

March 1, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: Eric Gilbertson, CMS MACRA Team
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS Quality Measure Development Plan: Supporting the Transition to the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) (DRAFT)

Dear Acting Administrator Slavitt:

On behalf of the American College of Physicians (ACP), I am writing to share our comments on the Centers for Medicare and Medicaid Services' (CMS) draft Quality Measure Development Plan to support the implementation of the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

#### I. Guiding Principles

First, ACP would like to reiterate our call for CMS to use the opportunity provided through the new MACRA law to build a learning health and healthcare system. It is critically important that the new payment systems that are designed through the implementation of MACRA reflect the learnings from the current and past programs and also effectively allow for ongoing innovation and learning. Also important is the need to constantly monitor the evolving measurement system to identify and mitigate any potential unintended consequences, such as increasing clinician burden and burn-out, adversely impacting underserved populations and the clinicians that care for them, and diverting attention disproportionately toward the things being measured to the neglect of other critically important areas that cannot be directly measured (e.g., empathy, humanity).

Second, the College recommends that CMS work to ensure that patients, families, and the relationship of patients and families with their physicians are at the forefront of the Agency's thinking in the development of both the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APM) pathways, including the development and implementation of the performance measures to be used within these programs. It is critically important to recognize that the legislative intent of MACRA is to truly improve care for Medicare beneficiaries and thus, the policy that is developed to guide these new value-based payment programs must be thoughtfully considered in that context.

Third, the College strongly recommends that CMS collaborate with specialty societies, frontline clinicians, and EHR vendors in the development, testing, and implementation of measures with a focus on decreasing clinician burden and integrating the measurement of and reporting on performance with quality improvement and care delivery.

## II. Summary of ACP Recommendations

# **CMS Strategic Vision of the Measure Development Plan**

- The College strongly recommends that CMS actively work to improve the measures to be used in the quality performance category of MIPS. Therefore, we believe that CMS should NOT consider the existing quality measure sets within Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VBM), and Meaningful Use (MU) as the starting point for its measure development plan.
- In the short term, ACP recommends that CMS utilize the core set of quality measures identified and recently released by the America's Health Insurance Plans (AHIP) collaborative.
  - Additionally, the College recommends that any measures outside of the core set that have been identified by the AHIP collaborative and that have not been endorsed by the Measure Application Partnership (MAP) not be used within the MIPS program.
  - Further, the College recommends that CMS consider the recommendations made by ACP's Performance Measurement Committee with regard to measure selection within MIPS.<sup>1</sup>
- Over the longer term, ACP stresses that it will be critically important for CMS to
  continue to improve the measures and reporting systems to be used in MIPS to ensure
  that they measure the right things; move toward clinical outcomes, patient- and familycenteredness measures, care coordination measures, and measures of population
  health and prevention; and do not create unintended adverse consequences.
  - o In the progression toward longer term goals, ACP is strongly supportive of filling the critical gaps in quality measurement.

2

<sup>&</sup>lt;sup>1</sup> "ACP Performance Measure Recommendations." American College of Physicians. https://www.acponline.org/clinical\_information/performance\_measurement/.

- CMS must begin to work with stakeholders, ideally starting with practicing clinicians and their patients, as well as specialty societies, to openly discuss the next steps that can be taken to build a more meaningful measure portfolio.
- ACP also strongly recommends electronic specification of the measures as one of the top considerations for filling measure gaps.
- While clinicians within MIPS need to satisfy the quality, resource-use, and clinical practice improvement categories, as well as meaningful use (MU), their MU activities should be in support of and NOT an additional set of unrelated requirements.
- In defining new, more appropriate MU-function measures and activities, the College recommends that CMS and the Office of the National Coordinator for Health Information Technology (ONC) start by collaborating with physicians and other clinicians to determine the key tasks that physicians and other clinicians and staff will need to perform better to improve care.
- The College believes that the current nine-measure reporting requirement for PQRS is arbitrary, burdensome, and does not contribute to the delivery of effective and efficient care. Rather, practices should be required to report only measures within any National Quality Strategy (NQS) domain that are truly applicable to their patient population. Therefore, we do not recommend that CMS establish a minimum number of outcomesbased measures, at least initially.
- ACP recommends that CMS include an additional general principle that specifically
  prioritizes addressing the significant administrative burden that clinicians and their staff
  face under the current quality reporting systems.
- CMS needs to collaborate with clinicians and specialty societies to ensure that individuals are not held accountable for measures that are designed to assess community-level outcomes.

## **Operational Requirements of the Quality Measure Development Plan**

- CMS should be open to not only adding measures to the reporting portfolio as appropriate, but also regularly removing measures from that are determined to be of little value.
- It is critical that patients consistently receive the highest quality, most evidence-based, and appropriate care possible; therefore, the College recommends that CMS ensure that all quality measures used within the MIPS or APM pathways be based on the most upto-date clinical practice guidelines, to the extent feasible.
- The College recommends that CMS consider establishing safe harbors for entities that are taking on innovative approaches to quality measurement and improvement.
- ACP strongly recommends that patients and families be involved in all aspects of measurement development and improvement across all of the domains outlined within the Measure Development Plan.
- The College recommends that measure developers carefully consider risk-adjustment models and ensure flexibility as a key part in maintaining professional buy-in and removing incentives for clinicians to disenroll patients considered to be problematic or to provide treatment that the clinician judges is not in the patient's interest.
- Regarding care coordination measures, ACP recommends:

- That CMS consider our recent <u>comments</u> to the agency's request for information (RFI) on certification frequency and requirements for the reporting of quality measures. New electronic Clinical Quality Measures (eCQMs) should be constructed based on a standard model, including standard structures, vocabularies, expression language, and value-sets that express real-world practice.
- That CMS consider how to advance truly practical interoperability, rather than as the movement of structured sets of non-contextual data from place to place without a defined purpose (as was outlined in detail in our recent <u>comments</u> on Stage 3 of Meaningful Use).
- That the use of high-value care coordination tools by clinicians should be deemed as counting toward ones score within the Clinical Practice Improvement Activity (CPIA) category and could also help facilitate the longer term development of care coordination measures.
- The College strongly recommends that the term <u>patient experience</u> be thoughtfully considered by CMS as new measures are being developed.
  - Along these lines, the College seeks clarity from CMS with regard to their statement that they "will continue to develop new patient experience surveys."
  - Further, ACP recommends that CMS remove the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey from the quality performance category of MIPS and instead allow use of CAHPS as one possible component of the clinical practice improvement activities, in the subcategory of beneficiary engagement.
- The College recognizes that individual clinicians do have a responsibility to work collaboratively with their patients to address and mitigate, to the extent possible, <u>population- and community-level issues</u> that impact patient health and well-being.
  - However, attributing population health measure outcomes to specific clinicians is not appropriate and, in fact, defeats the purpose of population health measures.
  - In order to move toward developing measures that are appropriate for individual clinicians, CMS must collaborate with clinicians and specialty societies to ensure that individuals are not held accountable for measures that are designed to assess community-level outcomes.
- With regard to efficiency and cost reduction, the College recommends that CMS:
  - Consider the recommendations that ACP has developed as part of our High-Value Care Initiative<sup>2</sup> as they look to develop measures and also for clinicians to receive credit for the CPIA category of MIPS.
  - Make it a priority to ensure that clinicians are provided with the most up-to-date data at the point of care in order to facilitate cost-conscious decision making.
- In terms of <u>applicability of measures across healthcare settings</u>, ACP recommends that the Agency proceed carefully as it strives to meet this requirement. Measures intended

4

<sup>&</sup>lt;sup>2</sup> "High Value Care: Clinical Recommendations." American College of Physicians. https://hvc.acponline.org/clinrec.html

to assess other healthcare settings, such as hospitals and facilities, may not be appropriate for determining the performance of individual clinicians.

- Therefore, it is critical that CMS collaborate with clinicians and specialty societies to ensure that individuals are held accountable only for measures that are designed to assess outcomes within the reasonable control of the clinician.
- For Clinical Practice Improvement Activities, the College recommends the following:
  - Multiple pathways to Patient-Centered Medical Home (PCMH) or PCMH specialty practice should qualify to achieve full credit in this category, including certification as a PCMH through a national recognition or accreditation program; by a private payer and/or state government program, including state Medicaid programs; as well as those developed by national specialty societies, state medical societies, county medical societies, community-based physician groups, or other entities as deemed appropriate.
  - In addition to the subcategories and examples specified in MACRA legislation, any quality improvement activity that an eligible professional (EP) is involved in should count toward the clinical practice improvement activities category.
  - O In assessing the performance of EPs on clinical practice improvement activities, CMS must ensure that administrative burden associated with documentation of the activities, as well as the cost of performing the activities and submitting documentation is minimal and constructed to be extremely flexible in the early years as the Agency and the participating clinicians gain experience with this new reporting category.
  - Consistent with the guiding principle of a learning health and health care system outlined at the beginning of this letter, CMS should not initially establish overly prescriptive thresholds or quantities of activities.
  - Given that the PCMH and PCMH specialty practice are two models that are designated by statute to achieve the highest score, CMS should look closely at the activities that have been consistently identified as components of those models and consider giving them more weight.
- The College recommends CMS strictly enforce requirements around the use of tools and standards for eCQM development in order to establish consistency among all stakeholders and measure developers.

## **Challenges in Quality Measure Development and Potential Strategic Approaches**

## Patient Engagement:

• The College recommends that CMS consider an approach recently outlined by McGlynn, Schneider, and Kerr,<sup>3</sup> which calls on measure developers to actively consider how to integrate patient preferences and goals into measure design—this would involve investments in new methods and systems with a focus on having quality measurement be part of care delivery "rather than existing as a parallel."

<sup>&</sup>lt;sup>3</sup> Elizabeth A. McGlynn, Ph.D., Eric C. Schneider, M.D., and Eve A. Kerr, M.D., M.P.H. "Reimagining Quality Measurement." N Engl J Med 2014; 371:2150-2153. http://www.nejm.org/doi/full/10.1056/NEJMp1407883.

## Provider Burden:

- ACP strongly recommends that CMS collaborate with EHR vendors and frontline clinicians as outlined in the measure development plan. Additionally, ACP recommends that clinician specialty societies should also be involved in these collaborations.
  - Further, the College recommends that CMS consider our recent recommendations on improving eMeasure construction over the medium to longer term as part of these collaborative discussions among EHR vendors, clinicians, and specialty societies.
- Overall, it is critically important that the data collection and reporting burden related to all of the MIPS categories be minimized.

## Measure Development Timeframe:

- When measures that have not been endorsed by the consensus-standards process are considered by CMS, the College strongly recommends that the Agency adopt a strict definition of what is meant by "evidence-based" to include systematically reviewed evidence—peer review alone is not enough to ensure the validity of the measures.
- Further, ACP recommends that individual clinicians, practices, and health care systems
  that participate in the testing process of these new measures receive credit via the CPIA
  category of MIPS—and they should not be penalized if they do not perform well on
  these measures.

## Developing Patient-Reported Outcomes Measures (PROMs):

 The College recommends that CMS ensure that any PROMs being developed undergo substantive testing to ensure that they are valid and reliable, do not place additional burdens on physicians in the collection and reporting of data, are minimally burdensome on patients, and are actually shown to have an evidence base that indicates that they are measuring quality improvement.

## Shared Accountability Across Settings:

- It is critical that CMS collaborate with clinicians and specialty societies to ensure that individuals are held accountable only for measures that are designed to assess outcomes within the reasonable control of the clinician.
- As per our <u>comments</u> on the draft Shared Nationwide Interoperability Roadmap, the
  College strongly recommends that we stop thinking about incentivizing the use of a
  standard, or interoperability in general. Instead, we must move towards a sustainable
  business case for appropriate use of an effective interoperable infrastructure.
  Incentives, penalties, mandates, and structural and process measures are inappropriate
  for this purpose and only point out that the business case for exchange in many
  situations is lacking.

## III. CMS Strategic Vision of the Measure Development Plan

*Background:* CMS intends to build on existing quality measure sets to develop a patient-centered portfolio of measures. This portfolio of measures will address critical measure gaps; facilitate alignment across federal, state, and private programs; and promote efficient data collection, while also balancing individual and shared provider accountability.

When publicly reported, these measures will help consumers make informed decisions regarding their choice of healthcare provider, facility, and services. As the CMS portfolio of measures evolves to support the transformation of the healthcare payment system, CMS will seek early and frequent input from clinicians, payers, patients, caregivers, and stakeholders.

CMS will expand and enhance existing measures to promote alignment and harmonization, while concurrently developing new (de novo) measures to fill measure and performance gap areas. We solicit public comment on specific areas and specialties to prioritize through MACRA funding over the next five years.

#### **ACP Comments**:

#### **Quality Measures**

The College strongly recommends that CMS actively work to improve the measures to be used in the quality performance category of MIPS. <u>Therefore, we believe that CMS should NOT consider the existing quality measure sets within PQRS, VBM, and MU as the starting point for its measure development plan.</u>

In the short term, ACP recommends that CMS utilize the core set of quality measures identified and recently released by the America's Health Insurance Plans (AHIP) Core Quality Measures Collaborative. This collaborative, which has included input from ACP and other professional organizations, the Centers for Medicare and Medicaid Services, health plans, the National Quality Forum, the National Committee for Quality Assurance, in addition to consumers and employers, has worked to create consistency and alignment across measures being used by both public and private payers. The participants in this collaborative have reached agreement on core measure sets for select areas of practice – Accountable Care Organizations (ACO)/Patient-Centered Medical Homes (PCMH)/Primary Care, Cardiology, Gastroenterology, HIV/Hepatitis C, Medical Oncology, Obstetrics and Gynecology, and Orthopedics.

Additionally, in the short term, ACP recommends that any measures outside of the core set that have been identified by the AHIP Core Quality Measures Collaborative and that have not been endorsed by the Measure Application Partnership (MAP) not be used within the MIPS program. The College remains concerned that a majority of the new measures that CMS added to PQRS for the 2016 reporting year were given a MAP recommendation of "encourage continued development." This MAP designation is reserved for measures that often lack strong feasibility and/or validity data. Therefore, measures given the "encourage continued development" recommendation should be resubmitted to the MAP once the suggested development occurs.

\_

<sup>&</sup>lt;sup>4</sup> CMS and AHIP Core Quality Measures Collaborative. February 16, 2016. <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html</a>

<sup>&</sup>lt;sup>5</sup> ACP Supports Core Quality Measures Collaborative Agreement. February 16 2016. https://www.acponline.org/acp-newsroom/american-college-of-physicians-supports-core-quality-measures-collaborative-agreement

Further, the College recommends that CMS consider the recommendations made by ACP's Performance Measurement Committee with regard to measure selection within MIPS. These recommendations are based upon a scientific review process that involves four domains: purpose and importance to measure, clinical evidence base, measure specifications, and measure implementation and applicability.

However, over the longer term, it will be critically important for CMS to continue to improve the measures and reporting systems to be used in MIPS to ensure that they measure the right things, move toward clinical outcomes and patient- and family-centeredness measures, and do not create unintended adverse consequences. A 2013 article by Berenson and Kaye, noted that "the current PQRS measures reflect a vanishingly small part of professional activities" and that there are currently many "overlooked aspects of physician performance that we would want to measure include[ing] making accurate diagnoses, avoiding overuse of diagnostic and therapeutic interventions, and caring for the growing number of patients with multiple chronic conditions and functional limitation." The article also notes that patients care about "physicians' confidence, empathy, humanity, personability, forthrightness, respect, and thoroughness" but that "available measures in PQRS and elsewhere are relevant to few of these professional qualities." Improvements such as these must be made in an ongoing way as the MIPS program is implemented. It is important to note that there is no way to directly measure all of the important aspects of good patient care; however, these aspects should still be supported, valued, and not undermined by the new measurement system. Further, the measurement targets must remain patient centered and reflect potential differences in risk/benefit for specific populations. For example, targets for the frail elderly frequently differ from younger patients.

More recently, an article by McGlynn, Schneider, and Kerr<sup>8</sup> states "that doing more of the same is misguided: the time has come to reimagine quality measurement." The authors go on to lay out a set of goals for quality measurement, including that it should:

- 1. Be integrated with care delivery rather than existing as a parallel, separate enterprise;
- 2. Acknowledge and address the challenges that confront doctors every day common and uncommon diseases, patients with multiple coexisting illnesses, and efficient management of symptoms even when diagnosis is uncertain;
- 3. Reflect individual patients' preferences and goals for treatment and health outcomes and enable ongoing development of evidence on treatment heterogeneity.

Others have called for these types of changes as well, for instance in a recent New York Times article, Robert M. Wachter<sup>9</sup> states that, "Measurement cannot go away, but it needs to be

<sup>&</sup>lt;sup>6</sup> https://www.acponline.org/clinical\_information/performance\_measurement/. Accessed: February 16, 2016.

<sup>&</sup>lt;sup>7</sup> Berenson, Robert A. and Deborah R. Kaye. "Grading a Physician's Value—The Misapplication of Performance Measurement." *NEJM*. 2013. Accessed at: http://www.nejm.org/doi/full/10.1056/NEJMp1312287.

<sup>&</sup>lt;sup>8</sup> Elizabeth A. McGlynn, Ph.D., Eric C. Schneider, M.D., and Eve A. Kerr, M.D., M.P.H. "Reimagining Quality Measurement." N Engl J Med 2014; 371:2150-2153. http://www.nejm.org/doi/full/10.1056/NEJMp1407883.

<sup>&</sup>lt;sup>9</sup> Robert M. Wachter. January 16, 2016. "How Measurement Fails Doctors ad Teachers." New York Times. http://www.nytimes.com/2016/01/17/opinion/sunday/how-measurement-fails-doctors-and-teachers.html? r=4.

scaled back and allowed to mature. We need more targeted measures, ones that have been vetted to ensure that they really matter."

In the progression toward these goals, ACP is strongly supportive of filling the critical gaps in quality measurement; obtaining stakeholder input into the measure development process; and focusing on outcomes-based measures, patient- and family-centeredness measures, care coordination measures, and measures of population health and prevention. ACP also strongly recommends electronic specification of the measures as one of the top considerations for filling measure gaps. This issue, and the specifics of our recommendations about how to rethink eMeasure construction and certification, will be discussed in greater depth later in this letter.

ACP also continues to believe that it would be preferable for all measures, whenever possible and regardless of source, to go through a multi-stakeholder evaluation process—a role that is performed by the National Quality Forum (NQF). This process is important as it involves measures being evaluated against four important criteria—importance to measure, scientifically acceptable, usable and relevant, and feasible to collect.

## Meaningful Use Measures (i.e., EHR Functional Use Measures)

As indicated above, <u>ACP believes that CMS should NOT consider the existing quality measure sets within PQRS</u>, VBM, and MU as the starting point for its measure development plan. While clinicians within MIPS need to satisfy the quality, resource-use, and clinical practice improvement categories, as well as MU, their MU activities should be in support of and NOT an additional set of unrelated requirements. For example, requiring clinicians to report on a separate set of clinical QMs for MU is duplicative and burdensome as they are already required to report on the same clinical QMs to fulfill the other components of MIPS.

Therefore, while MACRA mandates an MU component within MIPS, it does not specify what that component should look like. We believe that CMS has a golden opportunity then for a MU "do-over" – and a do-over that in our view should not be focused on incremental changes from the prior program. Rather, without the need for EHR functional-use measurement—we believe the relevant question for CMS is, "what would otherwise be missing from technology or workflow, if EHR technology and use were only incented by quality and resource-use measures (as per the current Physician Quality Reporting System (PQRS) and Value-Based Payment Modifier (VBM) programs), as well as by newly established clinical practice improvement activities?" This is where a new, more relevant MU program should be focused.

The College is very pleased that CMS has responded to this call for significant change in MU, per the recent announcement by Acting Administrator Slavitt, where he stated, "In 2016, MU as it had existed—with MACRA—will now be effectively over and replaced with something better." Therefore, the CMS measure development plan needs to be reflective of this new approach to MU.

<sup>&</sup>lt;sup>10</sup> blog.cms.gov/2016/01/12/comments-of-cms-acting-administrator-andy-slavitt-at-the-j-p-morgan-annual-health-care-conference-jan-11-2016/. January 12, 2015.

In defining new, more appropriate MU-functional measures and activities, the College recommends that CMS and the Office of the National Coordinator for Health Information Technology (ONC) start by collaborating with physicians and other clinicians to determine the key tasks that physicians and other clinicians and staff will need to perform better to improve care. Our more detailed proposals for how to address MU within the new MIPS program are outlined within our letter to CMS on the Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule, <sup>11</sup> and are listed briefly below:

- 1. Eliminate all EHR-functional-use measure thresholds.
- 2. Judiciously continue EHR-functional-use measurement reporting (without thresholds) to develop new learnings on health IT-enabled care.
- 3. Demonstrate continuing education within the domains of health IT. CMS/ONC should work with the medical and other clinical professional societies to develop and carry out a broad-based health IT education program as a component of MU.
- 4. Advance practical interoperability—i.e., EHR-functional-use measurement of data exchange should not specify the data to be exchanged.
- 5. Support bi-directional and less burdensome reporting to public health.
- 6. Develop and use flexible measures of patient- and family-centeredness that respect patient and family needs and preferences.
- 7. Encourage clinician engagement and innovation by allowing for new types of activities to replace existing measures.

## A. CMS Quality Strategy

*Background*: The CMS Quality Strategy, first released in 2013 and updated in 2015, articulates six goals to improve the quality of care in our healthcare system:

- Make care safer by reducing harm caused in the delivery of care
- Strengthen person and family engagement as partners in their care
- Promote effective communication and coordination of care
- Promote effective prevention and treatment of disease
- Work with communities to promote healthy living
- Make care affordable

To succeed in its mission of improving healthcare outcomes, beneficiary experience of care, and population health while also reducing healthcare costs, the CMS Quality Strategy identifies four foundational principles that guide actions toward the achievement of these goals:

- Eliminate racial and ethnic disparities to achieve an equitable healthcare system.
- Strengthen infrastructure and data systems essential to a robust public healthcare system.
- Enable local innovations to allow each community to meet its needs.

<sup>&</sup>lt;sup>11</sup> http<u>s://www.acponline.org/acp\_policy/letters/acp\_mu\_stage\_3\_comments\_2015.pdf</u>. December 14, 2015.

 Foster learning organizations to promote learning and education as key parts of quality programs and initiatives.

We intend to require measure developers with funding from section 102 of MACRA to fully incorporate the CMS Quality Strategy and explicitly link proposed measure concepts to the goals while addressing the foundational principles.

#### **ACP Comments:**

ACP is strongly supportive of all public and private payers transitioning their payment systems to support innovative payment and delivery models linked to the value of the care provided. In that vein, the College appreciates the ambitious but achievable goals set by HHS in early 2015 of tying 30 percent of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models, such as Patient-Centered Medical Homes (PCMHs), Accountable Care Organizations (ACOs), or bundled payment arrangements by the end of 2016, and tying 50 percent of payments to these models by the end of 2018. Therefore, we are supportive of CMS aligning its approach with that of the National Quality Strategy to achieve better care, smarter spending, and healthier people and communities and setting the six goals outlined above, as well as the four foundational principles. The College believes that these goals and principles could be profoundly important to improving quality, and should be encouraged in measure development and measure evolution, as well as with regard to counting toward the clinical practice improvement activities component of MIPS.

However, the College would like to reiterate our <u>comments</u> on the CMS RFI for MACRA where we stated that the current nine-measure reporting requirement for PQRS is arbitrary, burdensome, and does not contribute to the delivery of effective and efficient care. Rather, practices should be required to report only measures within any National Quality Strategy (NQS) domain that are truly applicable to their patient population. Further, while ACP is strongly supportive of moving toward outcomes-based measures, as well as those focused on patient- and family-centeredness, care coordination, and population health and prevention, we do not recommend that CMS establish a minimum number of outcomes-based measures, at least initially. CMS could instead incentivize clinicians to report on outcomes-based measures by assigning them more weight within the MIPS program.

#### B. Physician Quality Reporting Programs Strategic Vision

*Background*: In the Physician Quality Reporting Programs Strategic Vision, CMS noted that five statements define the CMS strategic vision for the future of its quality reporting programs:

- CMS quality reporting programs are guided by input from patients, caregivers and healthcare professionals.
- Feedback and data drives rapid cycle quality improvement.
- Public reporting provides meaningful, transparent, and actionable information.
- Quality reporting programs rely on an aligned measure portfolio.

<sup>12</sup> CMS Quality Strategy. <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html</a>. Accessed February 16, 2016.

• Quality reporting and value-based purchasing program policies are aligned.

#### **ACP Comments:**

The College supports the strategic vision outlined by CMS via the five statements above. We also would recommend that CMS add two additional statements to this list:

- "Quality reporting is aligned with the quadruple aim of (1) improving the health of populations, (2) enhancing the patient experience of care, and (3) reducing the per capita cost of health care, plus (4) improving the work life of health care clinicians and staff." Minimizing the burden of reporting and improving the lives of the individuals providing health care must be central to the Agency's thinking as it moves forward to build the future quality reporting programs.
- "Quality measurement is aligned with learning, quality enablement, and quality improvement." This statement would be consistent with and reinforcing of the foundational principles outlined earlier, particularly the idea of fostering innovation and enabling learning organizations to promote learning and education.

Further, ACP appreciates that it will be a significant effort for CMS to maintain and consistently apply this strategic vision, and thus we urge the Agency to carefully monitor its actions to ensure that the vision becomes reality.

## C. CMS Measures Management System (MMS)

*Background*: The measure evaluation criteria adopted by the MMS Blueprint align with those of NQF:

- Importance to measure and report (evidence, performance gap, and impact)
- Scientific acceptability of measure properties (reliability and validity)
- Feasibility
- Usability and use
- Related and competing measures (harmonization)

Measures recommended for development under MACRA must meet the above evaluation criteria and be regularly maintained to form a sound basis for public reporting and MIPS payment adjustments.

CMS will strive to ensure the availability of carefully evaluated and tested clinical quality measures for use across multiple care settings—a critical objective in the transition from paying for volume to rewarding value.

#### **ACP Comments:**

The College is supportive of the approach to measures management as proposed by CMS. It is consistent with our call, in a 2012 ACP policy paper titled, "The Role of Performance

<sup>&</sup>lt;sup>13</sup> Bodenheimer, Thomas and Christine Sinsky. "From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider" Annals of Family Medicine. Nov/Dec. 2014. <a href="http://www.annfammed.org/content/12/6/573.full">http://www.annfammed.org/content/12/6/573.full</a>.

Assessment in a Reformed Health Care System,"<sup>14</sup> for measures that evaluate physician performance to be:

- Reliable, valid, and based on sound scientific evidence
- Clearly defined
- Based on up-to date, accurate data
- Adjusted for variations in case mix, severity, and risk
- Based on adequate sample size to be representative
- Selected based on where there has been strong consensus among stakeholders and predictive of overall quality performance
- Reflective of processes of care that physicians and other clinicians can influence or impact
- Constructed to result in minimal or no unintended harmful consequences (e.g., adversely affect access to care)
- As least burdensome as possible
- Related to clinical conditions prioritized to have the greatest impact on improving patient health

Additionally, ACP recommends that the development, validation, selection, refinement, and integration of performance measures should be a multilevel process that takes advantage of the most recent scientific evidence on quality measurement and has broad inclusiveness and consensus among stakeholders in the medical and professional communities, as well as with patients and families. This entire process should be transparent to all stakeholders involved or impacted by the measures. Measures should be field-tested prior to adoption to ensure their viability in the medical setting. Once in use, performance measures that have not been shown to improve value to include higher quality, better outcomes, and reduced costs (and higher patient and physician satisfaction) should be removed from performance—based payment programs.<sup>15</sup>

Further, as is noted above, ACP also continues to believe that it would be preferable for all measures, whenever possible and regardless of source, to go through a multi-stakeholder evaluation process—a role that is performed by the National Quality Forum (NQF). As noted above, this process involves measures being evaluated against four criteria—importance to measure, scientifically acceptable, usable and relevant, and feasible to collect.

In terms of having the same measures apply across multiple settings of care, the College recommends that CMS carefully consider this approach, as this may not always lead to better care. For example, cancer screenings are irrelevant in the hospital setting. Also, blood pressure management (e.g., via NQF 0018, which is currently the last single reading of a measure period)

<sup>&</sup>lt;sup>14</sup> The Role of Performance Assessment in a Reformed Health Care System. An ACP Policy Paper (2012) https://www.acponline.org/acp\_policy/policies/role\_of\_performance\_assessment\_in\_reformed\_healthcaresyste\_ms\_2012.pdf

<sup>&</sup>lt;sup>15</sup> The Role of Performance Assessment in a Reformed Health Care System. An ACP Policy Paper (2012) https://www.acponline.org/acp\_policy/policies/role\_of\_performance\_assessment\_in\_reformed\_healthcaresystems\_2012.pdf

becomes extremely problematic when readings are taken during an emergency department visit or when someone is recuperating on bed rest, as they can lead to numerous aberrant readings by the managing clinician.

#### D. CMS General and Technical Principles

*Background*: CMS has identified a number of measure development principles, both general and technical, to guide the development of quality measures. We intend to require organizations that develop measures for MIPS and APMs with funding from section 102 of MACRA to embrace these principles.

## **General Principles**

- 1. Develop measures that explicitly align with the CMS Quality Strategy and its goals and objectives.
- 2. Align with other payers, including Medicaid, other federal partners, and private payers.
- 3. Address a performance gap where there is known variation in performance, not just a measure gap, and where there is important opportunity to advance population health.
- 4. Solicit patient/caregiver input in addition to provider input in the development of measures.
- 5. Develop measures in a rapid-cycle fashion in accordance with Lean principles.
- 6. Collaborate with other developers freely and share best practices and new learning.
- 7. Reorient and align measures around patient-centered outcomes that span across settings—this may require different versions of the same measure (i.e., different cohorts but same numerator).
- 8. Focus on outcomes (including patient-reported outcomes, such as functional status after knee replacement), safety, patient experience, care coordination, and appropriate use.
- 9. Develop measures meaningful to patients/caregivers, providers, and the general public.
- 10. Monitor disparities in the delivery of care and unintended consequences of measure implementation, including overuse and underuse of care.
- 11. Focus on what is best for patients and caregivers for each decision made during the development life cycle.

#### **ACP Comments:**

The College supports a national strategy for quality improvement that establishes national goals, attends to high-leverage priority areas that will lead to significant gains in quality and value of care (such as care coordination), fills gaps where few performance measures exist, develops universal terminology for measurement developers, and harmonizes measure sets to improve coordination and reduce duplication and confusion.

However, in terms of physician reporting on performance measures, we believe that the current nine-measure reporting requirement for PQRS is arbitrary, burdensome, and does not contribute to the delivery of effective and efficient care. Rather, practices should be required to report only measures within any National Quality Strategy (NQS) domain that are truly

**applicable to their patient population.** CMS could instead incentivize clinicians to report on outcomes-based measures by assigning them more weight within the MIPS program.

Also, ACP recommends that CMS include an additional general principle that specifically prioritizes addressing the significant administrative burden that clinicians and their staff face under the current quality reporting systems.

Further, the College strongly agrees with the need to align measure development and implementation across all payers. As indicated earlier in this letter, in the short term, ACP recommends that CMS utilize the core set of quality measures identified and recently released by the America's Health Insurance Plans (AHIP) Core Quality Measures Collaborative.

Additionally, ACP is supportive of filling the critical gaps in quality measurement as rapidly as is feasible; obtaining stakeholder input into the measure development process, including input from patients and caregivers; and focusing on outcomes-based measures, patient and family experience measures, care coordination measures, and measures of population health and prevention. We also appreciate that General Principle 3 clearly notes that CMS considers gaps to not only be an absence of current measures, but also a gap in performance on existing measures that must be addressed.

#### Technical Principles

- 1. Develop a rigorous business case for an evidence-based measure concept—a critical first step in the development process.
- 2. Prioritize electronic data sources (EHRs, registries) over claims and chart-abstraction when possible, while maintaining measure reliability and validity.
- 3. Define outcomes, risk factors, cohorts, and inclusion/exclusion criteria based on clinical as well as empirical evidence.
- 4. Judiciously select exclusions to ensure that measures capture as broad a patient population as possible and appropriate.
- 5. Adopt statistical risk adjustment models that account for differences in patient demographic and clinical characteristics across providers that may affect the outcome but are unrelated to the quality of care provided.
- 6. Develop risk adjustment models to distinguish performance between providers rather than predict patient outcomes.
- 7. Include measure stratification across different patient demographic characteristics to support the ability to monitor disparities and unintended consequences.
- 8. Harmonize measure methodologies, data elements, and specifications when applicable and feasible.
- Strive to develop each measure with sufficient statistical power to detect and report statistically significant differences in provider performance based on available data sources.

#### **ACP Comments:**

Overall, ACP is supportive of the technical principles as laid out by CMS above and notes that it is important that these principles be followed throughout the development process. The College calls on CMS to consider the recommendations made by the National Quality Forum in a recent report, "Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors," with regard to addressing principle 5. Additionally, it is unclear in principle 1 what is meant by a "rigorous business case" for a measure concept—this needs to be defined.

## E. Consideration of Recent Publications and Recommendations

Background: In the development of this MDP, CMS considered recommendations from recent relevant publications including a National Academy of Medicine report, Vital Signs: Core Metrics for Health and Health Care Progress and Performance Measurement for Rural Low Volume Providers, a final report of the NQF Rural Health Committee.

#### **ACP Comments:**

ACP appreciates that CMS has considered the recommendations of the recent National Academy of Medicine report, *Vital Signs: Core Metrics for Health and Health Care Progress.*<sup>17</sup> The core measure set recommended in the *Vital Signs* report can serve as a framework to help with sharpening the focus of the measurement community on key priorities and ensuring the importance of population health, social determinants of health, and systems-based approaches are actively considered in the development, testing, and implementation of performance measures that are applicable at the individual clinician level. However, it is important to note that it will be difficult to translate the NAM recommended core measure set into measures that are appropriate for individual clinicians; therefore, **CMS needs to collaborate with clinicians and specialty societies to ensure that individuals are not held accountable for measures that are designed to assess community-level outcomes.** 

The College also appreciates the consideration of the NQF report titled, *Performance Measurement for Rural Low Volume Providers*, particularly with regard to the issues providers in these geographic areas may face in terms of low volume, which can be a barrier to successful participation in quality reporting and payment incentive programs.

#### F. Measure Integration to Support MIPS and APMs

*Background*: Existing measures from PQRS, VM, and the EHR Incentive Program will be the starting point for measures to be used in MIPS and APMs. Development of new measures funded under MACRA will begin to address gaps in the measure portfolio. The resulting portfolio will evolve to include measures that:

 Follow the patient trajectory across the continuum of care for patient populations with one or more chronic conditions.

<sup>&</sup>lt;sup>16</sup> National Quality Forum. August 15, 2014. "Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors."

<sup>&</sup>lt;sup>17</sup> Institute of Medicine/ National Academy of Medicine. April 2015. Vital Signs: Core Metrics for Health and Health Care Progress. <a href="http://iom.nationalacademies.org/Reports/2015/Vital-Signs-Core-Metrics.aspx">http://iom.nationalacademies.org/Reports/2015/Vital-Signs-Core-Metrics.aspx</a>.

- Emphasize outcomes, including global outcome and population-based measures, balanced with process measures that are proximal to outcomes.
- Address patient experience, care coordination, and appropriate use (e.g., overuse and underuse).
- Promote multiple levels of accountability (e.g., individual clinicians, group practices, system level, population level).
- Apply to multiple providers, including clinical specialists, non-physician professionals, and non-patient-facing professionals.
- Are adopted from other payment systems and are applicable to physicians and other professionals.
- Use data generated from EHRs, based as much as possible on existing provider workflows, and inherently created as a by-product of providing clinical care.
- Incorporate broader use of clinical data registries.
- Can produce results that are stratified by race, ethnicity, gender, and other available demographic variables to enable providers to identify and reduce disparities among vulnerable populations.
- Are suitable for public reporting on the CMS Physician Compare website.
- Account for the variation and diversity of payment models.
- Align with other models and reporting—including with Medicaid, other federal
  partners and the private sector—and are specified for multi-payer applicability.
- Are appropriate for low-volume (particularly rural) providers.

#### **ACP Comments:**

The College would like to again reiterate our strong concern about CMS using the existing quality measure sets within PQRS, VBM, and MU as the starting point for its measure development plan. The development and implementation of the new MIPS and APM pathways should be considered an opportunity for significant revision of the existing programs and the measures that are used within them. While ACP recognizes that this level of change cannot occur immediately, CMS should lay out an innovative vision for where the measures within these programs can go, ensuring that they measure the right things, move toward clinical outcomes and patient experience, and do not create unintended adverse consequences. The characteristics outlined above do begin to lay out this vision—and indicate that there is a real need to think more practically and concretely about how the entire measurement community and other key stakeholders can work individually and together accomplish these goals in the short, medium, and long term. Therefore, ACP recommends that CMS begin to work with stakeholders, ideally starting with practicing clinicians and their patients, as well as specialty societies, to openly discuss the next steps that can be taken to build a more meaningful measure portfolio. As is noted in the MDP, MACRA does require CMS to consult with "relevant eligible professional organizations and other relevant stakeholders" for the selection of measures for MIPS—ACP believes that this consultation should take place throughout the entire measure pipeline, from development to implementation and maintenance.

## IV. Operational Requirements of the Quality Measure Development Plan

#### A. Incorporating MACRA Requirements

## i. Multi-payer Applicability of Measures

Approach – CMS supports efforts to create aligned core measure sets across payers from both the private and public sectors that are meaningful to patients and providers and that will reduce administrative burden. Measures should derive data elements from a common set of clearly defined concepts with structured metadata and share logical constructs when possible. CMS will leverage multi-stakeholder groups to identify the issues related to the development of measures that can be applied across payers and delivery systems. Specific stakeholder groups include the Measure Applications Partnership (MAP), the Core Quality Measures Collaborative, and the Health Care Payment Learning and Action Network (HCPLAN).

#### **ACP Comments:**

As noted earlier, ACP strongly supports alignment of a core measure set across payers and was therefore an active member of the AHIP core quality measures collaborative to create consistency and alignment across measures being used by both public and private payers. As we move forward, it is critically important that clinicians, specialty societies, and patient organizations be actively involved in improving upon the measure portfolio.

With regard to the data elements for measures, the College recommends that CMS:

- Adopt new and more functional standards for eCQMs that reflect real-world practice and
- Certify functions instead of measures so that vendors can certify against the underlying components of the measures rather than against each version of each individual measure.

Additional details around these recommendations and further feedback in terms of data collection and reporting for measures can be found in the College's recent <u>letter</u> to CMS in response to the RFI on Certification Frequency and Requirements for the Reporting of Quality Measures under CMS Programs.

## **Measure Applications Partnership**

Approach – CMS has received valuable input from the MAP committees, other stakeholders, and the public as part of the MAP review, discussion, and public comment for the measures under consideration. Additionally, in the annual report to CMS, the MAP provides not only recommendations on the prioritization of measures for CMS programs, but also input on key concepts for new measure development to address critical gaps identified during the measure review. The MAP process is completing its fifth pre-rulemaking cycle. CMS will continue to leverage the MAP and its processes for gathering and providing input from stakeholders on measures that will meet the needs of CMS and align with the needs of other payers to support multi-payer applicability of recommended measures.

#### **ACP Comments:**

ACP is supportive of the MAP process and reiterates our earlier recommendation that, in the short term, any measures outside of the core set that have been identified by the AHIP core quality measures collaborative and that have not been endorsed by the Measure Application Partnership (MAP) not be used within the MIPS program. The College remains concerned that a majority of the new measures that CMS added to PQRS for the 2016 reporting year were given a MAP recommendation of "encourage continued development." This MAP designation is reserved for measures that often lack strong feasibility and/or validity data. Therefore, measures given the "encourage continued development" recommendation should be resubmitted to the MAP once the suggested development occurs

## The Core Quality Measures Collaborative

Approach – CMS will continue actively participating in the Collaborative and promote the development of core measure sets for quality reporting programs to support multi-payer applicability. CMS will consider adopting core measures identified by the Collaborative through the rulemaking process.

## **ACP Comments:**

ACP is also planning to continue our participation in this collaborative and appreciates that CMS will do the same. The measures that have been identified via this process are a starting point that CMS can use as they work to develop and implement a much more innovative approach to quality measurement within the new MIPS and APM pathways, working with key stakeholders throughout this process, and ensuring that the new measure portfolio is meaningful across all specialties.

#### Health Care Learning and Action Network

Approach – CMS will consider strategies generated from the HCPLAN work groups related to quality measures to align measures in MIPS and APMs.

#### **ACP Comments:**

ACP is strongly supportive of the HCPLAN work groups and has been actively participating this this effort since it was initiated. Further, we would like to reiterate our earlier call for CMS to use the opportunity provided through the new MACRA law to build a learning health and healthcare system. The HCPLAN structure may be one of the ways that CMS could facilitate ongoing learning and innovation as the LAN has demonstrated its ability to facilitate multistakeholder collaboration and sharing of experiences.

## A. Coordination and Sharing Across Measure Developers

Approach – CMS employs a multi-targeted approach to coordinate measure development. CMS cultivates collaboration internally across operating divisions and with other federal agencies to promote consistency in quality measure development and use of measures in programs.

<sup>&</sup>lt;sup>18</sup> ACP Joins HHS in Accelerating Alternative Payment Methods Through 'Health Care Payment Learning and Action Network.' (March 2016) <a href="https://www.acponline.org/newsroom/payment">https://www.acponline.org/newsroom/payment</a> methods.htm.

In addition, CMS provides resources to measure developers to facilitate sharing of information and coordination of efforts.

To support the development of eCQMs, CMS established cross-cutting measure development initiatives that actively engage developers and stakeholders in key areas

#### **ACP Comments:**

ACP agrees with this multi-targeted approach by CMS, and would advise that these initiatives not only focus on measure development, but also on how the measures lend themselves to meaningful quality improvement. Further, while ACP strongly believes that measures for reporting purposes should be endorsed by the MAP, CMS should consider how physicians that are using measures developed through the use of QCDRs can receive credit for their efforts, perhaps via the clinical practice improvement activities category, until such measures are able to undergo a more formal consensus-based endorsement process. This will foster an environment of learning and innovation that is not feasible in the current system where CMS only is able to receive and review data from successful reporters. Additionally, CMS should be open to not only adding measures to the reporting portfolio as appropriate, but also regularly removing measures from that are determined to be of little value.

#### **B.** Clinical Practice Guidelines

Approach – CMS fully understands the importance of maintaining and updating quality measures through a combination of routine clinical practice guideline review, NQF maintenance cycles, and, for electronic clinical quality measures, annual update processes. Additionally, measure developers and stewards should be cognizant of Medicare covered services when creating or maintaining measure specifications.

Physicians and other clinicians, as agents of the patient, have a central role in healthcare delivery. CMS will ensure that measure developers continue to include members from clinical specialty societies and other healthcare organizations that create clinical practice guidelines in the Call for Technical Expert Panel process, in which their participation is essential to quality measure development. CMS will encourage efforts to synchronize the release of revised measure specifications with publication of the relevant guidelines.

CMS directs measure developers to evaluate clinical practice guidelines as described in the CMS MMS Blueprint. The MMS Blueprint details the methods for identifying (e.g., National Guideline Clearinghouse) and selecting the most appropriate evidence and clinical practice guidelines to support quality measures and provides additional references (e.g., IOM: *Clinical Practice Guidelines We Can Trust*).

To focus explicitly on the need for clinical guideline developers to address multiple chronic conditions, HHS and IOM convened a meeting of expert stakeholders in May 2012 that developed *Multiple Chronic Conditions: A Strategic Framework*. The framework is a set of new and previously identified principles for addressing issues related to multiple chronic conditions

in the guideline development process. CMS will continue to work with specialty societies and other guideline developers to provide data addressing multiple chronic conditions.

We solicit comments on these recommendations as well as new approaches to aligning clinical practice guidelines with measure development.

#### **ACP Comments:**

The development, maintenance, and updating of clinical practice guidelines involves extensive evidence evaluations via comprehensive systemic reviews or meta-analyses on the clinical topic under review. The quality of this evidence is evaluated using clearly defined grading systems, including ACP's Guideline Grading System.<sup>19</sup> The College has been developing clinical practice guidelines since 1981; therefore, we appreciate CMS' interest in working with specialty societies to ensure that any new guidelines developed to address multiple clinical conditions meet the same level of evidence as those that have been developed to date, address meaningful clinical gaps, and can potentially lead to better measures that facilitate improved quality. It is important to note that patients and families are also key stakeholders in the development and ongoing maintenance of clinical guidelines—along these lines, ACP is currently working to actively engage patients in our guideline efforts in order to more closely align their interests with those of the clinician.

It is critical that patients consistently receive the highest quality, most evidence-based, and appropriate care possible; therefore, the College recommends that CMS ensure that all quality measures used within the MIPS or APM pathways be based on the most up-to-date clinical practice guidelines, to the extent feasible. If a measure is not yet updated based on a revised guideline or is in the pipeline to be updated (e.g., undergoing field testing, the endorsement process, etc.)—but is still in use by clinicians, as it has not been changed via rulemaking and/or their EHR or registry is not yet enabled to collect and report on the revised measure—then the clinician should be held harmless in the assessment of their performance on that measure (however, the individual should still receive credit for having reported on it).

Further, we would like to reiterate our earlier recommendations that any measures outside of the core set that have been identified by the AHIP core quality measures collaborative and that have not been endorsed by the Measure Application Partnership (MAP) not be used within the MIPS program.

#### C. Evidence Base for Non-Endorsed Measures

Approach – CMS plans to use the rating criteria established by NQF to evaluate the quality, quantity, and consistency of the evidence for the development of quality measures included in this plan. For measures that are not consensus-endorsed, CMS will ensure that each measure is evidence-based and in alignment with NQF requirements for the consensus review process. Unless targeting a specific subset of patients, it is expected that this evidence will have been

<sup>19</sup> Qaseem, A. et al. The Development of Clinical Practice Guidelines and Guidance Statements of the American College of Physicians: Summary of Methods. *Ann Intern Med.* 2010;153(3):194-199. http://annals.org/article.aspx?articleid=745942 informed by a diverse population that represents proportionate numbers of patients across genders, races, and ethnicities.

CMS will also continue to require that measure developers submit a well-crafted business case for a measure concept that includes a thorough review of evidence in addition to a demonstration of the extent to which provider performance varies and the potential impact of the measure in terms of lives saved and cost saved. Measure concepts for which there is minimal variation in performance or for which the evidence base is weak will receive much lower priority for development. In addition, with the exception of measures developed for QCDRs and existing quality measures, MACRA requires submission of the measure and supporting evidence to a peer-reviewed journal.

#### **ACP Comments:**

ACP continues to believe that it would be preferable for all measures, whenever possible and regardless of source, to go through a multi-stakeholder evaluation process—a role that is performed by the National Quality Forum (NQF). We appreciate that CMS does intend to use the rating criteria established by NQF to evaluate the quality, quantity, and consistency of the evidence for measures to be included in the MIPS portfolio. Further, ACP believes that only measures endorsed by the Measure Application Partnership (MAP) should be used within the quality component of the MIPS program.

Additionally, ACP would like to note that while some measures may have limited variability in terms of performance, such as the existing smoking cessation measure that addresses counseling and/or medication for patients on this issue, the outcomes may be profoundly important and not yet improving (i.e., if the smoking prevalence is not decreasing). In this case, there is not a clear gap in terms of either the existence of a measure or of performance on it, but rather the gap is perhaps that a new approach needs to be taken to address smoking cessation in a patient population—and thus the current measure should be abandoned.

## D. Quality Domains and Priorities

#### **ACP Overarching Comments on Quality Domains and Priorities:**

It is critically important that CMS' efforts across all quality domains serve to facilitate innovation, learning, and new measure development, with an eye toward reimagining quality measurement and improvement as part of the new payment systems. Along these lines, the College recommends that CMS consider establishing safe harbors for entities that are taking on innovative approaches to quality measurement and improvement. In a recent article by McGlynn and Kerr, <sup>20</sup> the authors recommend the establishment of a coordinated program of safe harbors (that could involve CMS, other payers, as well as accrediting entities) where health care entities would be held harmless from penalties or other incentive systems if they take on the pursuit of measurement innovation. Taking this recommendation a step further, the College also calls on CMS to consider individual clinician participation in these types of activities as part of the clinical practice improvements category of MIPS.

-

<sup>&</sup>lt;sup>20</sup> McGlynn, E.A. and E.A. Kerr. Creating Safe Harbors for Quality Innovation and Improvement. *JAMA*. 2016;315(2):129-130. http://jama.jamanetwork.com/article.aspx?articleid=2481012

Further, ACP recommends that CMS work to ensure that patients, families, and the relationship of patients and families with their physicians are at the forefront of the Agency's thinking in the development of both the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APM) pathways, including the development and implementation of the performance measures to be used within these programs. It is critically important to recognize that the legislative intent of MACRA is to truly improve care for Medicare beneficiaries and thus, the policy that is developed to guide these new value-based payment programs must be thoughtfully considered in that context. Therefore, ACP strongly recommends that patients and families be involved in all aspects of measurement development and improvement across all of the domains outlined below.

Additionally, it is important to note that many of the thresholds included in current performance measures are interpreted from Healthcare Effectiveness Data and Information Set (HEDIS) data, which creates issues with practical application of quality measures (i.e., these percentiles are not evidence-based and can become arbitrary and unachievable). Clinicians' work requires customization that is based on essential human variables and expert judgment; thus, standardization (or specific percentiles, etc.) can be counterproductive.

#### Clinical Care

Approach – CMS will collaborate with specialty groups and associations to develop measures where there are important gaps in performance and for topics that are important to both patients and providers. Outcome measures (including PROMs and measures of functional status), intermediate outcome measures, and measures assessing diagnostic skills and adherence to clinical practice guidelines are measure development priorities for MIPS and APMs. We solicit comments and suggestions for development of measures in this domain.

#### **ACP Comments:**

As is outlined earlier in this letter, as a starting point, ACP recommends that CMS utilize the core set of quality measures identified and recently released by the America's Health Insurance Plans (AHIP) core quality measures collaborative. We further recommend that all measures to be used in the MIPS and APM pathways, for the purposes of clinical quality, be endorsed by the MAP. Additionally, ACP continues to believe that it would be preferable for all measures, whenever possible and regardless of source, to go through a multi-stakeholder evaluation process—a role that is performed by the National Quality Forum (NQF).

Over the medium to longer term, ACP is strongly supportive of filling the critical gaps in quality measurement; obtaining stakeholder input into the measure development process; and focusing on outcomes-based measures, patient and family experience measures, care coordination measures, and measures of population health and prevention. ACP also strongly recommends electronic specification of the measures as one of the top considerations for filling measure gaps.

## <u>Safety</u>

Approach – CMS will develop safety measures for EPs as a high priority in alignment with the goals of the CMS Quality Strategy. Where appropriate, CMS will align new measures with safety measures in other care settings. Measure topics to consider for development include medication errors, complications from procedures, and all-cause harm in the outpatient or ambulatory setting. We solicit comments and suggestions for development of measures in this domain.

#### **ACP Comments:**

The College recommends that CMS approach the development of safety measures with a focus on learning and improving, and take into account not only the clinical needs of the patient, but also the patient and caregiver's perspectives and experiences.

Additionally, the College recommends that measure developers consider careful risk-adjustment models and flexibility as a key part in maintaining professional buy-in and removing incentive for clinicians to disenroll patients considered to be problematic (e.g., cherry-picking patients for complicated procedures like CABG) or to provide treatment that the clinician judges is not in the patient's interest (e.g., adherence to antiplatelet therapy after stent implantation when the patient has a history of gastrointestinal bleeding). Several of the current safety measures do not employ careful risk-adjustment models and could therefore result in unintended consequences.

The Agency could also consider including the use of a near miss registry as part of the CPIA category within MIPS. While these registries are not currently configured to develop measures, they can help clinicians understand factors that can lead to close calls and how medical errors can be averted. The ACP has facilitated the nationwide expansion of a Near Miss Registry<sup>21</sup> to improve patient safety, working with our New York Chapter.

#### **Care Coordination**

Approach – The MIPS performance category of clinical practice improvement activities includes a subcategory of care coordination. Through the care coordination subcategory, performance gaps and best practices may be identified, resulting in potential concepts for new measure development. For purposes of clinical practice improvement activities, MACRA provides examples of care coordination activities, including timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth. When evaluating and/or funding measure development specific to CPIAs submitted for telehealth, CMS and measure developers must be cognizant of the services Medicare covers in this area.

To promote improved collaboration across providers, CMS intends to incorporate both primary care and specialist accountability across care settings. For example, the EHR Incentive Program building block measure *PQRS #374*: Closing the Referral Loop – Receipt of Specialist Report evaluates the effectiveness of tracking referrals from the primary care physician to the specialist. Expansion of this measure is being considered to include specialist reports to primary

<sup>21</sup> Near Miss Registry. ACP Quality Improvement. American College of Physicians. https://www.acponline.org/practice-resources/acp-quality-improvement/near-miss-registry care physicians. Additionally, the ability to link disparate data sources is critical to the development of innovative care coordination quality measures. Therefore, CMS promotes the development of measures using hybrid data sources to link information between care settings. For example, measures that link EHR data and claims data, such as NQF #2732: International Normalized Ratio (INR) Monitoring for Individuals on Warfarin after Hospital Discharge, support the documentation of appropriate follow-up care provided post-discharge from the hospital setting (i.e., INR lab test is performed within 14 days following discharge for a patient on warfarin). We solicit comments and suggestions for development of measures in this domain.

#### **ACP Comments:**

ACP is supportive of the need for measure developers to consider services currently covered by Medicare, such as chronic care management and transitional care management, as they develop new measures in order to help ensure alignment of the data needs for the measure with those of CMS for payment purposes. Along these lines, in a recent letter to the Senate Finance Committee, <sup>22</sup> the College asked that Congress call on CMS to:

- Establish new codes (perhaps initially as G codes, then using the G codes as models for a CPT code that would be developed) for additional increments of time (beyond the current 20 minutes/month) for CCM services.
- Establish reimbursement for two complex chronic care management codes (CPT codes 99487 and 99489) for patients who have more complex diseases or require a higher level of medical decision-making.
- Create codes to provide reimbursement for diabetic care management and econsultations.

Additionally, the College agrees that care coordination activities, such as those outlined in the measure development plan, should be included as clinical practice improvement activities (CPIAs). Physicians and other clinicians who engage in formal activities related to improving care coordination should receive credit toward their score in the CPIA category with minimal burden related to data collection.

With regard to the data needed to develop and then implement meaningful measures for care coordination, ACP recommends that CMS consider our recent comments on the Agency's RFI on certification frequency and requirements for the reporting of quality measures. New eCQMs should be constructed based on a standard model, including standard structures, vocabularies, expression language, and value-sets that express real-world practice. This then will allow the measures to be certified based on their underlying components rather than against each version of the individual measure. This is important for all new measures—and is also discussed later in this letter—but is raised here specifically due to the complexities involved in meaningfully measuring care coordination across multiple clinicians.

\_

<sup>&</sup>lt;sup>22</sup> Letter to the Senate Finance Committee Regarding Chronic Care Policy Options. American College of Physicians. https://www.acponline.org/acp\_policy/letters/acp\_letter\_sfc\_chronic\_care\_policy\_options\_2016.pdf. January 26, 2016.

Practical interoperability is also particularly important in the context of care coordination measurement. Along these lines, as was outlined in detail in our recent comments on Stage 3 of Meaningful Use, ACP strongly recommends that CMS consider how to advance truly practical interoperability, rather than as the movement of structured sets of non-contextual data from place to place without a defined purpose. Each instance of interoperability is performed for a specific purpose and in a specific clinical context. Government regulators should not believe that it is appropriate for them to define sets of data that must be exchanged regardless of the specific context. Any data exchange measures within MIPS should be focused on the testing and demonstration of exchange capabilities. They should not be applied to actual transactions involving the care of real patients. CMS should be willing to accept eligible professional (EP) and patient decisions regarding data to be exchanged and not impose friction on clinical processes for any purpose.

ACP has actively worked with internal medicine subspecialty societies and patient advocacy groups to develop a High-Value Care Coordination Toolkit.<sup>23</sup> This toolkit includes:

- Pertinent data sets of patient information not typically included in a generic referral request to help ensure an effective and high value clinical engagement by the referred to out-patient specialist/subspecialist.
- Model Specialty Out-Patient Referral Request and Response Checklists, which include recommended elements that were established through a consensus process following a review of the literature and recommendations from participating medical societies. The goal of these recommendations is to facilitate high value and effective referral engagements.
- Recommendations to help referring physicians and other healthcare professionals engage in an effective "patient- and family-centered" referral process.
- Care coordination agreements that define expectations and responsibilities for the practices involved in a referral relationship.
- Patient education materials to reinforce high value care messages to patients in order to promote high value choices and reduce over- and under-use.

The use of these high-value care coordination tools by clinicians should be deemed as counting toward one's score within the CPIA category and could also help facilitate the longer term development of care coordination measures.

Finally, as noted above and throughout this letter, it is critically important that patients be at the forefront in the development, testing, and implementation of care coordination measures. It is through the eyes of the patient and their family and care givers that meaningful care coordination should be defined.

26

<sup>&</sup>lt;sup>23</sup> ACP High Value Care Coordination Toolkit. <a href="https://www.acponline.org/clinical-information/high-value-care/resources-for-clinicians/high-value-care-coordination-hvcc-toolkit">https://www.acponline.org/clinical-information/high-value-care/resources-for-patients</a>. <a href="https://www.acponline.org/clinical-information/high-value-care/resources-for-patients">https://www.acponline.org/clinical-information/high-value-care/resources-for-patients</a>.

#### Patient and Caregiver Experience

Approach – CMS will continue to develop new patient experience surveys to ensure that these important measures of quality encompass all care settings and providers (e.g., specialists). CMS will also refine patient experience surveys based on stakeholder feedback to incorporate additional topics that are important to patients and families/caregivers (e.g., patient knowledge, skill, and confidence for self-management and whether the provider acted in accordance with the patient's preferences; participation of family members in care discussions or electronic communications; accurate documentation of family members who are authorized decision-makers). CMS will balance the need to obtain important information from patients with the need to minimize patient and provider burden in implementing and responding to the surveys. CMS is interested in the development and use of specialty-specific surveys in MIPS and APMs. We solicit public comment regarding the utility of specialty-specific patient experience surveys and whether such surveys exist and are in use in Medicaid or the private sector—through either plans or providers.

#### **ACP Comments:**

As indicated earlier, the College strongly recommends that CMS work to ensure that patients, families, and the relationship of patients and families with their physicians are at the forefront of the Agency's thinking in the development and implementation of the performance measures to be used within the MIPS and APM programs. However, we recommend that the term patient experience be thoughtfully considered by CMS as new measures are being developed. It is a term that often appears in conjunction with the phrase "patient- and family-centered care." The Beryl Institute describes patient experience as "the sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care."<sup>24</sup> Other terms that are often used interchangeably with patient experience or patient- and familycentered care are patient engagement and patient empowerment. Patient engagement is defined by the Center for Advancing Health as "actions individuals must take to obtain the greatest benefit from the health care services available to them."<sup>25</sup> Anderson and Funnell define patient empowerment as helping patients enhance and use their own innate ability to manage chronic conditions.<sup>26</sup> Finally, related to all of these terms, but not typically used as interchangeably is "patient reported outcomes," which are discussed separately later in the measure development plan. The confusion over these terms has therefore made it difficult for stakeholders to agree upon what patient- and family-centeredness truly is.

These differing terms also have an impact on performance measurement. Patient engagement, for example, could be measured by how often patients access a practice's portal; however, this unfairly places accountability on the physician, without necessarily providing true benefit to the patient. Patient empowerment could be measured by a patient feeling ready to participate in or having access to an effective weight loss program—and this too could unfairly penalize a physician, as a patient's readiness for or the availability of an effective program (based on the

2/

<sup>&</sup>lt;sup>24</sup> "About the Beryl Institute." The Beryl Institute. <a href="http://www.theberylinstitute.org/?page=Mission">http://www.theberylinstitute.org/?page=Mission</a>

<sup>&</sup>lt;sup>25</sup> Center for Advancing Health. "A New Definition of Patient Engagement: What Is Engagement and Why Is It Important?" 2010. Accessed at: http://www.cfah.org/pdfs/CFAH\_Engagement\_Behavior\_Framework\_current.pdf.

<sup>&</sup>lt;sup>26</sup> Funnell MM, Anderson RM, Arnold MS, Barr PA, Donnelly M, Johnson PD, Taylor-Moon D, White NH.

<sup>&</sup>quot;Empowerment: an idea whose time has come in diabetes education." Diabetes Educ. 1991 Jan-Feb; 17(1):37-41.

patient's specific genetics, conditions, social and demographic factors, etc.) is not fully under the physician or necessarily even the patient's control. Patient experience is typically measured by patient satisfaction (e.g. whether a patient liked the care they received), which is largely where the CAHPS survey is focused. Often, all of the components cited above are included when one talks about patient experience performance measures. All of these issues are important, but greater clarity is needed in terms of what and how each component is captured and used, with a strong eye toward identifying any unintended consequences that are not aligned with improving quality within a learning health care system.

Given the issues outlined above, the College seeks clarity from CMS with regard to their statement that they "will continue to develop new patient experience surveys." Further, ACP recommends that CMS remove the CAHPS survey from the quality performance category of MIPS and instead allow use of CAHPS as one possible component of the clinical practice improvement activities, in the subcategory of beneficiary engagement.

#### Population Health and Prevention

Approach – MIPS allows for the use of "global and population based measures" in the quality performance category. In addition to measuring the use of preventive services at the individual patient level, CMS will consider developing or adapting outcome measures at a population level, such as a community or other identified population, to assess the effectiveness of the health promotion and preventive services delivered by professionals. As with other types of outcome measures, these measures would reflect actions of others in a community and could be developed or used in combination with process measures that assess the actions of the individual, facility, or practice. The IOM *Vital Signs* report contains suggestions for 15 core measures that could be applicable to the population level. Eight of the topics for core measures identified by the IOM fall in this domain and can be considered for measure development: life expectancy, well-being, overweight and obesity, addictive behavior, unintended pregnancy, healthy communities, preventive services, and community engagement. We solicit comments and suggestions for development of measures in this domain and for attributing measure results to specific EPs and/or EP groups.

#### **ACP Comments:**

The College recognizes that individual clinicians do have a responsibility to work collaboratively with their patients to address and mitigate, to the extent possible, population- and community-level issues that impact patient health and well-being. However, attributing population health measure outcomes to specific clinicians is not appropriate and, in fact, defeats the purpose of population health measures. As noted earlier, the core measure set recommended in the *Vital Signs* report can serve as a framework to help with sharpening the focus of the measurement community on key priorities and ensuring the importance of population health, social determinants of health, and systems-based approaches are actively considered in the development, testing, and implementation of performance measures that are applicable at the individual clinician level. However, in order to move toward developing measures that are appropriate for individual clinicians, CMS must collaborate with clinicians and specialty societies to ensure that individuals are not held accountable for measures that are designed to assess community-level outcomes. Additionally, ACP recommends that CMS consider risk

adjustment and stratification principles throughout the measure development process in order to avoid unintended consequences for clinicians, particularly for those who practice in disadvantaged areas.

Further, while there is evidence that community-level interventions improve individual health outcomes, the College recommends that CMS, and HHS more broadly, consider other approaches to support public health interventions intended to facilitate these interventions and the efforts of the physicians involved in those efforts. Additionally, physicians and other clinicians that are involved in public health interventions should receive credit for that participation within the CPIA category of MIPS.

#### **Efficiency and Cost Reduction**

Approach – CMS considers appropriate use measures to be a very high priority for MIPS and APMs. CMS will ensure that measure developers consider evidence-based practices related to overuse. For example, the Choosing Wisely initiative of the American Board of Internal Medicine (ABIM) Foundation aims to reduce inappropriate use of certain tests and procedures to support patients in their efforts to make informed and effective healthcare decisions. Recommendations for clinicians on the Choosing Wisely website are supported by evidence and developed by specialty societies and organizations. The website includes lists of recommendations for the appropriate use of tests and procedures covering 31 topics submitted by 70 professional organizations. Recommendations by the U.S. Preventive Services Task Force, U.S. Government Accountability Office, and HHS Office of the Inspector General also include topics suitable for the development of appropriate use measures.

As providers focus on performance on overuse measures, a potential unintended consequence of quality measurement is underuse of services. As measures are developed for other quality domains, CMS will consider the development of "balancing measures" that can mitigate the potential for unintended consequences.

CMS seeks comments from the public as to relevant topic areas for this category of measures. CMS is also aware of concern about the unintended consequence of underuse of services once overuse measures are implemented and seeks comments from the public on mitigation strategies, including the use of balancing measures and suitable exclusions.

#### **ACP Comments:**

ACP believes that it is the responsibility of the medical profession to become cost-conscious and decrease unnecessary care that does not benefit patients. Therefore, the College is supportive of the Choosing Wisely campaign and has participated in developing recommendations and tools that are included within that educational initiative (some of which are described further below); however, we recommend that measure developers proceed cautiously with regard to developing efficiency and cost reduction measures based on all of the Choosing Wisely recommendations as there is variation in terms of the evidence-base behind them.

Additionally, the College recommends that CMS consider the recommendations that ACP has developed as part of our High-Value Care Initiative<sup>27</sup> as they look to develop measures and also for clinicians to receive credit for the CPIA category of MIPS. As part of this initiative, in addition to the High-Value Care Coordination Toolkit described earlier, the College has developed:

- Best practice advice and patient materials for high value care medical interventions and best practice advice regarding the appropriate use of antibiotics for acute respiratory tract infections.
- High-value cases, which can be used by physicians to learn how to eliminate unnecessary health care costs and improve patient outcomes—and for completion of these cases, physicians can earn free CME and ABIM MOC patient safety and medical knowledge points. CMS should therefore consider offering CPIA credit to those clinicians that choose to complete these cases.
- Learning modules, which are a set of interactive skill-building video modules to enhance
  physician communication. The goal is to encourage physicians, patients and other health
  care stakeholders to think and talk about medical tests and procedures that may be
  unnecessary, and in some instances can cause harm. These modules were developed in
  collaboration with ABIM, are a component of the Choosing Wisely campaign, and should
  be considered for credit within the CPIA category.
- Ethics Case Studies related to the stewardship of health care resources that are currently available for CME credit—and could be considered as part of the CPIA category.
- Recommendations from ACP's Performance Measurement Committee specific to utilization and cost measures<sup>28</sup> that CMS should consider.

However, it is important to note that physicians and other clinicians often find it impossible to obtain accurate, current, and complete cost data when they need it to make diagnostic and therapeutic decisions. Therefore, they cannot be held accountable for controlling costs without reliable, easy to obtain data. **CMS must make it a priority to ensure that clinicians are provided with the most up-to-date data at the point of care in order to facilitate cost-conscious decision making.** 

Related to the area of efficiency and cost reduction are appropriate use criteria (AUC), and the College recognizes that PAMA outlines a specific plan and timeline for CMS to implement AUC for advanced diagnostic imaging services. We would like to reiterate our concerns regarding the effective roll-out of this project by January 2017 and continue to strongly recommend that CMS roll-out this project with an initial focus on a limited number of clinical conditions and related AUC.

https://www.acponline.org/clinical-information/performance-measures/utilization-and-cost

<sup>&</sup>lt;sup>27</sup> "High Value Care: Clinical Recommendations." American College of Physicians. https://hyc.acponline.org/clinrec.html

## E. Gap Analysis

Approach – The strategic approach for gap analyses related to MIPS and APMs will consider measure gaps in each of the quality domains identified in section 102 of MACRA. Prioritized measure gaps identified by national stakeholders include measures addressing patient safety, care coordination, and affordable care. Measure concepts identified to fill these gaps should emphasize patient-reported outcomes and processes closely linked to outcomes, as well as clinical outcomes. Clinically relevant measures for physician specialties/subspecialties, including non-patient-facing professionals, should also be identified.

The areas that the MAP and other stakeholders have identified as gaps in the current set of clinician measures align with the priorities identified in MACRA. CMS will focus on the development of measures in these high-level gap areas that address true gaps in performance by providers, where there is demonstrable variation in care and therefore opportunity for improvement. To improve measure coverage across all EPs, CMS intends to evaluate gaps in measures for specialties and subspecialties, as reporting ability can vary significantly across different types of clinicians.

## **ACP Comments:**

As indicated earlier, ACP is strongly supportive of filling the critical gaps in quality measurement; obtaining stakeholder input into the measure development process; and focusing on outcomes-based measures, patient and family experience measures, care coordination measures, and measures of population health and prevention. ACP also strongly recommends electronic specification of the measures—with new eCQMs being constructed based on a standard model, including standard structures, vocabularies, expression language, and value-sets that express real-world practice.

## F. Applicability of Measures across Healthcare Settings

Approach – CMS will gather stakeholder input related to measures that are applicable across settings of care and types of clinicians (e.g., furthering the evolution of PROMs and consideration of system-level measures to assess care for patients with multiple chronic conditions). MACRA authorizes the Secretary to use certain measures from non-physician payment systems for purposes of the quality and resource use performance categories. CMS will assess options for allowing facility-based EPs to use their facility's performance on quality metrics (e.g., metrics in the Hospital Value-Based Purchasing Program for hospitalists) to apply to the quality domain for their MIPS composite performance score in certain circumstances—for example, where facilities have a strong incentive to hold EPs accountable for meeting facility performance goals. CMS will seek comment on such options through the rulemaking process.

CMS also seeks comments from the public regarding which measures in use in other healthcare settings may be appropriate for modification at the physician or other healthcare professional level and what types of measures would be most appropriate for use across a health system that spans multiple settings of care.

#### **ACP Comments:**

The College recommends that the Agency proceed carefully as it strives to meet this requirement. Measures intended to assess population health or other healthcare settings, such as hospitals and facilities, may not be appropriate for determining the performance of individual clinicians. Therefore, it is critical that CMS collaborate with clinicians and specialty societies to ensure that individuals are held accountable only for measures that are designed to assess outcomes within the reasonable control of the clinician. Additionally, ACP reiterates our recommendation that CMS consider risk adjustment and stratification principles throughout the measure development process in order to avoid unintended consequences for clinicians, particularly for those who practice in disadvantaged areas.

## **G.** Clinical Practice Improvement Activities

Background – The clinical practice improvement activities performance category of MIPS is required to include at least the following subcategories (to which the Secretary may add):

- 1. Expanded practice access
- 2. Population management
- 3. Care coordination
- 4. Beneficiary engagement
- 5. Patient safety and practice assessment
- 6. Participation in an APM (as defined in section 1833(z)(3)(C) of the Act)

These subcategories of clinical practice improvement activities have some overlap with the quality measure domains defined in section 1848(s)(1)(B) of the Act. As professionals identify areas of their practice for improvement, track their results, and engage in continual practice improvement, they may identify areas of true performance gaps that can serve as the basis for new measures and new clinical practice improvement subcategories. The practices of the professionals may serve as sites for new measure development and testing. This provides the opportunity to both improve care at the practice level and inform the broader quality ecosystem through innovative approaches to measurement that may be developed and more widely adopted.

Approach – CMS will review clinical practice improvement activity submissions to evaluate whether the activity submitted can be further developed into quality measures within the defined clinical practice improvement activity subcategories. For the purposes of MIPS, specific activities will be established through rulemaking. As an example for illustrative purposes only, providers who use patient-reported tools (e.g., PHQ-9 for depression) for improvement purposes could submit data to CMS from the use of these tools, and this could inform patient-reported outcome measure development. CMS solicits comments from the public on how the use of such tools and other clinical practice improvement activities could inform future quality measure development.

#### **ACP Comments:**

ACP first would like to reiterate our appreciation that Congress recognized the value of the Patient-Centered Medical Home (PCMH) by mandating in MACRA that PCMHs and PCMH specialty practices receive full credit for the clinical practice improvement activities

performance category. The College strongly recommends that multiple pathways to PCMH or PCMH specialty practice should qualify to achieve full credit in this category, including certification as a PCMH through a national recognition or accreditation program; by a private payer and/or state government program, including state Medicaid programs; as well as those developed by national specialty societies, state medical societies, county medical societies, community-based physician groups, or other entities as deemed appropriate.

Further, any practice participating in practice improvement activities under CMMI-sponsored models such as the Transforming Clinical Practices Initiative (TCPI) and the State Innovation Models (SIM) should automatically get full credit for the clinical practice improvement activities category, and no further reporting by the practice should be necessary. CMMI should report to CMS on which practices are participating in these models.

In addition to the subcategories and examples specified in MACRA legislation, the College believes that any quality improvement activity that an EP is involved in should count toward the clinical practice improvement activities category. These activities should include the following:

- Participation in a local quality improvement initiative such as that offered by a local hospital or health system and quality improvement activities done as a part of a program with private insurers;
- Participation in quality improvement programs such as Bridges to Excellence;
- Participation in a broader range of quality improvement activities such as participation in hospital, health system, or other health care organization's quality improvement committee (even if that organization is separate from a clinician's own practice);
- Participation in patient safety improvement efforts, such as reporting to a near miss registry and/or conducting root cause analyses;
- Participation in initiatives such as the Million Hearts Initiative;
- Participation in quality improvement initiatives that are part of a national organization's program such as ACP Quality Connect programs for adult immunizations and diabetes;
- Documented preventive screenings and vaccinations;
- New measure development and testing via QCDRs; and
- Use of patient reporting tools and surveys (such as CAHPS, rather than having CAHPS be part of the quality reporting category) and patient-reported outcomes measures (PROMs).

In assessing the performance of EPs on clinical practice improvement activities, the College urges CMS to ensure that administrative burden associated with documentation of the activities, as well as the cost of performing the activities and submitting documentation is minimal and constructed to be extremely flexible in the early years as the Agency and the participating clinicians gain experience with this new reporting category.

CMS should use existing data whenever possible to verify EPs completion of clinical practice improvement activities. The College recommends that CMS work with specialty societies to deem their relevant programs as meeting the requirements of MIPS, and CMS should accept

society-supplied records as evidence of completion of appropriate activities with no additional burden on EPs to report completion of clinical practice improvement activities to CMS. Practice improvement is generally well defined and understood by practices and by their specialty societies, which have developed mature programs focused on the needs of the specialty. By allowing specialty societies to report completion of clinical practice improvement activities by their members, CMS can both minimize the reporting burden on EPs and allow societies to develop practice improvement activities that are better tailored to the unique needs of their specialty members. The College recommends that EPs should be able to work with their specialty societies and boards to determine appropriate clinical practice improvement activities, report appropriate levels of participation in those activities, and also establish appropriate validation of completion.

Consistent with the guiding principle of a learning health and health care system outlined at the beginning of this letter, ACP would recommend that CMS not initially establish overly prescriptive thresholds or quantities of activities. The clinical practice improvement activity category, in particular, should be used to gain a better understanding of exactly what activities—and in what quantity—truly contribute to increasing value. Practices should in no way be penalized if they are taking on activities in good faith and with a goal of quality improvement and should, in fact, be encouraged to take on innovative approaches that "count" in order to further the goal of learning. Until the Agency and the practices, working together with ongoing interaction with specialty societies, are better able to determine their capacity for conducting, documenting, and quantifying these activities (and their impact on value) in the most effective and efficient manner, greater flexibility should be applied.

However, given that the PCMH and PCMH specialty practice are two models that are designated by statute to achieve the highest score, CMS should look closely at the activities that have been consistently identified as components of those models and consider giving them more weight. This approach would serve to incentivize movement toward achievement of these more comprehensive models over time. Some examples of these activities include setting up a system for after-hours patient care, engaging in shared decision-making approaches<sup>29</sup>, using high-value care coordination resources<sup>30</sup>, and adopting specific population health management approaches<sup>31</sup>.

An additional consideration with regard to the number of activities or hours that should be completed—if CMS determines that some level of specificity is needed—is that the Agency must take into account the size, structure, location, and patient population of the practices. Practices of greater size and/or organization will likely have significantly increased ability to take on a larger number of activities; whereas smaller, independent, and rural practices will be

<sup>29</sup> "The SHARE Approach." Agency for Healthcare Research and Quality. U.S. Department of Health and Human Services. <a href="http://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/index.html">http://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/index.html</a>. Care Coordination - High Value Care Coordination Toolkit. American College of Physicians.

https://hvc.acponline.org/physres care coordination.html.

<sup>&</sup>lt;sup>31</sup> Shaljian, M. Nielsen, M. Managing Populations, Maximizing Technology: Population Health Management in the Medical Neighborhood. Patient-Centered Primary Care Collaborative (2013). https://www.pcpcc.org/resource/managing-populations-maximizing-technology.

significantly hampered in this regard, particularly if their patient populations include those with multiple chronic conditions.

Taking an approach toward data collection and engagement of patient, clinicians, and professional societies with an eye toward learning as described above will then allow the clinical practice improvement activity category to inform future quality measure development by CMS and other measure developers.

## H. Consideration for Electronic Specifications

Approach – CMS intends to prioritize the development of eCQMs in a manner that ensures patient relevance, improves measure quality, increases clinical data availability, accelerates development cycle times, and drives innovation. Specifically, CMS, in concert with ONC and the private sector, is championing eCQM development in the areas of standards, tools, and processes that are open to all measure developers.

- **Standards**: ONC is tasked with managing and driving the development of industry standards to support the eCQM ecosystem.
- Tools: CMS collaborates jointly with ONC and external stakeholders to further the development and/or integration of tools such as these to facilitate eCQM measure development
- Processes: To drive improvement in eCQM processes, CMS and ONC have championed Lean Kaizen events, where a multi-disciplinary stakeholder group worked collaboratively to review current processes, identify inefficiencies, and design improvements in the eCQM development cycle (i.e., the "future state").

The continuing evolution of these standards, tools, and processes will streamline eCQM development. We solicit comments on how to collaborate further with specialty societies and measure developers in the broader use of the tools and standards for eCQM development.

#### **ACP Comments:**

As discussed in our recent <u>comment letter</u> regarding CMS' RFI on Certification Frequency and Requirements for Reporting of Quality Measures under CMS Programs, ACP agrees that focus should be placed on fixing the measure development process, as the move to value-based care is based on meaningful, reliable, accurate, and actionable measures and measurement. The CMS eCQM management process is predicated on enforcing a predictable annual cycle of activity – and as we have seen – a predictable annual cycle is not currently possible. Groups need sufficient time with the measures to perform their responsibilities effectively. Sources of change include changes to standards, value sets, measures, and tooling, as well as the need to identify and fix errors that are found in all of these components throughout the process.

Furthermore, the College recommends CMS strictly enforce requirements around the use of tools and standards for eCQM development in order to establish consistency among all stakeholders and measure developers.

## V. Challenges in Quality Measure Development and Potential Strategic Approaches

## A. Engaging Patients in the Measure Development Process

Strategic Approach – CMS evaluates best practices related to patient/caregiver involvement in the measure development process and disseminates this information through a variety of channels, such as measure developer forums and updates to the MMS Blueprint. Recent best practices identified for the patient/caregiver engagement process include:

- Conducting outreach to patients through patient organizations and other organizations that focus on engaging patients (e.g., PatientsLikeMe, Patient-Centered Outcomes Research Institute) and condition-specific patient organizations (e.g., the Arthritis Foundation, the Cancer Support Center).
- Screening candidates for background relevant to the measure development project.
- Preparing patients/caregivers by orienting them to the measure development process and patient/caregiver role during measure development and establishing a mentor on the measure development team.
- Educating meeting facilitators/moderators on how to engage patients.

#### **ACP Comments:**

ACP agrees that it is critical to involve patients and families/caregivers in the development of patient-centric measures in order to get measures that matter to both physicians and those for whom they care. In the past, measures have largely been limited to physician-, payer- or health system-centric criteria—an approach that has limited the view of these measures to whether the outcomes that are important to the health system, rather than the patient, are achieved. One example is door-to-balloon time. The patient may have received the catheterization within the allotted timeframe, but did the patient understand the procedure? Did anyone communicate with them about why he/she needed the procedure? Did anyone communicate with the family member? All of these questions are important to the patient, but they are not often captured by the current measures.

The College recommends that CMS consider an approach recently outlined by McGlynn, Schneider, and Kerr.<sup>32</sup> This approach calls on measure developers to actively consider how to integrate patient preferences and goals into measure design—this would involve investments in new methods and systems with a focus on having quality measurement be part of care delivery "rather than existing as a parallel."

Additionally, we would like to reiterate our earlier comments regarding the need for the Agency to very thoughtfully consider the definition of the term patient engagement, and other related terms such as patient experience, as new measures are being developed.

## B. Reducing Provider Burden of Data Collection for Measure Reporting

Strategic Approach – CMS strives to minimize provider burden by collecting data that are part of the existing clinical workflow. CMS also prioritizes the development of measures based on

<sup>&</sup>lt;sup>32</sup> Elizabeth A. McGlynn, Ph.D., Eric C. Schneider, M.D., and Eve A. Kerr, M.D., M.P.H. "Reimagining Quality Measurement." N Engl J Med 2014; 371:2150-2153. http://www.nejm.org/doi/full/10.1056/NEJMp1407883.

data from EHRs that can decrease the data collection burden while maintaining measure validity.

CMS collaborates with EHR vendors and frontline providers during the measure development process to maximize the use of existing clinical workflows to capture information required for quality measurement. Additionally, collecting data directly from the patient or caregiver can supplement provider-generated data and allow broader data mining for a given measure. CMS has also been working closely with private payers and other stakeholders to develop consensus around core sets of quality measures that would be used by all payers. CMS will continue to promote the development of measure sets that are aligned across payers and settings by ensuring that developers collaborate across public and private sectors.

#### **ACP Comments:**

The College strongly recommends that CMS collaborate with EHR vendors and frontline clinicians as outlined in the measure development plan. Additionally, ACP recommends that clinician specialty societies should also be involved in these collaborations. As outlined in our recent letter in response to CMS' RFI on Certification Frequency and Requirements for Reporting of Quality Measures under CMS Programs, there are a number of problems with current e-Clincial Quality Measures (eCQMS) that must be considered as part of these collaborations, including structural issues, data collection approaches/expectations, measure upkeep based on new evidence, and expectations of a predictable cycle for updates. As noted earlier, in the near term, ACP is supportive of the AHIP core quality measures collaborative approach which has identified an initial core set of measures; however, a longer term approach, particularly with regard to addressing burden and data collection is critical. In our letter on the certification frequency RFI referenced above, the College makes specific recommendations for approaches that CMS should consider to improve eMeasure construction over the medium to longer term. These recommendations, as listed briefly below, should be considered as part of collaborative discussions among EHR vendors, clinicians, and specialty societies:

- Approving eCQMs that meet stringent requirements for data elements that are readily available in common EHR systems and that are reasonably collected during the course of care delivery;
- Adopting new and more functional standards for the identified elements of these eCQMs;
- Certifying the functions/underlying components of the eMeasures, rather than each version of the individual measure as a whole;
- Performing automated testing instead of certification for specific eCQMs;
- Leveraging clinical decision support logic and structure to better enable eCQMs;
- Reorienting eMeasurement functionality from EHRs to secure cloud-based services; and
- Leveraging clinical data registries for eMeasurement and reporting.

Overall, as noted throughout this letter, it is critically important that the data collection and reporting burden related to all of the MIPS categories be minimized. Data collection should be driven by the needs of the physician and the patient at the point of care—with those data

being reused for the purposes of reporting quality measures, as well as for quality improvement at the practice level. QCDRs can help significantly with reducing this burden—and their development and use should continue to be strongly encouraged by CMS. Payment, quality, public health, and other agencies should then have access to the appropriate data contained in these registries that are relevant to their needs.

## C. Shortening the Time Frame for Measure Development

Strategic Approach – CMS has reduced the measure development time frame by incorporating Lean principles into the measure development workflow. For example, measure developers now move measures individually through the development and testing phases (i.e., single piece flow) rather than waiting for an entire batch of measures to complete one phase of the process. CMS also requires measure developers to have a multi-level, external review process to improve the accuracy, consistency, and efficiency of the HQMF measure logic and the associated value sets. In addition, improved functionality and integration of the MAT and the VSAC tools has reduced measure development time. CMS will promote the continued adoption of Lean principles to reduce waste throughout the measure development process and use established forums for dissemination. CMS intends to streamline the interactions and transitions between members of the measure development community.

To further reduce the timeline for the measure development process, CMS will facilitate cross-developer transparency and knowledge sharing through expanded use of the CMS measure developers library and forums. The Web-based library stores documents and work products from measure development projects across CMS. Knowledge sharing between measure developers assists in the rapid development of measures. For example, sharing measure specifications and computer programming code for similar measures reduces duplication of effort, minimizes overlap, and increases efficiency.

#### **ACP Comments:**

ACP is broadly supportive of the efforts CMS has taken to date with regard to reducing the timeline for measure development, as outlined above. We would also like to reiterate our support for CMS using measures that have undergone the NQF consensus-standards endorsement process, which entails measures being evaluated against four criteria—importance to measure, scientifically acceptable, usable and relevant, and feasible to collect. It is important to note that NQF has taken significant steps over the past several years to improve and streamline the endorsement and maintenance process for measures, including hosting a LEAN improvement event in 2013 and then implementing a number of changes recommended during that event starting in October 2015.<sup>33</sup>

When measures that have not been endorsed by the consensus-standards process are considered by CMS, the College strongly recommends that Agency adopt a strict definition of what is meant by "evidence-based" to include systematically reviewed evidence—peer

<sup>&</sup>lt;sup>33</sup> Measuring Performance: Improving NQF's Process. National Quality Forum.

<a href="http://www.qualityforum.org/Measuring\_Performance/Improving\_NQF\_Process/Improving\_NQF\_s Processes.asp">http://www.qualityforum.org/Measuring\_Performance/Improving\_NQF\_Process/Improving\_NQF\_s Processes.asp</a>
x

review alone is not enough to ensure the validity of the measures. Additionally, medical societies should be given adequate opportunity to comment on the measures prior to their final print publication, perhaps via posting on a journal website. Further, ACP recommends that individual clinicians, practices, and health care systems that participate in the testing process of these new measures receive credit via the clinical practice improvement activities (CPIA) category of MIPS—and they should not be penalized if they do not perform well on these measures. Rather, aligned with the concept of a learning health care system, CMS should use the data submitted from these testing entities to obtain feedback on the reliability, variability, usefulness, relevance, etc. of the measures being tested—and also provide this testing data to the public so that they can be taken into account in future measure development.

#### D. Streamlining Data Acquisition for Measure Testing

Strategic Approach – CMS will leverage broader data sources for measure development and promote the formation of a National Testing Collaborative (NTC). As part of the NTC, CMS is investigating the potential to implement overarching agreements with clinical data registries, data repository vendors, health plans, and provider groups to make administrative and clinical data more accessible and less costly to acquire. Use of these data would inform early measure specification development, enhance testing of measure reliability and validity, and facilitate risk adjustment of outcome measures. In turn, costs and time for developers to acquire data would be reduced, and the number of providers participating in measure testing would be expanded.

#### **ACP Comments:**

The College is supportive of CMS leveraging broader data sources for measure development and testing, particularly using options such as clinical data registries, health plans, and other options in order to reduce the cost and increase the accessibility of the necessary data.

# E. <u>Developing Patient-Reported Outcomes Measures (PROMs) and Appropriate Use</u> Measures

Strategic Approach – To initiate the development of PROMs, CMS introduced several "building block" measures as part of the Medicare EHR Incentive Program. For example, process measures capturing pre- and post-surgical functional status assessment for hip and knee replacement surgery and congestive heart failure were developed. These process measures provide the foundational framework for capturing PROM data within EHR systems and bridge the gap to future corresponding outcome measures. To facilitate the transition from building-block process measures to corresponding PROMs, CMS will need to develop and test PROMs based in part on the data received from the existing process measures. CMS may also leverage emerging initiatives such as the joint HHS and U.K. National Health Service cooperative related to PROMs. We solicit comments on ways to capture patient-reported data in a manner that does not create undue burden (e.g., minimizing overall patient paperwork, forms, etc.).

For appropriate-use measures, CMS plans to emphasize the concepts in the Choosing Wisely campaign, which has expanded to include more than 300 recommendations from 70 organizations. CMS will also promote the development of balancing measures that serve to mitigate unintended consequences, such as underuse of services. Finally, CMS will encourage

the development of appropriate use measures through the HHS eCQM National Testing Collaborative, the AcademyHealth Electronic Data Methods Forum, and the NQF Incubator.

#### **ACP Comments:**

In developing PROMs, the College recommends that CMS ensure that any PROMs being developed undergo substantive testing to ensure that they are valid and reliable, do not place additional burdens on physicians in the collection and reporting of data, are minimally burdensome on patients, and are actually shown to have an evidence base that indicates that they are measuring quality improvement. While it may not be possible to capture the data associated with PROMs in EHRs currently, it is critical that data be able to be easily collected and aggregated and integrated with the EHR in a manner that minimizes the burden on the physician practice including time, resources, and investment in additional technology or interfaces. According to a recent RTI report on PROMs, "Key design principles to successful use of patient-reported measurement systems include fitting PROMs into the flow of care, designing the systems with stakeholder engagement, merging data with other types of data (clinician reports, medical records, claims), and engaging in continuous improvement of the systems based on users' experiences and new technology."<sup>34</sup> ACP recommends that CMS carefully consider these design principles developing measures that place a minimal burden on both patients and physicians, with special consideration given to those physicians in solo or small group practices who may not have the resources to invest in complicated or costly technologies associated with patient reporting.

Additionally, to decrease the burden on patients and physicians, CMS should make PROMs as flexible as possible by allowing for multiple methods and modes of administration to best fit with the unique needs of both the patient and physician practice (i.e., computer/internet access, Smart phone technologies, computer software/programming, EHR interfaces, etc.). CMS should also ensure that patients and families/caregivers be included throughout the PROM development process. It is important that the patients and families who will be tasked with reporting any data be involved in providing input in any patient measures being developed to ensure that the burden on patients is minimized and the measures being developed are evaluating outcomes that matter to the patient.

For appropriate use measures, the College recommends that CMS look to sources such as ACP's High Value Care Initiative, <sup>35</sup> discussed in greater detail earlier in this letter, which was designed with a goal of helping physicians and patients understand the benefits, harms, and costs of interventions and helping to determine whether services provide good value to the health care system. For more specific recommendations on how to develop performance measures to better value care, ACP recommends CMS look to the College's recent policy paper in the *Annals of Internal Medicine* on "Design and Use of Performance Measures to Decrease Low-Value

<sup>&</sup>lt;sup>34</sup> Cella, D., Hahn, E.A., Jensen, S.E., Butt, Z., Nowinski, C.J., Rothrock, N., Lohr, K.N. (2015). Patient-reported outcomes in performance measurement: RTI Press Publication No. BK-0014-1509. Research Triangle Park, NC: RTI Press. DOI: 10.3768/rtipress.2015.bk.0014.1509

<sup>35</sup> High-Value Care. American College of Physicians. http://hvc.acponline.org/

Services and Achieve Cost-Conscious Care."<sup>36</sup> Decreasing the use of interventions that provide little or no benefit and are of little value may be a good first step in addressing the high cost of health care. Further, the College would like to reiterate that the Choosing Wisely campaign is designed to be an educational tool, and the recommendations included in the campaign may not be able to be easily translated into measures of appropriate use.

# F. Developing Measures That Promote Shared Accountability Across Settings and **Providers**

Background – Developing measures of shared accountability requires improved provider coordination across care settings and interoperable health information exchange among a variety of healthcare stakeholders, including clinicians, laboratories, health plans, payers, and patients. While initial progress has been made in these areas, sustained improvement is dependent on broad-based adoption and use of HIE to provide the framework for data-driven measure development and attribution.

Strategic Approach – Agencies across HHS are working to increase the adoption and use of HIE through longstanding relationships with the National Committee on Vital and Health Statistics and industry partners such as the Workgroup for Electronic Data Interchange and the Council for Affordable Quality Healthcare. To encourage HIE adoption more broadly across settings, CMS proposes to:

- Enable HIE, where possible, in support of state-led delivery and payment reform through federal and state partnerships.
- Encourage interoperability across states' electronic information infrastructures, including Medicaid and state survey agencies.
- Continue stakeholder collaboration to facilitate the adoption and use of health IT standards and interoperability requirements.

To promote improved collaboration across providers, CMS intends to incorporate both primary care and specialist accountability across care settings. For example, the EHR Incentive Program building block measure PQRS #374: Closing the Referral Loop - Receipt of Specialist Report evaluates the effectiveness of tracking referrals from the primary care physician to the specialist. Expansion of this measure is being considered to include specialist reports to primary care physicians.

#### **ACP Comments:**

centered on the needs of the patient and family across settings of care; however, as outlined earlier in this letter, we recommend that the Agency proceed carefully as it strives to develop measures that will hold multiple clinicians accountable for the health of populations. Measures intended to assess population health or other healthcare settings, such as hospitals and facilities, may not be appropriate for determining the performance of individual clinicians.

The College is supportive of CMS considering how to better facilitate care coordination,

<sup>&</sup>lt;sup>36</sup> Baker DW, Qaseem A, Reynolds PP, Gardner LA, Schneider EC, on behalf of the American College of Physicians Performance Measurement Committee. Design and Use of Performance Measures to Decrease Low-Value Services and Achieve Cost-Conscious Care. Ann Intern Med. 2013;158:55-59. doi:10.7326/0003-4819-158-1-201301010-00560

Therefore, it is critical that CMS collaborate with clinicians and specialty societies to ensure that individuals are held accountable only for measures that are designed to assess outcomes within the reasonable control of the clinician. Additionally, ACP reiterates our recommendation that CMS consider risk adjustment and stratification principles throughout the measure development process in order to avoid unintended consequences for clinicians, particularly for those who practice in disadvantaged areas.

In the above approach outlined by CMS to promote shared accountability, the Agency discusses the need to increase the adoption and use of health information exchange (HIE). However, as per our comments on the draft Shared Nationwide Interoperability Roadmap, the College strongly recommends that we stop thinking about incentivizing the use of a standard, or interoperability in general. Instead, we must move towards a sustainable business case for appropriate use of an effective interoperable infrastructure. Incentives, penalties, mandates, and structural and process measures are inappropriate for this purpose and only point out that the business case for exchange in many situations is lacking. If there are real and visible benefits to exchange in a particular situation, there will be no need for incentives, penalties, mandates, and measures. The focus should be on identifying supportive business cases for exchange, and then reducing the current barriers and friction points that are impeding implementation. In order for this to succeed, measurement must then focus on outcomes.

## VI. Conclusion

ACP sincerely appreciates the opportunity to submit comments to CMS on the Quality Measure Development Plan and looks forward to any opportunities to provide input and collaborate with the Agency and other key stakeholders to effectively implement the MACRA law. The College calls on CMS to approach this opportunity with an eye toward building a learning health and healthcare system—reflecting the learnings of the past and reimagining quality measurement as something that can truly be integrated with care delivery rather than existing in parallel to it. Patients and their families should be at the forefront of the Agency's thinking, as well as focusing on measuring the right things without creating unintended consequences and on decreasing clinician burden.

Thank you for considering ACP's comments. Please contact Shari M. Erickson, MPH, Vice President, Governmental Affairs and Medical Practice, by phone at 202-261-4551 or e-mail at <a href="mailto:serickson@acponline.org">serickson@acponline.org</a> if you have questions or need additional information.

Sincerely,

Robert McLean, MD, FACP, FACR

Chair, Medical Practice and Quality Committee

Roth MIN. MILL ME