soon as practicable. We*
agree that enabling clinicians to report through a single means would reduce administrative burden—freeing clinicians to focus on patient care.

Quality Category:

NCHC supports requiring MIPS measures to be evidence-based, reliable and valid.

NCHC strongly supports CMS’ focus on encouraging the use of high-quality outcome measures, and particularly appreciates the proposal to award additional bonus points for MIPS clinicians who select more than one outcome measure.

NCHC supports the move toward core measure sets across payers, as exemplified by the work of the Core Measures Collaborative. We applaud the identification of core measure sets in the NPRM and believe it is a constructive step toward broader adoption. Broader use of core measure sets can support comparability across clinicians, ultimately making the reported measures more useful for consumers, providers and plans.

We urge CMS to clearly communicate its interest in the selection of Patient-Reported Outcome Measures (PROMs) as well as clinical outcome measures. While PROMs are indeed a form of outcome measure, it is necessary to specifically prioritize those outcome measures using patient-generated data. Assessing what is important to patients is a key element of patient-centered care and can enable shared decision-making and care planning.

NCHC also strongly supports the proposal to award additional bonus points for MIPS clinicians who submit measures electronically via QCDRs, qualified registries, CEHRT and CMS web interface. NCHC is also pleased by CMS’ interest in enabling MIPS providers to report through qualified registries on all subcategories, including ACI and CPIA. Use of a single reporting mechanism will reduce reporting burden and enable clinicians to focus their attention on patient care. We urge CMS to do all it can to make this a reality for MIPS clinicians as soon as possible.

NCHC supports the proposal to assess clinicians on global, population-based metrics, and particularly appreciates the proposal to do so without imposing additional reporting burden on clinicians.

Finally, we were encouraged by the inclusion of thirty pediatric-specific quality measures in the MIPS measure set described in Table A. Although the bulk of Medicare beneficiaries are adults, this is a welcome recognition that children and adolescents will be impacted by this Medicare rule. In addition to promoting quality care for Medicare-enrolled children, CMS’ attention to pediatric measures helps support alignment across the measure sets used by Medicare, Medicaid, CHIP, commercial and employer-based coverage. However, we note that only the pediatrics measures in the Rule appear to be included within the Children’s Health Insurance Program Reauthorization Act (CHIPRA) Core Set. We suggest that CMS align these lists.
Non-Clinical Measures and the MIPS Quality Category

The Centers for Disease Control and Prevention has estimated that 90% of health care outcomes are due to factors external to the health care services received or the health care setting. Therefore, MIPS’s ultimate success in incentivizing physicians to improve care outcomes will substantially depend on whether quality measures assess the extent to which clinicians are reaching beyond the four walls of the clinic to address a range of non-clinical factors that influence health outcomes and costs.

Admittedly, current statute presents barriers to broader use of effective non-clinical interventions. Medicare generally does not reimburse providers or most plans for non-medical services like in-home support, nutrition services (except for post-operative care), or other social services—even when they might prevent future downstream medical costs. Congressional action is necessary to address some of these barriers.

But even under existing statute, CMS can do more to encourage MIPS and Advanced APM clinicians to pay attention to non-clinical factors and deploy non-clinical interventions.

1. NCHC supports the proposed inclusion of several specific measures that begin to broaden the clinician’s focus in the proposed list of quality measures for MIPS in 2017, including but not limited to:
   - Dementia: Caregiver Education and Support
   - Falls: Risk Assessment
   - Falls: Plan of Care
   - Initiation of Alcohol and Other Drug (AOD) Dependence Treatment
   - Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy

2. Moving forward, we encourage CMS to work with the measure developers, the National Quality Forum and the Measures Application Partnership to ensure that a broader array of measures in this area are available for inclusion in MIPS and other quality programs. For example, the recently launched Prevent Diabetes STAT program is working to increase the number of physicians who screen patients for pre-diabetes and refer them to community diabetes prevention programs. One analysis estimates pre-diabetes screenings and lifestyle change interventions have the potential to save $539 billion in medical costs over a 10 year period. The dramatic potential for savings underscores the need to make such screening for and referrals to the programs like this a priority.

3. Moving forward, CMS may wish to consider additional incentives for MIPS clinicians who select certain non-clinical measures, either by providing additional bonus points for their

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selection, including the measures in the relevant core measure sets, or including such measures in
the cross-cutting measure set.

As stated below, NCHC supports the inclusion of a Social/Community Involvement sub-category under
the Clinical Practice Improvement Activities (CPIA) category. However we note that the entirety of
CPIA activities would account for only 15% of total MIPS score, whereas the Quality category accounts
for 50%. Including measures of the use of and referral to appropriate non-clinical services and
interventions under the Quality category will maximize the impact of these interventions on Medicare
beneficiaries’ health outcomes and costs.

**Resource Use Category:**

We agree that resource use is an integral part of value.

We also appreciate CMS’ interest in starting with existing condition and episode-based measures, the
Medicare Spending per Beneficiary measure and the total per capita costs for all attributed beneficiaries
measure (total per capita cost measure). These measures are currently used in the Value-Based Modifier,
and their use in the first year may serve as a helpful transition for clinicians. However, we note that
physician organizations have expressed concern that the MSPB and total cost measures were designed
for hospitals. NCHC looks forward to working with CMS as the resource use measures evolve in the
future.

To ensure fairness and accuracy and to encourage clinicians to treat the sickest patients, we support
adjusting both of the resource use measures for beneficiary risk factors.

However, we recognize that resource use measurement, when poorly implemented, has some potential to
discourage needed care. We, therefore, urge CMS to build in mechanisms for monitoring Medicare
beneficiaries’ access to care and develop safeguards to prevent adverse outcomes for consumers (in
both the MIPS and APM pathways). Education for clinicians about how the resource use performance
scores are computed and risk-adjusted will be essential. Evaluations of access to care and appropriate
services for beneficiaries must have the ability to examine impact for vulnerable subpopulations (and not
just average beneficiaries).

**Clinical Practice Improvement Activities Category:**

*NCHC strongly supports the NPRM’s proposal to offer higher CPIA scoring for CPIA activities that
help develop the capacities providers need to manage populations and move toward more advanced
payment models.*

*NCHC supports the proposal to establish a Behavioral Health Integration sub-category in 2017. An
integrated approach to delivering behavioral health services and primary care enjoys robust evidentiary*
support in both the primary care and specialty mental health settings. Including Behavioral Health Integration as a sub-category can help encourage broader adoption of such integration.

_NCHC urges recognition of Social/Community Involvement activities that increase beneficiaries’ use of community services or foster partnerships between MIPS clinicians and community service providers._ Specifically, evidence-based activities that merit particular attention include a Diabetes Prevention Program or Chronic Disease Self-Management Training, falls prevention assessments, and appropriate beneficiary utilization of nutrition or housing resources.

_NCHC suggests that capturing and using patient-reported outcomes be given greater weight in CPIA (from medium to high) and that specific guidance is provided to be used to support development of patient-reported outcome measures._

We note that proposed list of Clinical Practice Improvement Activities, detailed in Table H of the proposed rule, includes a variety of activities involving registries: participation in a QCDR, use of a QCDR to analyze practice patterns and outcomes, and Participation in a QCDR, clinical data registry or other registry establishing by government agencies or medical organizations, and participation in a QCDR accompanied by a variety of patient engagement activities, use of QCDR data for practice assessment and patient safety improvement, participation in a QCDR demonstrating performance of social determinants of health screening, participation in a QCDR supporting patient-reporting outcome tools and data, participation in a QCDR with use of standard questionnaires related to disparities in functional outcomes.

_NCHC greatly appreciates the proposed rule’s recognition of the contribution that registries in general and QCDRs in particular can make to the improvement of clinical practice._

**Advancing Clinical Information (ACI) Category**

Today, the fundamental challenge in health information technology policy is the lack of interoperability and exchange of health information. If provider and plan organizations remain siloed with non-interoperable technology, even substantially broader adoption of technology will be insufficient to achieve the population-wide improvement in outcomes and efficiency the United States needs.

But currently, most EHR vendor products simply exchange static documents that really only satisfy the minimum meaningful use requirements. The lack of interoperability is one of the major reasons why the promise of electronic health records has not been fulfilled. MACRA offers an opportunity to change this disappointing situation, and CMS ought to take advantage of it. _NCHC urges CMS to refocus the ACI requirements to support the urgent task of promoting interoperability and health information exchange._

CMS should also redesign the Advancing Care Information requirement to support the exchange of clinical and administrative data between and among providers and payers. For example, CMS may wish to consider moving toward a requirement that all clinicians to report on health information exchange.
To enhance alignment across payers and reduce reporting burden, CMS should explore the feasibility of allowing clinicians to submit advancing care information data for other payers through the same mechanisms as proposed in MIPS—qualified registry, EHR, QCDR, and CMS Web Interface submission methods—and at the same time permit other payers to use these mechanisms to exchange data with clinicians.

**Timeliness of Performance Feedback**

Based on dialogue with NCHC’s member organizations engaged in quality improvement from the perspective of fee schedule clinicians, hospitals, plans and consumers, NCHC has concluded that once-annual feedback is fundamentally inadequate to support ongoing quality improvement efforts. We respectfully ask that CMS take this opportunity to indicate whether it shares this conclusion and the basis for its view.

**MIPS APMs**

NCHC strongly supports scoring APM participants under a MIPS APM scoring standard, enabling participating providers to be scored collectively. By offering MIPS clinicians a degree of relief from the financial risk and reporting burden associated with reporting individually, this policy should go a long way toward achieving the Quality Payment Program’s stated aim of encouraging APM participation.

However, CMS must address a fundamental problem with its definition of MIPS APMs. If the NPRM’s proposed criteria for MIPS APMs are finalized along with the NPRM’s proposed definition of Advanced APMs, bundled payment models outside oncology would be excluded from MIPS APM and the Advanced APM. This amounts to a policy decision to push Medicare providers into population health models rather than episodic bundling models. Such a decision would be precipitously premature. CMS has neither explained the empirical or policy justification for this course of action nor has CMS sought comment on it.

To address this problem, NCHC offers two specific recommendations, described below.

*First, NCHC suggests that CMS use a consistent approach for who is considered a participant under Advanced APMs and MIPS APMs. Under the APM Incentive, CMS proposes to use affiliated practitioners, eligible clinicians who are in a contractual relationship with an Advanced APM Entity based at least in part on supporting the Advanced APM Entity’s quality or cost goals under the APM, to determine the eligible clinicians used for the Qualified Participant (QP). We believe this approach can also be applied to MIPS APMs.*

*Second, we encourage CMS to eliminate the requirement that the MIPS APM entity base payment incentives on quality performance. Rather, in the particular case of MIPS APMs, the requirement should be simply that the MIPS APM entity reports measures of quality and bases incentives on cost/utilization. The Merit-based Incentive Payment System (MIPS) itself adjusts clinician payment based on quality measures. Since MIPS APMs quality performance information is applied to determine a MIPS*
composite performance score, it is not necessary to require that the APM model also base incentives on quality. Regardless of the payment incentives, all clinicians in APM Entities have a goal of collective success under the terms of the APM entity are ultimately working in coordination to achieve quality and cost benchmarks, similar to group reporting.

**Physician Compare**

Publicly available performance information is central to understanding value-based performance, and we applaud CMS for increasing the availability of this information. NCHC supports placing MIPS performance information on a public Web site (for example, Physician Compare).

**Detailed Comments on Advanced APMs and Other Payer Advanced APMs**

**Advanced APM Criteria**

*Certified EHR Technology:*
NCHC supports requiring at least 50% of eligible clinicians to use CEHRT in 2017, while enabling that percentage to be increased in future years. The flexibility associated with this approach is important as it permits existing APMs to continue to build upon their current practices.

*Applicable Quality Measures:*
NCHC supports the proposal to require one outcome measure and one measure from a defined set of measurement sources. This approach provides appropriate flexibility for Advanced APMs to require additional quality measures that best fit the needs of that payment/care delivery model and support the development of new, innovative quality measures. Advanced APMs are free to select additional measures from the named sources or add additional outcomes measures, but are not constrained to do so.

Ultimately, though, the Advanced APM quality measures will only be as strong as the underlying models’ requirements. Currently, there is no consistency across models in obtaining stakeholder feedback on the quality measure sets. NCHC strongly recommend that multistakeholder input on APM quality measures and other design elements be a standard part of the process.

*Financial Risk Standard:*
In our RFI response, NCHC recommended two general goals that enjoyed broad agreement among stakeholders:

a. Encourage progression among the subset of Medicare providers who participate in [APMs] currently and
b. Actively seek to increase the percentage of providers participating in APMs and the proportion of patients relying on their care.
We were pleased to see these goals reflected in CMS’ own stated goal of “maximizing participation in both Advanced APMs and other APMs.”

However, it is not clear that the approach to risk proposed in the NPRM best serves that goal. Under the proposed rule as little as 4.5 percent of eligible clinicians are anticipated to qualify as a participant in an Advanced APM. **NCHC urges CMS to carefully evaluate whether its overall approach could lead some clinicians to give up pursuit of AAPMs rather than seek out more advanced models and, if so, explain how such an outcome is consistent with its stated goals prior to finalizing any of its proposed financial risk standards.**

Should CMS finalize the ‘high bar’ approach as detailed in the NPRM, it still has at its disposal strategies to expand Advanced APM participation without compromising CMS’ stated commitment to “financial risk criterion that should be met only by those APMs that are most focused on challenging organizations, physicians, and practitioners to assume financial risk and provide high-value care.” **NCHC strongly urges CMS to pursue four such strategies:**

First, NCHC notes the relative lack of models focused on specialty care which would qualify under the NPRM as Advanced APMs. **CMS, through the Center for Medicare and Medicaid Innovation, should prioritize the aggressively development and testing of specialty-focused models that meet the final rule’s Advanced APM criteria.**

Second, in the Medicare Shared Savings Program, to facilitate more rapid progression toward two-sided risk models, **CMS should enable track 1 ACOs to move up to risk-based contracts after any performance year.** We note that early-adopting MSSP ACOs that decided to pursue a second three-year contract in Track One will lack a mechanism to advance to higher tracks—at least until the conclusion of their contract period in 2019. This particular misalignment between MACRA’s incentives and ACOs’ ability to act in response to those incentives could undercut CMS’ stated goal of promoting participation in Advanced APM Models.

Third, CMS should vigorously monitor the progress of CPC, CPC+ and other advanced primary care models. **In the event that any of these primary care models produce positive results, we urge the Secretary to proceed as rapidly as possible with the process of certifying and expanding them.**

Fourth, we urge CMS to make the adjustments necessary to ensure that those Alternative Payment Models which have produced the greatest per-beneficiary savings qualify as Advanced APMs—provided those models do not negatively affect quality. According to information released to date, episodic...
bundling for orthopedic procedures\(^2\) and the Independence at Home Practice Demonstration\(^3\) have demonstrated substantially greater per-beneficiary savings than other CMS models. Yet CMS has crafted a definition of Advanced APMs that excludes both. Excluding these models would actually incentivize providers to choose APMs that produce less cost savings. The adverse consequences of such a decision are clear. In Medicare, forgoing those cost savings would negatively impact the Medicare Trust Funds and increase Medicare premiums. If other payers were to mirror CMS’ approach, they too would push providers away from those cost saving models and toward more costly APMs.

**Medical Home Financial Risk Standard:**
Given the importance of primary care services to person-centered, value-based payment arrangements, NCHC supports establishing a financial risk standard specific to medical home models which would permit a performance-based forfeiture of an expected payment to count as risk. We agree with CMS that requiring medical home models to meet the generally applicable standard at this time would be inadvisable because smaller medical homes typically lack the financial capacity to assume risk and because other payers have yet to require assumption of risk in their medical home payments.

However, a payment arrangement that causes an APM entity to lose the right to all or part of an otherwise guaranteed payment should be a qualifying financial risk standard for all types of APM entities, not just medical homes. The logic underlying this behavioral economics theory should apply to physicians regardless of the type of APM they are participating in, and will be a significant incentive to realizing the desired physician behavior across all APM models.

**Medical Home Nominal Amount Standard:**
NCHC supports the establishment of a lower numerical nominal amount standard for medical home models.

**Capitation:**
NCHC agrees that fully capitated models meet the Advanced APM financial risk criteria for financial risk bearing and nominal risk amounts

We also encourage CMS to consider partial capitation models to have met the financial risk criteria if the portion of payment that is capitated surpasses the nominal risk requirement applicable to similar APMs.

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Qualifying Advanced APM Participant Determination and Partially Qualifying APM Participant Determination

NCHC is deeply concerned that the NPRM’s proposed Advanced APM and Partially Qualifying APM Participant Determination provisions could weaken the incentive to participate in Advanced APMs originally intended by Congress.

Congress established the Advanced APM Incentive to encourage participation in Advanced APMs – defined as those facing more than nominal risk, utilizing Certified Electronic Health Record Technology, and relying on quality-based payment. That encouragement came in the form of increased certainty. That certainty was to come operationally through relief from MIPS reporting requirements and penalties for Qualifying APM Participants (QPs) and Partially Qualifying APM Participants. It was to come financially through the Advanced APM Incentive payment and in 2026 through a higher payment update.

Regrettably, this NPRM would alter that deal, by informing providers whether they would be QPs by the middle of the year after the performance year. The uncertainty that follows from this seemingly innocuous delay meaningfully undermines the achievement of a core goal of MACRA: expanding participation in Advanced APMs.

First, it will force APM Entities and their participating providers to gather performance information sufficient to report under MIPS – even if they ultimately will be achieve QP or Partial QP status. With little way of knowing whether they are exempt, all or nearly all participants in advanced, two-sided risk models like Track 2 and 3 MSSP ACOs, ESRD Model, the Oncology Care Model or Next Gen ACOs could find it necessary to assume reporting burdens for both their chosen APM and MIPS.

Second, providers participating in these Advanced APMS will face significant uncertainty that they will meet the thresholds for Advanced APM status and thereby secure the 5% APM bonus. Providers’ decision to pursue Advanced APM status or not is further complicated by the fact that the maximum potential upside under MIPS in the first year is substantially higher than the 5% Advanced APM Incentive Bonus.

As a consequence of this delay then, some providers will choose not to participate in Advanced APM models who might otherwise have done so. For this reason, CMS should explore the feasibility of alternative regulatory arrangements that provide greater certainty regarding reporting requirements and access to the Advanced APM Incentive Bonus.

If, however, the NPRM approach and timeline is finalized, at a minimum, we urge that CMS adopt a strategy to ameliorate the negative impacts on Advanced APM participation. CMS should allow those providers who qualify for Advanced APM status and report under MIPS to choose either the 5% APM bonus or the bonus which they would receive under MIPS. By ensuring that providers who succeed in the most advanced payment models can be certain of better payment under MACRA’s provisions, this
recommended approach would better serve CMS’ stated goal of “maximizing participation in current and future Advanced APMs.”

**Medicare Advantage Plans**

Under the proposed rule, clinicians would not be able to count Medicare Advantage Advanced APM revenues or Medicare Advantage Advanced APM patients toward the Qualifying Advanced APM Determination thresholds. Additionally, Clinicians participating in these Medicare Advantage Advanced APMs would not receive a 5% bonus on the revenue they received to treat these beneficiaries. From a policy perspective, failure to integrate MA Advanced APMs into the Advanced APM Incentive runs counter to CMS’ stated aim of maximizing participation in Advanced APMs. After all, as of today, the most advanced, fully capitated provider payment models are only available to Medicare beneficiaries through Medicare Advantage.

From a statutory perspective, because MA and other Medicare plans do pay providers to furnish Part B services to Medicare beneficiaries, we believe CMS has discretion to take a different approach toward Advanced APMs furnishing Part B services to MA beneficiaries.

*NCHC recommends that CMS count payments from MA plans for Part B professional services furnished through an Advanced APM towards the Qualifying Advanced APM Determination thresholds. We further suggest that the plan should receive an upward adjustment in its payment from CMS, equal to 5% of the Part B professional services furnished through an Advanced APM paid by the MA plan, and that the plan would have to pass through this upward adjustment to the clinician. We urge CMS to implement these changes for the 2019 payment year.*

**Advanced APM Incentive Payment**

NCHC also has concerns regarding the NPRM’s approach to calculating the Advanced APM Incentive Payment—specifically its approach to payments made on other than a fee-for-service basis. Taken together, the exclusion of financial risk payments (like the bonuses ACOs pay to their participants), the proposal to assess supplemental service payments (like per member per month payments in primary care models) on a case by case basis, and the treatment of cash flow mechanisms (like Next Gen ACO Model’s Population Based Payments) ensure that the calculation of the incentive payment remains based on the volume of Part B services. This replicates, in miniature, the very volume incentives which MACRA was enacted to reform. *CMS should expand its definition to include financial risk payments, supplemental service payments and cash flow mechanisms associated with Advanced APM models.*

**Consumer Protections in Alternative Payment Models**

As CMS continues to develop new payment and delivery models, and as providers take on more risk (with associated rewards and responsibilities), it is important that CMS ensure that consumer protection policies keep pace with the changing environment. Therefore, we urge CMS to clarify how consumer protections will meet these new challenges. *Specifically, we ask that CMS address issues related to*
noticing consumers about their participation in an advanced APM, as well how the Agency intends to conduct consumer outreach and education around advanced APMS, and how the Agency will ensure adequate protections concerning alignment, attribution, and data sharing.

Additionally, CMS must monitor the impact of the new payment models on patients and families, and build in capabilities or processes to respond to and adjust as appropriate to prevent or minimize unintended negative consequences.