



November 20, 2017

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Room 445–G, Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

**Re: Centers for Medicare & Medicaid Services: Innovation Center New Direction Request for Information**

Dear Administrator Verma:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) Innovation Center New Direction Request for Information (RFI). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 152,000 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. Overarching Recommendations**

The College strongly supports the move to value-based payment and the role that the Center for Medicare and Medicaid Innovation (CMMI) plays in designing, testing, and implementing new payment models that move health care toward this goal. As ACP notes in our recent paper<sup>1</sup> outlining the College's forward-looking agenda, the College supports continued implementation of Medicare's new Quality Payment Program (QPP), as established by MACRA, and improvements to make it more meaningful for clinicians and patients, including the creation more opportunities for physician-led alternative payment models (APM). Along these lines, ACP has been active in providing feedback on the implementation of the QPP via its letters on both the [2017](#) and [2018](#) proposed rules, as well as on the [Measure Development Plan](#) and other requests for information and feedback from the Agency. ACP encourages CMMI to continue to accelerate the transition from fee-for-service (FFS) payment systems to bundled

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<sup>1</sup> [https://www.acponline.org/acp\\_policy/policies/forward\\_looking\\_policy\\_agenda\\_2017.pdf](https://www.acponline.org/acp_policy/policies/forward_looking_policy_agenda_2017.pdf)

and risk-adjusted capitation payments, hybrid FFS + bundled/capitated payments, and other payment systems that incentivize value rather than volume. Our key APM recommendations focus on:

- Continuing flexibility and a phased-in approach to participation that will allow physicians and other clinicians to be successful;
- Allowing multiple pathways for patient-centered medical homes (PCMHs) to qualify as Advanced APMs, including options that do not require physicians to bear more than nominal financial risk; and
- Prioritizing the testing of models involving physician specialty/subspecialty categories for which there are no current recognized APM/Advanced APM options.

In recognition that all clinicians are not willing or able to move directly into models with significant payment at risk, there should be pathways to help clinicians transition to models with increasing levels of risk at stake. Additionally, ACP encourages CMS to develop an expedited process for CMMI to develop, test, and expand APMs. This should include a pathway for testing models recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC), as well as models from Medicaid and private payers.

### **CMMI “New Direction” Guiding Principles**

The College’s comments below on these guiding principles are summaries of what is further outlined in our remarks on the potential models in section II of this letter. There are a number of components of these principles that ACP supports; however, we also have significant concerns about some of the language used in terms of what it will mean for the implementation of the key concepts. For instance, as discussed further below, promoting patient choice and competition is a laudable goal, but the current measurement systems and means of sharing the information with consumers are simply not ready to support a rapid implementation of that approach. We therefore recommend that the Agency proceed with great care to ensure that patients and their families do not experience unintended negative consequences by relying on potentially flawed or unclear data to choose a clinician or type of payment structure.

1. **Choice and competition in the market** – Promote competition based on quality, outcomes, and costs.

ACP supports transparency of valid and reliable information, including quality, outcomes, and cost data. We agree that this potentially can have the result of empowering consumers, physicians, payers, and other stakeholders to reduce health care spending and improve quality of care. However, the College recommends caution in terms of moving too quickly toward systems that depend significantly on consumer choice based on quality, outcome, and cost data. The currently available performance measures, measurement systems, and means of sharing performance information with consumers, which would be the basis for and means of patients and families making their health care decisions, are not adequate. Until quality measures are developed that appropriately assess high priority areas and improved patient

outcomes, patients will not have valid and reliable data available with which to properly assess quality. These data also need to be provided to patients and their families in usable and useful formats for decisionmaking. In announcing new initiatives related to “Meaningful Measures” and “Patients Over Paperwork,” CMS Administrator Seema Verma acknowledges the challenges with administrative tasks, regulatory burdens, and the quality measures that currently are used by Medicare—and ACP is hopeful that the work under those initiatives can lead to an environment that would eventually be able to support a greater, and more informed, ability of consumers to make choices based on quality and cost.

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

The College agrees that physician participation in payment models of their choice should be voluntary. ACP also understands the need to have defined control groups or comparison populations to allow proper analysis of the effectiveness of models in improving quality and decreasing costs. However, we recommend that CMS make every effort to minimize the amount of qualified APM applicants who are randomized into control groups and therefore unable to benefit from enhanced payments or other potential incentive payments that participants in the model receive.

Additionally, ACP strongly supports efforts to reduce burdens and unnecessary regulatory requirements, as outlined in ACP’s policy paper titled, “Putting Patients First by Reducing Administrative Tasks in Health Care,”<sup>2</sup> which was published in *Annals of Internal Medicine* in March 2017 and recently supported by the American Congress of Obstetricians and Gynecologists. This will better allow participants in APMs to make the transformational practice changes needed to test new and innovative ways to deliver better quality care at lower costs. Physicians and patients must also have the tools and information that they need—in usable and useful formats—to make informed decisions about participation in new payment models and benefit designs.

3. **Patient-centered care** – Empower beneficiaries, their families, and caregivers to take ownership of their health and ensure that they have the flexibility and information to make choices as they seek care across the care continuum.

ACP strongly supports patient-centered care as it needs to be the critical underpinning of all delivery systems and payment models, whether they are APMs or not. This is why the College has long advocated for testing and implementation of the Patient-Centered Medical Home

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<sup>2</sup> <http://annals.org/aim/fullarticle/2614079/putting-patients-first-reducing-administrative-tasks-health-care-position-paper>

(PCMH) model and the Patient-Centered Medical Neighborhood/Patient-Centered Specialty Practice model<sup>3</sup>—both of which are incentivized in various ways within the Quality Payment Program. Additionally, as the College has recommended in numerous comment letters, CMS must 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 APM pathways.

However, the College does have significant concerns with the language within this principle in terms of how it may ultimately be operationalized. As noted above, current quality and cost measures and the system used to collect and share the data from these measures are simply not adequate at this time. Again, ACP calls on CMS to move forward with caution in terms of developing and implementing programs that depend significantly on consumer choice based on quality, outcomes, and cost. Otherwise, there is a real risk of patients experiencing poor outcomes and even harm if they are making decisions based on potentially flawed or unclear information. Additionally, patient participation in such programs should be voluntary, and participants in models should not have financial penalties imposed simply for failing to achieve health goals and outcomes.

As discussed in more detail in this letter under CMS’s proposals for *Consumer-Directed Care & Market-Based Innovation Model*, ACP has major concerns that models that impose coverage limitations or financial penalties on patients who fail to meet health goals will disproportionately hurt poorer patients (such as Medicare-Medicaid dual eligibles) who cannot afford to contribute additional out-of-pocket funding to their care. Patient-centered care should help patients, especially poorer patients with the greatest need, improve their health, not punish them if they are unable to achieve better outcomes, especially when personal and population-based health outcomes are largely determined by social determinants that are beyond the patient’s control.

4. **Benefit design and price transparency** – Use data-driven insights to ensure cost-effective care that also leads to improvements in beneficiary outcomes.

ACP’s newly released position paper on “Improving Health Care Efficacy and Efficiency Through Increased Transparency”<sup>4</sup> provides detailed recommendations that CMS should consider in terms of operationalizing this principle. In this paper, the College outlines our support for transparency of reliable and valid price information, expected out-of-pocket costs, and quality data that allows consumers, physicians, payers, and other stakeholders to compare and assess medical services and products in a meaningful way. However, it is also important to note that price should never be used as the sole criterion for choosing a physician, other health care professional, or health care service. Additionally, payers, plans, and other health care organi-

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[https://www.acponline.org/system/files/documents/advocacy/current\\_policy\\_papers/assets/pcmh\\_neighbors.pdf](https://www.acponline.org/system/files/documents/advocacy/current_policy_papers/assets/pcmh_neighbors.pdf)

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[https://www.acponline.org/acp\\_policy/policies/improving\\_health\\_care\\_efficacy\\_and\\_efficiency\\_through\\_increased\\_transparency\\_2017.pdf](https://www.acponline.org/acp_policy/policies/improving_health_care_efficacy_and_efficiency_through_increased_transparency_2017.pdf)

zations must work to develop patient-targeted health care value decision-making tools that are written for patients at all levels of health literacy that make price, estimated out-of-pocket cost, and quality data available to consumers. And, as noted earlier, this information should be communicated in an easy-to-understand way.

5. **Transparent model design and evaluation** – Draw on partnerships and collaborations with public stakeholders and harness ideas from a broad range of organizations and individuals across the country.

The College supports the need for transparency in model design and for CMS to collaborate with a broad range of stakeholders—and would strongly recommend that those stakeholders include specialty societies, frontline clinicians, and patients and families. Stakeholder collaboration should be incorporated into the development, testing, and implementation of alternative payment models with a focus on ensuring that those models are truly leading toward improved quality and value that is meaningful not only to payers and clinicians, but also to patients and their families.

Further, collaboration with stakeholders is a critical component of decreasing unnecessary administrative tasks that lead to clinician and patient burden. This is why ACP has been conducting outreach as part of our Patients Before Paperwork initiative<sup>5</sup> to engage key stakeholders, including CMS, in collaborative discussions and activities to address the fundamental components of successful delivery and payment models, such as improving EHR interoperability and usability, addressing problems with the current performance measurement system, and reducing tasks that may no longer be necessary within a value-based payment system focused on patient outcomes (e.g., certain prior authorization requirements).

6. **Small Scale Testing** – Test smaller scale models that may be scaled if they meet the requirements for expansion under 1115 A(c) of the Affordable Care Act (the Act). Focus on key payment interventions rather than on specific devices or equipment.

The College supports testing smaller scale models and using 1115A(c) authority to expand models that prove successful. However, we note that testing on a more limited scale restricts the number of physicians who can participate in Advanced APMs. CMS should take steps to expedite reviews of models that are undergoing small-scale testing and take immediate steps to expand the models should data show that it meets the criteria under 1115A(c). As noted later in our comments on expanded Advanced APM opportunities, few primary care physicians have a patient-centered medical home (PCMH) option available in the Advanced APM pathway due to small-scale testing. CMS should take steps to accelerate review of the Comprehensive Primary Care Initiative (CPCi) and Comprehensive Primary Care Plus (CPC+) models and expand them nationally should the data meet the 1115A(c) expansion criteria.

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<sup>55</sup> <https://www.acponline.org/advocacy/where-we-stand/patients-before-paperwork>

## II. Potential Models

### 1. Expanded Opportunities for Participation in Advanced APMs

#### **CMS Proposal:**

In April 2015, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) that repealed the Sustainable Growth Rate formula for updating the Medicare physician fee schedule, and replaced it with a series of fixed statutory updates and a Quality Payment Program that includes the Merit-Based Incentive Payment System (MIPS) and Advanced APMs. CMS administers the Quality Payment Program, and the Innovation Center bears primary responsibility for development of policies and operations relating to Advanced APMs. Eligible clinicians who are Qualifying APM Participants (QPs) for a year from 2019 through 2024 receive a lump sum APM incentive payment and, beginning for 2026, a differentially higher update under the Medicare physician fee schedule. Eligible clinicians who are QPs for a year are also not subject to the MIPS reporting requirements and payment adjustment.

CMS expects that the number of eligible clinicians choosing to participate in Advanced APMs will grow over time. To facilitate this growth, CMS seeks comment on ways to increase opportunities for eligible clinicians to participate in Advanced APMs and achieve threshold levels of participation to become QPs. CMS has received feedback from the healthcare provider community on the extensive and lengthy process that is required for a model to qualify as an Advanced APM. CMS seeks feedback from stakeholders on ways the Administration can be more responsive to eligible clinicians and their patients, and potentially expedite the process for providers that want to participate in an Advanced APM. CMS also seeks guidance from the stakeholders on ways to capture appropriate data to drive the design of innovative payment models and strategies to incentivize eligible clinicians to participate in Advanced APMs.

#### **ACP Comments:**

As noted above, ACP strongly supports expanding the options that are available for internal medicine physicians and subspecialists to participate in value-based models through the Advanced APM pathway. Currently, there are few APMs available for internal medicine physicians, especially subspecialists, to participate in through the Innovation Center, and those that include the most participants, such as the Medicare Shared Savings Program ACOs in Track 1, do not even qualify as Advanced APMs due to strict financial risk requirements. Those Advanced APMs that are available are often very limited in scope and only allow participants in certain regions or who meet very limited criteria. Many specialists and subspecialists lack any Advanced APMs that are relevant to their specialization. And for primary care physicians, a patient-centered medical home model that is an Advanced APM simply is not available yet.

ACP recommends that CMMI take into account a number of options and considerations to make Advanced APMs more readily available including:

- **Expand opportunities for primary care physicians to participate in medical home models as Advanced APMs.** Additional medical home models should include both models that meet the medical home model nominal amount standard, as well as by using 1115A(c) authority to expand PCMH models that do not have a nominal risk requirement. The details of ACP’s recommendations regarding medical home options can be found in our comments on the 2018 QPP rule.<sup>6</sup>
  - In this context, the College also would like to re-iterate our strong support for the Comprehensive Primary Care Plus (CPC+) program. As indicated in our November 8, 2017 [testimony](#) before the Energy and Commerce Health Subcommittee on “MACRA and Alternative Payment Models: Developing Options for Value-based Care,”<sup>7</sup> ACP believes that CPC+ offers the potential of greatly strengthening the ability of internists and other primary care clinicians, in thousands of practices nationwide, to deliver high value, high performing, effective, and accessible primary care to millions of their patients. The success of this program will depend on Medicare and other payers providing physicians and their practices with the sustained financial support needed for them to meet the goal of providing comprehensive, high value, accessible, and patient-centered care, with realistic and achievable ways to assess each practices’ impact on patient care. The College is committed to working with CMS on the ongoing implementation of this program to ensure that it is truly able to meet such requirements of success. Further, ACP recognizes that, in addition to CPC+ being a currently available advanced APM, it is also an ongoing research project whose methodology needs to be as sound as feasibly possible. Therefore, any new primary care programs that are to be tested by CMMI should be conducted in such a way as to not negatively impact the CPC+ methodology.
- **Apply medical home model standards to specialty practice models.** On the MIPS side, certified/recognized PCMHs and comparable specialty practice models are treated the same when it comes to receiving full credit for improvement activities. For APMs, CMS should allow comparable specialty practice models that are Advanced APMs to qualify for the medical home model nominal amount standard as well as utilize the non-risk-bearing standard for PCMHs that meet the criteria for expansion under 1115A(c).
- **Eliminate arbitrary limits on number of clinicians in an organization to be considered an Advanced APM.** We urge CMS to remove any limitations on Medical Home Models based on the number of clinicians in the organization that owns and operates the practice site. A TIN may have many practice sites under it but only one or two that are primary care and therefore able to be recognized PCMHs—or, more specifically, CPC+ practices. These practice sites are then not able to receive the bonus payments for being

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[https://www.acponline.org/acp\\_policy/letters/cms\\_comment\\_letter\\_re\\_cy\\_2018\\_macra\\_qpp\\_proposed\\_rule\\_2017.pdf](https://www.acponline.org/acp_policy/letters/cms_comment_letter_re_cy_2018_macra_qpp_proposed_rule_2017.pdf)

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[https://www.acponline.org/acp\\_policy/testimony/statement\\_house\\_energy\\_commerce\\_health\\_subcommittee\\_hearing\\_on\\_macra\\_and\\_apms\\_2017.pdf](https://www.acponline.org/acp_policy/testimony/statement_house_energy_commerce_health_subcommittee_hearing_on_macra_and_apms_2017.pdf)

an advanced APM when they are performing the same functions as other CPC+ practices.

- **Maintain or reduce nominal amount standards for risk to create stability as models are being developed.** Groups that are designing APMs expend significant time and resources during the development process, potential review by the PTAC, and possible work with CMS to further refine and implement. By the time this process, which can take years, is completed and a model is being tested, nominal amount standards will likely have changed or increased over what they were during the development process. In order to expand the available Advanced APMs, CMS should at a minimum maintain the current nominal amount standards indefinitely so that groups developing models know what risk target they need to meet. To bring models and participants into the fold more rapidly, a reduction in the arbitrary nominal amount standards should be considered.
- **Consider adding flexibility to the nominal risk standards for other-payer Advanced APMs.** Models that are being implemented by other payers often do not necessarily fit neatly within the CMS-defined nominal amount standard for Medicare Part B models as well as other design structures in Medicare models. More flexible standards for other payer APMs will expand options for participating in Advanced APMs.
- **Create lower nominal amount standard for models focused on small practices and those in rural areas and health professional shortage areas (HPSAs).** In recognition of the challenges that small and rural practices face in accepting the general nominal amount standard of risk, CMS should allow these practices to join Advanced APMs under a lower nominal risk standard (e.g., the medical home model standard). This would include small and rural practices that are part of a medical home model and those that join larger APM entities.
- **Consider the upfront costs of participating in APMs as well as the ongoing maintenance costs when determining whether models meet nominal financial risk criteria.** Significant “at risk” capital requirements are necessary to start and maintain APMs such as ACOs. The College reaffirms its belief that Track One MSSP ACOs should qualify as meeting the nominal risk requirement for determining an Advanced APM. This position was more fully articulated in a joint comment letter signed-onto by the College dated March 25, 2016.<sup>8</sup>
- **Ensure that reporting and other administrative tasks within current and new advanced APMs are developed, implemented, and monitored in a manner that ensures they do not add unnecessary burden to the clinician practice and/or to their patients and families.** This approach is aligned with the Administration’s recently announced “Patients Over Paperwork” initiative and with the College’s “Patients Before Paperwork”<sup>9</sup> initiative that has been in place since 2015, as well as our policy paper “Putting Patients First by Reducing Administrative Tasks in Health Care.”<sup>10</sup>

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<sup>8</sup> [https://www.acponline.org/acp\\_policy/letters/joint\\_comment\\_mssp\\_aco\\_benchmarking\\_2016.pdf](https://www.acponline.org/acp_policy/letters/joint_comment_mssp_aco_benchmarking_2016.pdf)

<sup>9</sup> <https://www.acponline.org/advocacy/where-we-stand/patients-before-paperwork>

<sup>10</sup> <http://annals.org/aim/fullarticle/2614079/putting-patients-first-reducing-administrative-tasks-health-care-position-paper>



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

### **CMS Proposal:**

CMS believes beneficiaries should be empowered as consumers to drive change in the health system through their choices. Consumer-directed care models could empower Medicare, Medicaid, and CHIP beneficiaries to make choices from among competitors in a market-driven healthcare system. To better inform consumers about the cost and quality implications of different choices, CMS may develop models to facilitate and encourage price and quality transparency, including the compilation, analysis, and release of cost data and quality metrics that inform beneficiaries about their choices. CMS will consider new options for beneficiaries to promote consumerism and transparency. For example, beneficiaries could choose to participate in arrangements that would allow them to keep some of the savings when they choose a lower-cost option, or that incentivize them to achieve better health. Models that we are considering testing include allowing Medicare beneficiaries to contract directly with healthcare providers, having providers propose prices to inform beneficiary choices and transparency, offering bundled payments for full episodes of care with groups of providers bidding on the payment amount, and launching preferred provider networks. CMS solicits feedback from patient and consumer advocacy groups, the healthcare provider community, as well as experts in the technology industry, and other stakeholders that can provide creative ideas on how to operationalize these principles in models that best serve patients in terms of cost, quality, and access to care.

### **ACP Comments:**

As discussed earlier in our comments on the Guiding Principles, the College recommends caution in terms of moving too quickly toward systems that depend significantly on consumer choice based on quality, outcomes, and cost. The currently available performance measures, measurement systems, and means of sharing performance information with consumers, which would be the basis for and means of patients and families making their health care decisions, are not adequate. Until quality measures are developed that appropriately assess high priority areas and improved patient outcomes, patients will not have valid and reliable data available with which to properly assess quality—and then these data also need to be provided to patients and their families in usable and useful formats for decision-making. In announcing new initiatives related to “Meaningful Measures” and “Patients Over Paperwork,” CMS Administrator Seema Verma acknowledges the challenges with administrative tasks, regulatory burdens, and the quality measures that currently are used by Medicare—and ACP is hopeful that the work under those initiatives can lead to an environment that would eventually be able to support a greater, and more informed, ability of consumers to make choices based on quality and cost.

As outlined in ACP’s newly released paper titled “Improving Health Care Efficacy and Efficiency Through Increased Transparency,”<sup>11</sup> price should never be used as the sole criterion in choosing a clinician, health care service, health plan, or payment model. Therefore, transparency of reliable and valid price information, expected out-of-pocket costs, and quality data that allows consumers, physicians, payers, and other stakeholders to compare and assess medical services and products in a meaningful way is critical.

Along these lines, the College recommends that CMS and other stakeholders work together to ensure proper patient education and that health literacy efforts are undertaken to promote better, more accessible, and objective information about any cost and quality information, cost-sharing requirements, patient incentives, etc. that may be associated with a beneficiary choosing to participate in a model. Comparison data on quality and price must be available in a format that allows consumers to directly compare performance across entities. CMS should also consider partnering with advocacy groups to host listening sessions and provide other materials to ensure that consumers are educated on new models and their potential impact on their care and relationships with physicians. More broadly, patient representatives should have a role in discussions related to benefit design, payment model development, and related patient education efforts.

The College also recommends that CMS consider supporting the development of all-payer claims databases (APCDs), which can play an important role in standardizing information that can be analyzed for use in APM development and price transparency. These databases should be setup in a manner that they can be expanded to incorporate information beyond claims such as qualified clinical data registry (QCDR) and vital statistics information.

ACP does not support Consumer-Directed Care and Market-Based Innovation Models that would “incentivize them [patients] to achieve better health” if that means penalizing patients who are unable to achieve desired health outcomes. While the College supports voluntary models that offer the support needed to help patients achieve better health, such as no-cost access to evidence-based smoking cessation, weight loss, and care coordination services, such must models not penalize patients that fall short of meeting desired health goals and outcomes. Models that would impose coverage limitations, financial penalties, or reduced access to care for failure to achieve health goals will disproportionately impact poorer patients who lack funds to pay for the additional out-of-pocket costs that may be imposed. Social determinants of health such as socioeconomic status, inadequate housing and transportation, lack of access to healthy foods, and racial and ethnic health disparities are known to negatively impact patients’ health. Accordingly, Consumer-Directed and Market-Based Innovation Models must not punish patients by withholding benefits or imposing financial penalties on them for behaviors or actions that may be associated with social determinants that are largely beyond their control. Models should recognize these factors and seek to identify causes, effects, and

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[https://www.acponline.org/acp\\_policy/policies/improving\\_health\\_care\\_efficacy\\_and\\_efficiency\\_through\\_increased\\_transparency\\_2017.pdf](https://www.acponline.org/acp_policy/policies/improving_health_care_efficacy_and_efficiency_through_increased_transparency_2017.pdf)

methods prevention of social determinants of health and their impact on patients while avoiding penalizing patients. Quality and other performance measures utilized in these models must also include risk adjustments that reflect the increased risk of disadvantaged patients.

ACP strongly recommends that models that are intended to promote behavior change by offering supportive services to patients be designed to allocate health care resources fairly without discriminating against a class or category of people. Furthermore, health plans should not interfere with the ability of patients to communicate freely with physicians and other health care clinicians. The physician should not be required to reveal information about the patient that could jeopardize the patient-physician relationship, as discussed in an ACP paper on Medicaid policy.<sup>12</sup> A physician cannot properly treat a patient who is untruthful about adherence to a medical plan for fear of loss of health benefits. Programs that use negative incentives may interfere with the physician's ability to exercise independent medical judgment in developing an individual plan of care.

With regard to testing consumer-directed models including those that allow beneficiaries to contract directly with clinicians such as direct patient care models, as outlined in our paper titled, "Assessing the Patient Care Implications of 'Concierge' and Other Direct Patient Contracting Practices: A Policy Position Paper From the American College of Physicians,"<sup>13</sup> the College supports physician and patient choice of practice and delivery models that are accessible, ethical, and viable and that strengthen the patient-physician relationship. ACP believes that physicians in all types of practices must:

- Honor their professional obligation to provide nondiscriminatory care, serve all classes of patients who are in need of medical care, and seek specific opportunities to observe their professional obligation to care for the poor and
- Be transparent with patients and offer details of financial obligations, services available at the practice, and the typical fees charged for services.

Further, physicians in practices that choose to downsize their patient panel for any reason should consider the effect these changes have on the local community, including patients' access to care from other sources in the community, and help patients who do not stay in the practice find other physicians. Additionally, the College has recommended that physicians who are in or are considering a practice that charges a retainer fee should consider the effect that such a fee would have on their patients and local community, particularly on lower-income and other vulnerable patients, and ways to reduce barriers to care for lower-income patients that may result from the retainer fee. These recommendations are also relevant for programs developed that incorporate either or both of these elements—of reduced patient panel size and charging of a retainer fee.

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[https://www.acponline.org/system/files/documents/running\\_practice/ethics/issues/policy/personal\\_incentives.pdf](https://www.acponline.org/system/files/documents/running_practice/ethics/issues/policy/personal_incentives.pdf)

<sup>13</sup> <http://annals.org/aim/fullarticle/2468810/assessing-patient-care-implications-concierge-other-direct-patient-contracting-practices>

The College has also called for independent research on direct patient contracting practices (DPCP) that addresses the following:

- The number of physicians currently in a DPCP, where DPCPs are located geographically, projections of growth in such DPCPs, and the number of patients receiving care from DPCPs;
- Factors that may undermine the patient–physician relationship, contribute to professional burnout, and make practices unsustainable and their effect on physicians choosing to provide care through DPCPs;
- The impact and structure of DPCP models that may affect their ability to provide access to underserved populations;
- The effect of DPCPs on the health care workforce;
- Patients' out-of-pocket costs and overall health system costs;
- Patients' experience with the care provided, quality of care, and outcomes; and
- The effect of physicians not participating in insurance and therefore not participating in national quality programs, interoperability with other electronic health record systems, and the associated effect on quality and outcomes.

The College notes that Administrator Verma recently announced a potential new Direct Primary Care project that may be tested or implemented by the Innovation Center. ACP looks forward to learning details of that project once available—and plans to provide feedback to the Agency regarding its implementation to ensure it is aligned with our recommendations as outlined above. Additionally, we would like to reiterate our comments from earlier that any new primary care project should not jeopardize the important research methodology of CPC+.

### **3. Physician Specialty Models**

#### **a. Specialty Models**

##### **CMS Proposal:**

The Innovation Center is interested in increasing the availability of specialty physician models to improve quality and lower costs and engage specialty physicians in alternative payment models, especially for independent physician practices. One potential option may be to include specialty physician management of a defined population of beneficiaries with complex or chronic medical conditions, including multiple chronic conditions. This may include the specialist serving as the primary source of care and providing care coordination for medically complex beneficiaries. Another option may be paying healthcare providers for limited episodes of care based on quality measure performance and competitive pricing. For cancer care in particular, a model could test full prepayment for Medicare and Medicaid beneficiaries, with care provided in collaborative networks, possibly incorporating elements from the existing Oncology Care Model. CMS solicits feedback from the provider community, patient and consumer advocacy groups, and other stakeholders regarding their best ideas for new physician specialty models and appropriate quality measures.

**ACP Comments:**

Overall, the College supports increasing the availability of models that are targeted to specialists and subspecialists. These groups currently have very few options, and many specialties and subspecialties lack an Advanced APM that has a focus related to their area of specialization. Many specialty-specific models are undergoing or have completed a review through the PTAC. CMMI should implement an accelerated platform for testing models that the PTAC makes a recommendation of at least limited testing. This should include models for both primary care and non-primary care specialists and subspecialists.

While we agree that more models are needed for non-primary care specialists/subspecialists, ACP is concerned that CMMI appears to be looking at models in which specialists assume the role of the primary care physician, taking on the care coordination role of the broad spectrum of needs that a medically complex patient may have. While there may be limited circumstances under which this model would be appropriate (such as for an oncologist treating a cancer patient), specialty APMs should consider how appropriate interaction between specialists and primary care physicians should occur rather than attempt to replace the primary care role in the care continuum with a non-primary care specialist.

Developing specialty APMs that do not embrace the roles that primary care physicians and specialists play in managing the patient's overall care in addition to any chronic and episodic treatment/care needs will result in siloed, fragmented care, to the detriment of the patient's health needs. Models should encourage specialists and primary care physicians to coordinate care. This is important so that if a specialist does provide the plurality of services for a period (such as in cancer care), the oncologist is not acting in isolation from the patient's other physicians. Incentives can encourage accountability for the totality of a patient's care integration across primary care and specialty silos. This will help avoid redundancy in services and fragmentation across multiple physicians.

As an example of a more appropriate way of interfacing a primary care PCMH with a specialty/subspecialty practice, the College strongly recommends that CMS consider the concepts outlined in our position paper on "The Patient-Centered Medical Home Neighbor: The Interface of the Patient Centered Medical Home with Specialty/Subspecialty Practices"<sup>14</sup> (PCMH-N), which was developed through representatives of ACP's Council of Subspecialty Societies (CSS). The concepts in that paper expand upon the typology of specialist roles offered by Forrest.<sup>15</sup> The College believes that the following clinical interactions between the PCMH and the PCMH-N (specialist/subspecialist) may be appropriate:

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[https://www.acponline.org/system/files/documents/advocacy/current\\_policy\\_papers/assets/pcmh\\_neighbors.pdf](https://www.acponline.org/system/files/documents/advocacy/current_policy_papers/assets/pcmh_neighbors.pdf)

<sup>15</sup> Forrest CB. A typology of specialists' clinical roles. Arch Intern Med. 2009;169(11):1062-1068.

<http://archinte.jamanetwork.com/article.aspx?articleid=415082>

- Preconsultation exchange—intended to expedite/prioritize care—a preconsultation exchange either answers a clinical question without the necessity of a formal specialty visit (“curbside consultation”) and/or better prepares the patient for specialty assessment.
- Formal consultation—to deal with a discrete question/procedure—is a formal consultation limited to one or a few visits that are focused on answering a discrete question. The specialty/subspecialty practice would not manage the problem on an ongoing basis.
- Co-management:
  - With Shared Management for the disease—the specialty/subspecialty practice provides guidance and ongoing follow up of the patient for one specific condition but will not manage the illness on a day to day basis.
  - With Principal care for the disease—both the PCMH/primary care practice and specialty/subspecialty practice are concurrently active in the patient’s treatment, but the specialty practice’s responsibilities are limited to a discrete group or set of problems.
  - With Principal care of the patient for a consuming illness for a limited period—the specialty/subspecialty practice needs to temporarily become the first contact for care of the patient because of the significant nature and impact of the disorder. However, the PCMH/primary care practice still receives on-going treatment information, retains input on secondary referrals, and may provide certain, well-defined areas of care.
- Transfer of patient to specialty/subspecialty PCMH for the entirety of care—this refers to situations in which the specialty/subspecialty practice assumes the role of the PCMH/primary care practice after consultation with the patient’s current personal physician, and approval by the patient. This situation is best represented by a specialty/subspecialty practice that is seeing a patient frequently over a relatively long period for the treatment of a complex condition that affects multiple aspects of his or her physical and general functioning. Representative examples include:
  - An infectious disease practice caring for a patient with HIV/AIDS with complex medical and treatment issues.
  - A nephrology practice caring for a dialysis patient with end-stage renal disease.

These recommendations have since been operationalized through the development of ACP’s [High-Value Care Coordination Toolkit](#). This toolkit includes:

- Pertinent data sets (PDS) 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;
- Recommendations to help referring physicians and other healthcare professionals engage in an effective “patient- and family-centered” referral process; and

- Care coordination agreements that define expectations and responsibilities for the practices involved in a referral relationship.

This toolkit, as well as other educational and practical resources, are also being incorporated into ACP's work on our Support and Alignment Network (SAN) grant, as part of the CMS Transforming Clinical Practice Initiative (TCPI). The efforts of our SAN, as well as the many Practice Transformation Networks (PTNs) and other SANs with whom we are coordinating, to improve care coordination across primary care and specialists is critically important and should be incorporated into any new CMMI projects for physician specialists.

Additionally, the College reiterates its recommendations from our comments on the QPP proposed rule<sup>16</sup> regarding how to address concerns about the limited number of opportunities now accessible for non-primary care specialists/subspecialists to participate in recognized APMs and Advanced APMs:

- As we previously noted, a period of stability and predictability for Advanced APMs in which the nominal amount standard remains constant is essential. Setting a bar for the nominal amount standard that is uncertain in a few years will create a moving target as groups are trying to properly design and test proposals for submission through the PTAC process or direct implementation by CMMI. CMS should also maintain the current standards for any new models being implemented for at least the initial years of implementation to ensure stability in model testing.
- Priority consideration and testing of models involving physician specialties/subspecialties with no current recognized APMs and Advanced APM options available should be provided through the PTAC and CMMI along with a clear pathway for models recommended by PTAC to be implemented as APMs under QPP, as detailed below.
- CMS must create a platform to accelerate the testing of bundled payments and similar episodes of care payment models. Bundled and episode of care payment models are best aligned with the type of services provided by many of our subspecialists. To accomplish this, CMS should consider extending the Bundled Payment for Care Initiative (BPCI) and expanding it beyond the current inpatient-based tracks or instituting a new ambulatory-based bundled payment initiative.

Additionally, a major problem faced by most bundled payment APMs being considered by our subspecialist members is how participants in these developing payment models will be able to meet the necessary qualifying participant (QP) payment amount or patient count thresholds. The bundled services within the developing models only cover a relatively small number of the overall patients within their panels. Alternative means of addressing this issue include:

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<sup>16</sup>

[https://www.acponline.org/acp\\_policy/letters/cms\\_comment\\_letter\\_re\\_cy\\_2018\\_macra\\_qpp\\_proposed\\_rule\\_2017.pdf](https://www.acponline.org/acp_policy/letters/cms_comment_letter_re_cy_2018_macra_qpp_proposed_rule_2017.pdf)

- Providing increased flexibility for eligible clinicians to participate in multiple Advanced APMs and combining payment/patient count amounts when determining whether the threshold has been obtained. CMS' decision to allow CPC+ practices to participate within the Medicare Shared Saving Program is an example of the type of flexibility that may assist physicians and other eligible health professionals to become QPs while engaged in a recognized bundled payment advanced payment model.
- Developing pathways using the "virtual group" language in MACRA allow practices to combine their Advanced APM activities and related payment/patient count amounts when determining whether the QP threshold has been obtained.

#### **b. Physician-Focused Payment Model Technical Advisory Committee (PTAC) Recommended Models**

##### **CMS Proposal:**

In addition to creating MIPS and Advanced APMs, MACRA also creates incentives for physicians to participate in Alternative Payment Models (APMs), including the development of physician-focused payment models (PFPMs). Section 101(e)(1) of MACRA creates the Physician Focused Payment Model Technical Advisory Committee (PTAC). PTAC makes comments and recommendations to the Secretary on proposals for physician-focused payment models submitted by individuals and stakeholder entities. The Secretary may choose to recommend Innovation Center testing of models recommended by PTAC.

##### **ACP Comments:**

ACP supports the PTAC and its important role in evaluating and making recommendations on physician-focused payment models. The College would like to reiterate recommendations from our comments<sup>17</sup> on the QPP proposed rule for CY 2018 on some improvements that can be made to accelerate the process for making additional Advanced APMs available.

**The College recommends that CMS provide a clear pathway for models recommended by PTAC to be implemented as APMs under MACRA.** As a part of this process, CMS should establish a date by which the Secretary will post an initial response to recommendations received from the PTAC. In order to maximize the availability of APMs to specialists and subspecialists, ACP recommends that CMS post a response within 60 days of the receipt of recommendations from the PTAC.

**ACP also urges CMS to make technical assistance available to stakeholders that are developing PFPMs for PTAC review.** Organizations that seek to propose PFPMs through the PTAC often lack sufficient expertise in at least a few areas that are needed to fully develop proposals for review, causing changes to be made throughout the PTAC process. CMMI should

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[https://www.acponline.org/acp\\_policy/letters/cms\\_comment\\_letter\\_re\\_cy\\_2018\\_macra\\_qpp\\_proposed\\_rule\\_2017.pdf](https://www.acponline.org/acp_policy/letters/cms_comment_letter_re_cy_2018_macra_qpp_proposed_rule_2017.pdf)



offer technical assistance to organizations as needed throughout the development process based on expertise gained in the design and testing of other models.

Access to appropriate data that is needed to design the payment structure underlying a model also presents challenges. ACP encourages CMS to provide access to data and analytics to assist stakeholders in the process of developing APM proposals that can benefit from refinements prior to submission to the PTAC. For groups without sufficient resources to hire analytics consultants, CMS should consider providing the claims analysis that is necessary for submission with proposals to the PTAC.

#### **4. Prescription Drug Models**

##### **CMS Proposal:**

CMS wants to test new models for prescription drug payment, in both Medicare Part B and Part D and State Medicaid programs that incentivize better health outcomes for beneficiaries at lower costs and align payments with value. Models that better align incentives and engage beneficiaries as consumers of their care can continue to improve patient outcomes while controlling drug costs. Models that contemplate novel arrangements between plans, manufacturers, and stakeholders across the supply chain, including, but not limited to innovative value based purchasing arrangements, and models that would increase drug pricing competition while protecting beneficiaries' access to drugs are of particular interest.

##### **ACP Comments:**

Prescription drug pricing and costs are of considerable interest to ACP members. ACP believes a truly competitive marketplace can help to keep prescription drug costs reasonable for consumers; however, the current marketplace is broken and is not efficiently self-regulating. ACP's position [paper](#) "Stemming the Escalating Costs of Prescription Drugs" puts forth several recommendations with regards to lowering the cost of prescription medications through transparency, competition, and multi-stakeholder engagement, including the following:

- There should be transparency in the pricing, cost, and comparative value of all pharmaceutical products:
  - a. Pharmaceutical companies should disclose:
    - i. Actual material and production costs to regulators;
    - ii. Research and development costs contributing to a drug's pricing, including those drugs which were previously licensed by another company.
  - b. Rigorous price transparency standards should be instituted for drugs developed from taxpayer-funded basic research.
- Medicare and other publicly funded health programs should have the flexibility to negotiate volume discounts on prescription drug prices and pursue prescription drug bulk purchasing agreements.

- Legislative or regulatory measures to develop a process to reimport certain drugs manufactured in the United States should be pursued, provided that the safety of the source of the reimported drug can be reasonably assured by regulators.
- Policies or programs that may increase competition for brand-name and generic sole-source drugs should be established.
- Research into novel approaches to encourage value-based decision making should be conducted, including consideration of the following options:
  - a. Value frameworks;
  - b. Bundled payments;
  - c. Indication-specific pricing;
  - d. Evidence-based benefit designs that include explicit consideration of the pricing, cost, value, and comparative effectiveness of prescription medications included in a health plan's benefit package.

Potential Prescription Drug Models should take into consideration the variation among drug classes with regard to the availability of alternative treatment options and the existing reimbursement rates for certain drugs. In certain drug classes, there are very few options for treatment or difference in price among drugs. Additionally, any Prescription Drug Model should not place the primary responsibility of keeping costs down on the prescriber.

ACP outlined ways physician engagement would be beneficial to potential drug pricing models in a May 2016 [letter](#) regarding CMMI's proposed Part B Drug Pricing Model. These benefits include a heightened understanding of how physicians measure effectiveness of drugs in patients long-term and ways to capture this information.

The College is also an active participant and partner in the Campaign for Sustainable Rx Pricing (CSRxP). The Campaign works foster a national dialogue focused on innovation and affordability in drug pricing, through support of market-based reforms that address the underlying causes of high drug prices in the U.S. through increased transparency, competition, and value. We encourage CMS to consider CSRxP's [recommendations](#) as the Agency considers developing prescription drug models.

## **5. Medicare Advantage (MA) Innovation Models**

### **CMS Proposal:**

CMS wants to work with Medicare Advantage (MA) plans to drive innovation, better quality and outcomes, and lower costs. CMS seeks to provide MA plans the flexibility to innovate and achieve better outcomes. CMS is currently implementing an MA plan model, the Medicare Advantage Value-Based Insurance Design (VBID) model, that provides benefit design flexibility to incentivize beneficiaries to choose high-value services; but this model could be modified to provide more flexibility to MA plans and potentially add additional states. More generally, CMS is interested in more models in the MA plan space and regulatory flexibility as necessary for purposes of testing such models. CMS is potentially interested in a demonstration in Medicare Advantage that incentivizes MA plans to compete for beneficiaries, including those

beneficiaries currently in Medicare fee-for-service (FFS), based on quality and cost in a transparent manner. CMS is also interested in what additional flexibilities are needed regarding supplemental benefits that could be included to increase choice, improve care quality, and reduce cost. Additionally, CMS seeks comments on what options might exist beyond FFS and MA for paying for care delivery that incorporate price sensitivity and a consumer driven or directed focus and might be tested as alternatives to FFS and MA.

**ACP Comments:**

ACP supports transparency in the development of payment models, including those MA plans that are designed as alternative payment models. While most MA plans currently operate on a fee-for-service basis, they have the flexibility to test alternate payment structures as well as offer supplemental services that are not covered under traditional Medicare. Along these lines, the College suggests that CMMI consider ACP’s recommendations in our recent position paper on “Promoting Transparency and Alignment in Medicare Advantage”<sup>18</sup> in contemplating how MA fits within the drive toward more value-based care, which include the following:

- MA plans must become transparent in their processes, policies, and procedures for how they develop and administer their MA plans and portfolios for all key stakeholders to ensure program integrity. This includes transparency in payment structure and design as well as financial and quality-based incentives to ensure that elements that prove successful can be considered for incorporation into other APM designs.
- All payment models and incentives, including new alternative payment models, implemented by MA plans with participating physicians should foster high-value care to all beneficiaries, and aim to engage participating physicians in designing and implementing value-based payment. They should also encourage delivery system reforms that allow them and other members of the clinical care team to share in savings associated with providing high-value, coordinated primary and comprehensive care.
- Increased research is necessary on the effects of excessive administrative tasks on physicians and beneficiaries who participate in MA plans as well as research on best practices to help reduce excessive and burdensome administrative tasks and further align administrative processes within the MA Program and across traditional Medicare.
- The quality measurement systems for both MA plans and traditional Medicare should align to promote high-quality care for all beneficiaries, streamline quality reporting across Medicare programs, encourage administrative simplification, and provide beneficiaries with a clear and understandable means to compare benefits and options across Medicare programs.
- Processes and requirements for risk stratification and capturing severity of illness should be transparent and align across all MA plans.

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[https://www.acponline.org/acp\\_policy/policies/promoting\\_transparency\\_and\\_alignment\\_in\\_medicare\\_advantage\\_2017.pdf](https://www.acponline.org/acp_policy/policies/promoting_transparency_and_alignment_in_medicare_advantage_2017.pdf)

- MA plans should provide beneficiaries with a clear and understandable means to compare benefits and options when deciding between an MA plan and traditional Medicare.
- More research on how federal payments to the MA Program are utilized by MA Organizations is needed. Specifically, ACP calls for further research on the types of payment models used and prices paid by Medicare Advantage Organizations (MAOs) to contracted physicians, hospitals, and other clinicians compared with the models used and prices paid by traditional Medicare and commercial health insurance plans.

Additionally, as the College notes in our comments<sup>19</sup> on the QPP proposed rule for CY 2018, ACP supports the idea of allowing an additional pathway for Qualifying Participant (QP) determination through the patient count test for clinicians participating in Advanced APMs in the MA program as long as they are able to clearly demonstrate they are participating in a qualifying payment arrangement that meets the Advanced APM criteria for QPP. The College recommends CMS use their authority to reconsider the types of beneficiaries included in the overall patient count for QP determination to include MA beneficiaries earlier than the proposed 2019 implementation of the Other Payer option. A simple and understandable attestation process that requires only the necessary information to determine Advanced APM qualifications should be developed to minimize burden.

Other-payer value-based payment designs often differ in structure from the strict criteria that CMS established for determining whether Medicare APMs are considered Advanced APMs. This includes differences in financial incentives and risk as well as variables like use of quality measures and use of EHRs. While Medicare Part B APMs are limited to quality measures that are comparable to those used in MIPS and require use of CEHRT rather than just use of EHRs, APMs from other payers including MA plans may not use identical wording in contracts. Therefore, we further recommend that CMS consider using significant flexibility in determining whether other-payer APMs can be considered Advanced APMs for the purposes of QP determinations under the other-payer combination option in QPP.

## **6. State-Based and Local Innovation, including Medicaid-Focused Models**

### **CMS Proposal:**

States play a critical role in innovation and delivery of high quality care. CMS wants to partner with states to drive better outcomes for people based on local needs. CMS and the Innovation Center have worked with states on a variety of initiatives including the State Innovation Models, Innovation Accelerator Program, Strong Start and Medicaid Incentives for the Prevention of Chronic Diseases Model. These efforts and a variety of successful State-led models provide lessons learned for advancing innovation. Through this model focus area, States could drive reform and innovation. Healthcare providers and states would work with CMS to

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[https://www.acponline.org/acp\\_policy/letters/cms\\_comment\\_letter\\_re\\_cy\\_2018\\_macra\\_qpp\\_proposed\\_rule\\_2017.pdf](https://www.acponline.org/acp_policy/letters/cms_comment_letter_re_cy_2018_macra_qpp_proposed_rule_2017.pdf)

develop state-based plans and local innovation initiatives to test new models. Models would vary based on the needs and goals of each state for improving care and lowering costs, but could include providing states with more flexibility for multi-payer reforms as well as increasing opportunities for physicians serving Medicaid and CHIP populations to participate in value-based payment models. Models specific to Medicaid populations would also be considered. CMS would rely on authority under sections 1115 and 1115A of the Act in developing and implementing such models.

**ACP Comments:**

In general, the College is supportive of state- or local-level innovative models and again would recommend that our earlier feedback regarding how best to increase and improve participation in Advanced APMs be considered—including maintaining or reducing nominal amount standards for risk to create stability as models are being developed; creating lower nominal amount standard for models focused on small practices and those in rural areas and health professional shortage areas (HPSAs); making other payer Advanced APM requirements more flexible; and allowing successful state and local models to be expanded through 1115A(c) authority to allow the model design to be used as a Medicare Advanced APM option, including medical home and specialty practice models with or without a risk-bearing requirement. For example, Medicaid medical home models such as the Arkansas PCMH model have shown success in improvements in quality and decreases in costs<sup>20</sup> that warrant consideration by the Innovation Center for expansion under 1115A(c).

ACP also appreciates the Administration’s interest in creating opportunities for physicians serving Medicaid and CHIP populations, where reimbursement rates are often significantly lower than for Medicare. Any new projects aimed at those populations must also ensure that the measures they use are appropriately risk adjusted including adjustments for socioeconomic status and other factors such as patient frailty. Failing to properly risk adjust creates a system that inappropriately penalizes physicians with higher numbers of lower income or frailer patients, which could cause physicians to cherry-pick the patients that will be less costly at the detriment of those most in need of care.

It is also important that models designed for Medicaid and CHIP populations ensure that these patients continue to have access the same high quality services that are available across the entirety of the program. Testing new payment models for these vulnerable populations should not be used as a mechanism to test limiting access to services or care that are otherwise available to other patients within the program. It is critical that these new innovative models are used to enhance patient care and improve outcomes rather than creating large variations in the services covered/provided to Medicaid and CHIP beneficiaries across different states.

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<sup>20</sup> <http://humanservices.arkansas.gov/pressroom/PressRoomDocs/DMSpatientcentermhawardsNRoct15.pdf>

## 7. Mental and Behavioral Health Models

### **CMS Proposal:**

CMS is actively exploring potential models focused on behavioral health, including focus areas such as opioids, substance use disorder, dementia, and improving mental healthcare provider participation in Medicare, Medicaid, and CHIP through models that enhance care integration and/or utilize episode payment. CMS is interested in stakeholders' views of the best payment models and state and local interventions to improve care in these areas.

### **ACP Comments:**

ACP supports the integration of behavioral health care into primary care and encourages its members to address behavioral health issues within the limits of their competencies and resources. To achieve this, public and private health insurance payers, policymakers, and primary care and behavioral health care professionals should work toward removing payment barriers that impede behavioral health and primary care integration. Stakeholders should ensure the availability of adequate financial resources to support the practice infrastructure required to effectively provide such care. The College also supports increased research to define the most effective and efficient approaches to integrate behavioral health care in the primary care setting.

Regarding the guiding principles, we concur that benefit design is important, especially related to pain management and treatment of substance use disorders. We strongly support further research and broader access to non-pharmacologic pain management. To accelerate the development of high-quality evidence for non-opioid pain treatments, ACP supports:

- PCORI-funded and AHRQ-funded research addressing safety, quality, comparative effectiveness, and cost effectiveness of non-opioid pain management strategies;
- Large randomized controlled clinical trials whenever possible; and
- Encourages the incorporation of patient-centered and patient-reported outcomes in new research to appropriately characterize and assess potential benefits of these therapies.

ACP also believes that to facilitate improved access to non-opioid methods of pain control, CMS should reduce cost sharing and eliminate the need for prior authorization for non-opioid pain management strategies.

We strongly encourage comprehensive coverage of evidence-based treatment of substance use disorders. CMS must reduce barriers that impede access to substance use disorder treatment services, including medications to treat opioid use disorder (methadone, buprenorphine, and naltrexone) and to medications for overdose prevention (naloxone). Public and private insurers should remove onerous limits on medications for overdose prevention and medication-assisted treatment, including burdensome prior authorization rules or lifetime limits on buprenorphine that prevent medically necessary care. For example, California's Medi-Cal program no longer

requires physicians to have a Treatment Authorization Request before using buprenorphine to treat opioid use disorder.

ACP does not endorse any specific model but several approaches to integrated behavioral health care in the primary care setting have received substantial validation in the literature, including the following:

- The PCMH model, with its emphasis on whole-person primary care, care coordination, and delivery of care by a team of professionals, is an excellent foundation for this integration of care.
- The Improving Mood–Promoting Access to Collaborative Treatment model for depression has been effective in multiple health care systems with several populations and various comorbid conditions.<sup>21</sup>
- Crystal Run Healthcare and Essentia Health, have sought to better integrate behavioral health in the primary care setting within an accountable care organization framework.<sup>22</sup>
- Montefiore Health System’s Henry Chung, MD and colleagues have developed a “continuum-based framework” designed to guide small and medium-size practices to integrate behavioral health into the primary care setting.<sup>23</sup>

ACP is also strongly supportive of the Collaborative Care model as an evidence-based approach for integrating physical and behavioral health services that can be implemented within a primary care-based Medicaid health home model, among other settings. Collaborative care includes: (1) care coordination and care management; (2) regular/proactive monitoring and treatment to target using validated clinical rating scales; and (3) regular, systematic psychiatric caseload reviews and consultation for patients who do not show clinical improvement.

The low physician reimbursement structure finalized by CMS for the collaborative care model has limited the primary care physician participation in the model. The reimbursement structure does not allow the primary care physician to sustain a care manager and provide the level of care needed to sustain this model in the primary care office. CMMI must make sure physician payment rates are set at levels to ensure there is sufficient participation.

## **8. Program Integrity**

### **CMS Proposal:**

CMS is seeking comment on ways that CMS may reduce fraud, waste, and abuse and improve program integrity. The costs and effectiveness of different approaches to program integrity could be tested to help CMS find the ideal balance between burdens on patients and additional

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<sup>21</sup> <http://aims.uw.edu/impact-improving-mood-promoting-access-collaborative-treatment/>

<sup>22</sup> [http://www.commonwealthfund.org/~media/files/publications/fund-report/2014/dec/1791\\_tierney\\_creating\\_connections\\_integration\\_behav\\_hlt\\_primary\\_care\\_final.pdf](http://www.commonwealthfund.org/~media/files/publications/fund-report/2014/dec/1791_tierney_creating_connections_integration_behav_hlt_primary_care_final.pdf)

<sup>23</sup> <https://uhfnyc.org/publications/881131>

workload created for the physician and effectiveness of the review. Such an approach could be tested as part of a new model and/or be layered on top of other models.

**ACP Comments:**

ACP supports healthcare resources being allocated in a prudent manner that emphasizes evidence-based care and mitigates inefficiencies, waste, and fraud. However, efforts to reduce fraud, abuse and waste under the healthcare system should not create unnecessary burdens for physicians who do not engage in illegal activities.

Fraud and abuse laws and their enforcement are an onerous burden on practicing internists. These laws have created an atmosphere in which physicians feel that almost all of their behavior is suspect. In particular, many physicians believe that inadvertent billing and coding errors made in the context of a complex system are being treated as fraud. The College seeks to: 1) reduce unnecessary burdens for physicians who do not engage in illegal activities and 2) prevent and punish fraud. ACP's position paper, "Putting Patients First by Reducing Administrative Tasks in Health Care: A Position Paper of the American College of Physicians,"<sup>24</sup> outlines a number of suggestions for how to reduce burdens on physicians who are meeting program integrity requirements.

To increase program integrity, CMMI could promote consistency by creating template or model fraud and abuse waivers that will generally apply to future models. Currently, the waivers' requirements vary by model. This may lead to clinician confusion and may make it more difficult to manage a growing portfolio of models. When contemplating template waivers, CMS should consider examining the pre-participation and participation waivers in the Medicare Shared Savings Program.

Additionally, ACP recommends that CMS consider waiving the reviewing medical record documentation of any history and/or any physical examination in determining the level of service. Rather, the only documentation reviewed should be the level of medical decision-making or time, particularly when counseling or coordination of care comprises more than 50% of the encounter. This will immediately improve care because it will allow physicians to spend more time with their patients, and will help to unclutter the medical record because documentation will be consistent with what physicians actually need to document to provide patient care.<sup>25 26</sup>

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<sup>24</sup> <http://annals.org/aim/fullarticle/2614079/putting-patients-first-reducing-administrative-tasks-health-care-position-paper>

<sup>25</sup> <http://annals.org/aim/fullarticle/2089368/clinical-documentation-21st-century-executive-summary-policy-position-paper>

<sup>26</sup>

[https://www.acponline.org/acp\\_policy/letters/comment\\_letter\\_to\\_cms\\_re\\_cy\\_2018\\_medicare\\_pfs\\_proposed\\_rule\\_2017.pdf](https://www.acponline.org/acp_policy/letters/comment_letter_to_cms_re_cy_2018_medicare_pfs_proposed_rule_2017.pdf)



### III. Conclusion

ACP appreciates the opportunity to provide feedback on the Innovation Center's New Direction RFI. We hope that CMS carefully considers our recommendations on accelerating the development of new and expanded options for Advanced APM participation, while also considering the challenges that exist in moving too quickly toward consumer-driven care and market-based models involving price transparency. The College looks forward to continuing to work with CMS to support the transition to innovative value-based care models and the development of performance measures that are truly meaningful to physicians and their patients. These new measures can better contribute to improved patient quality and outcomes and reduced costs, ultimately allowing enhanced price transparency for patients, physicians, and payers.

Thank you for considering our comments. Please contact Brian Outland, PhD, Director of Regulatory Affairs, by phone at 202-261-4544 or e-mail at [boutland@acponline.org](mailto:boutland@acponline.org) if you have questions or need additional information.

Sincerely,

A handwritten signature in black ink that reads "Jacqueline W. Fincher MD". The signature is written in a cursive, flowing style.

Jacqueline W. Fincher, MD, MACP  
Chair, Medical Practice and Quality Committee  
American College of Physicians