Population-Based Total Cost of Care (TCOC) Models Request for Input (RFI) Responses

On March 8, 2022, the Physician-Focused Payment Model Technical Advisory Committee (PTAC) requested input from the public on information that could describe current perspectives on the role that population-based TCOC models can play in optimizing health care delivery and value-based transformation in the context of alternative payment models and physician-focused payment models. PTAC received seven responses from the following stakeholders that are listed below in the order in which their responses were received:

1. Coalition to Transform Advanced Care
2. Medical Group Management Association
3. Stellar Health
4. National Association of Chain Drug Stores
5. American Physical Therapy Association
6. National Association of ACOs
7. American Society for Radiation Oncology

For additional information about PTAC's request, see PTAC's solicitation of public input.

C-TAC
COALITION TO TRANSFORM ADVANCED CARE

On behalf of the Coalition to Transform Advanced Care (C-TAC), which represents over 190 organizations across the country, we appreciate the opportunity to respond to the request for information that the Physician-Focused Payment Model Technical Advisory Committee (PTAC) solicited in March 2022 to inform the role that population-based total cost of care (TCOC) models can play in optimizing healthcare delivery and value-based transformation in the context of alternative payment models (APMs) and physician-focused payment models (PFPMs), specifically. In 2017, C-TAC was an active participant in the development and proposal of the Advanced Care Model (ACM) Service Delivery and Advanced Alternative Payment Model and remains fully supportive of the PTAC's role in evaluating APMs and PFPMs. Most recently, C-TAC participated as a panelist in a March 8, 2022, PTAC public meeting during the TCOC session. Our comments in this letter are meant to expand on that presentation, which focused on the need to address disparities in care for patients and family caregivers living with serious illness via: (1) systematically identify people living with serious illness, (2) building capacity among community-based organizations (CBOs) to partner with health systems and (3) exploring opportunities for both standalone care models and integrated, "nested", interventions across existing care models.

What are the options for defining and calculating TCOC?

Our starting point in addressing quality of care for those with serious illness is always focused on aligning care with what matters most to patients, as defined by them. This is best achieved through conversations over time using best practices in advance care planning and shared-decision-making. Within this context, the presence and accountability of a provider team that can solicit and then act on a person's holistic goals of care is critical for addressing Total Cost of Care (TCOC). Payers (MCOs or state Medicaid agencies) can delegate responsibility for cost and quality outcomes to these accountable networks of providers. Within TCOC tracks or options available to ACOs, Direct Contracting Entities, and managed care health plan participants, efforts should be made to create a more holistic concept of TCOC in general around meeting the needs of the patient and family, that includes (e.g.) home-based primary care, palliative care, hospice, dialysis, and community-based supports. Further, we urge federal partners to create sub-analyses or TCOC benchmarks for people with serious illness in particular to best assess outcomes. In other words, "success" for populations with serious illness might look like improved quality and reduced cost *trends* over time rather than reduced costs in a single year.

What services are typically included in population based TCOC models (as defined by the PCDT), and how does that set of services differ across payer types, multi-payer models, and model types?

Typically medical services incurred by the beneficiary have been included in population-based total cost of care models, rather than all forms of case management, community services, and other vendor services that may be offered by a beneficiary's health system or health plan. Additionally, while there has been an evolution in Medicare and Medicaid to incorporate some care management efforts like CCM and health homes, APMs do not consistently incorporate these programs. Team-based care is another notable gap. People with serious illness usually require the care of interdisciplinary teams, such as nurses, social workers, community health workers, spiritual care professionals, personal care aides, and other providers, often operating through community-based organizations (CBOs). These teams are essential in order to enable beneficiaries and their caregivers to remain at home and to manage their holistic needs. Because these teams are not always documented through claims or encounters if the team-

based approach does not align with a reimbursable model (e.g., collaborative care), their value is often lost when evaluating impacts to TCOC.

Further, when it comes to serious illness, critical services such as those cited above (home-based primary care, hospice, spiritual support etc) are often excluded from TCOC evaluations across payer types. Within Medicaid, direct reimbursement for social services such as in lieu of services or value-add services are also not consistently included in APMs.

These calculations are yet more complicated in the case of individuals who are enrolled in multiple insurance programs, like dually eligible individuals or individuals enrolled in separate prescription drug programs; in these cases costs/savings may occur across Medicare and Medicaid contexts and no single network of accountable providers has comprehensive lines of sight. In the case of dual eligibles, long-term care costs are often incurred by one plan (Medicaid) and acute/hospitalization related savings accrued by the other (Medicare). For models like home-based primary care, palliative care and hospice, this is even more pronounced, as multiple studies have demonstrated significant TCOC reduction, much of the savings accrues to Medicare, due (e.g.) to earlier and more timely referrals to hospice. C-TAC proposes that TCOC models consider all Medicare and Medicaid utilization in order to understand true model impacts.

Despite these challenges, we believe the raw ingredients are present in order to facilitate more holistic TCOC models moving forward. In the private sector, more payers are expanding benefits and services to include supplemental benefits for their beneficiaries and are turning to private vendors to manage unsustainable costs. These shifts ensure that more non-traditional types of services are increasingly being catalogued by payers and can be included in benchmark calculations.

Finally, we urge federal partners to consider up-front investment or pre-payment strategies alongside a reconsideration how TCOC is calculated. In many instances, savings or losses are calculated on the back-end, after a performance year and savings, if achieved, are not available to provider networks until many months later. This payment lag is challenging for incorporating social supports that may not be traditionally reimbursable by health payers or require some infrastructure supports to commence formal health system partnerships. TCOC models that consider these expenditures up-front and incorporate costs into pre-payment calculations will enable better and more consistent investment into such services and subsequent evaluations of comprehensive care models. For this reason, C-TAC also proposes that community-based services and health-plan based quality improvement programs be included in TCOC calculations, payments, and evaluations, as they are an integral part of the success of these models.

How can we establish measures to measure success among population based TCOC models based on providers, patients, and payers' perspectives?

There are few cross-cutting measures to evaluate beneficiaries across settings, other than reduction in utilization and overall reduction of costs. For those with serious illness, many clinical measures do not apply, and the population is carved out. This includes measures for cancer screenings, hypertension, HBA1C, and others. However, what is most important to the beneficiary is their overall experience of care and their confidence that their care is managed. In addition, most measures are setting or disease-specific, making it difficult for care transitions

to be evaluated and for a person's and caregiver's holistic needs to be measured and addressed. C-TAC proposes that more measures be included to document a person's overall experience of care when participating in a TCOC model. Examples include measures developed and tested by RAND and the American Academy of Hospice and Palliative Medicine (AAHPM) to collect a beneficiary's experience of feeling heard and understood by their care team (based on Glen Elwyn's CollaboRATE tool). These measures have been tested in the private sector and are being proposed by AAHPM for National Quality Forum (NQF) endorsement. C-TAC also proposes that efforts be taken to measure the proportion of beneficiaries with an annual wellness visit and with advance care planning performed during or following those visits. In addition, it is important to measure the experience of care of a person's family caregiver, as caregiver burden has demonstrated correlation with a beneficiary's ability to remain at home and outside of the hospital when facing a serious illness.

Under these models, what are the best practices for improving affordability to beneficiaries (for example, for copayments, prescription drugs, etc.)?

Many TCOC model evaluations carve out prescription drugs due to the prohibitive cost of treatments for those with serious illness and the unsustainable costs of medications related to a chronic medical condition. Patients and families often must incur these costs themselves, often paying co-payments. In addition, literature has shown that 50% of people receive advance care planning services outside of an annual wellness visit, incurring co-payments for having these important and necessary conversations. C-TAC proposes removing the co-pay for advance care planning and other codes that support a beneficiary and their caregiver to be assessed and referred to additional services (e.g., transitional care management, chronic care management). C-TAC supports efforts made under the CHRONIC Care Act that removes the uniformity requirements for people with complex and serious health conditions and recommends that removal of the co-pay for these services be adopted across all payers. In addition, C-TAC proposes waivers that allow for a beneficiary and caregiver facing serious illness so that they can receive concurrent care while receiving hospice services so that they can benefit from the support a hospice team provides while continuing to pursue disease-modifying treatment. Concurrent palliative care alongside disease-modifying treatment has demonstrated value in the pediatric population under the Affordable Care Act and emerging CMMI demonstrations such as Direct Contracting, the Kidney Care Choices Model, the VBID hospice component, as well as the completed Medicare Care Choices Model (MCCM). For Medicare beneficiaries and adult beneficiaries under Medicaid or private health insurance, families often must pay out-of-pocket to receive respite care or other personal care services from community-based organizations or private agencies. C-TAC recommends that these services be able to be integrated into medical care and TCOC models. These out-of-pocket payments for services disproportionately affect people with serious illness, dual eligibles, and underserved populations.

What are different approaches for integrating primary care and specialist care under population based TCOC models (e.g., attribution, accountability, payment disbursement, etc.)?

People with serious illness have multiple clinicians and care teams involved in their care. This makes it difficult to attribute a person to the right program. We suggest that the federal partners consider hybrid voluntary alignment for individuals with serious illness and other underserved populations, whereby individuals may select alignment to traditional primary or

specialty medical providers (e.g. hospice or palliative care) and secondary alignment to community-based organizations (CBOs) if individuals choose CBOs as their foremost care relationship. In such cases of dual alignment, medical and CBO partners would be required to collaborate on care plans and subsequent care monitoring.

As it relates to quality and payment, we recommend reimbursement for assessments and referrals to document a beneficiary's and caregiver's holistic needs and to assess the impact of referrals made by primary care providers to specialists and community-based services. C-TAC proposes that CBOs and specialists that manage the pain and other symptoms that arise from a serious illness be eligible for reimbursement for these services and for a proportion of the savings that is accrued by the provider attributed to the beneficiary. This would further promote care coordination and reduce the siloes those beneficiaries and their families often face.

To what extent are specific services (e.g., disease specific care, behavioral health, ancillary services) excluded or "carved out" in population based TCOC models as defined by the PCDT, and what are the pros and cons of this approach?

Currently, many of the highest or most unmanageable costs are being "carved out" of the equation, either due to lack of data available or because it is believed that these costs cannot be contained. However, that only perpetuates the challenge we face in improving care for those with serious illness and complex health needs or for those facing significant social determinants of health challenges (Medicaid beneficiaries, those with cognitive impairment, people who are disabled or frail, homeless, socially isolated, and those with severe mental illness). While this can allow for more straightforward evaluation and easier attribution of savings in risk-based models, carving out services such as hospice and dialysis treatments do not account for savings that come from reduction in unwanted medical treatment or patient choice for their treatment.

Co-pay and coinsurance, and ancillary services delivered by community-based organizations (e.g., care navigation, respite care, transportation, meals, and home care services) have historically not been factored into the TCOC models for evaluation, leaving beneficiaries and their caregivers to often to pay out-of-pocket for things not covered by these models or to pay higher costs to access the services they need. Additionally, many private payers have begun to charge higher co-pays and co-insurance when a beneficiary utilizes the hospital or emergency department. These population health models must consider the beneficiary and caregiver costs that can be reduced through improved coordination—a central objective of TCOC models. C-TAC proposes that more be done to collect information on beneficiary and caregiver out of pocket costs so that these can also be factored into TCOC.

How have payment models and incentives influenced physician participation in population based TCOC models (as defined by the PCDT) to date?

C-TAC supports participation by physicians in population-based TCOC models. However, many of our smaller and non-profit member organizations have reported difficulties in model participation due to lack of funding to support infrastructure and to sustain that infrastructure once model demonstrations are completed. C-TAC proposes that additional funding be made available to support the development of infrastructure, especially to support connectivity and

interoperability between care teams and CBOS, provider workforce development and training, and public outreach and engagement to generate referrals to these models.

4-14-22

April 15, 2022

Paul N. Casale, MD, MPH
Chairman
Physician-Focused Payment Model Technical Advisory Committee (PTAC)
200 Independence Avenue, SW
Washington, DC 20201

RE: Population-Based Total Cost of Care (TCOC) Models Request for Input (RFI)

Dear Dr. Casale:

On behalf of the Medical Group Management Association (MGMA), I am pleased to submit comments to the Physician-focused Payment Model (PFPM) Technical Advisory Committee (PTAC) in response to the "Population-Based Total Cost of Care (TCOC) Models" request for input following the March 2022 public meeting. MGMA appreciates the opportunity to provide input and feedback to support PTAC's continuing theme-based discussions regarding TCOC models.

With a membership of more than 60,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 medical groups comprising more than 350,000 physicians. These groups range from small independent practices in remote and other underserved areas to large regional and national health systems that cover the full spectrum of physician specialties.

With the introduction of the Center for Medicare and Medicaid Innovation (the "Innovation Center") and the Physician-focused Payment Model Technical Advisory Committee (PTAC), the healthcare system made significant strides in developing new models, spurred innovation, and created a new spectrum of innovation in healthcare.

The journey to value-based care is best described as a continuum; while fee-for-service (FFS) is the foundation for payment across healthcare, value-based care provides practices with new opportunities and flexibilities to implement novel clinical care pathways within alternative payment mechanisms. MGMA believes that this continuum must be preserved and that each individual practice will have a unique experience in value-based care. As such, MGMA supports the opportunity for practices to engage in TCOC models as they see fit but believes alternative options within value-based care are critical to ensure every practice can participate under a value arrangement that is meaningful, clinically relevant, and supports the financial goals of the practice.

Below, please find MGMA's responses to selected questions from PTAC's published RFI.

PTAC RFI: Population-Based Total Cost of Care Models

2. What type(s) of entity/entities or provider(s) should be accountable for TCOC in population-based TCOC models? Could the accountable entities look like current Accountable Care Organizations (ACOs) or Medicare Advantage (MA) plans? Could the accountable entities be delivery systems taking on risk, a combination of delivery organizations and payers, or fully integrated systems? Does the ability to manage TCOC vary by certain factors (e.g., type of provider, specialty, condition)?

The types of entities that could be accountable for the TCOC within a population-based model could look similar to an accountable care organization (ACO). Such organizations have been successful in managing care within other Innovation Center models and have successfully generated savings. An ACO arrangement supports team-based coordinated care by centralizing data and providing necessary tools to ensure participating providers have the tools necessary to succeed within a two-sided risk model.

As PTAC looks ahead to continue developing recommendations related to TCOC models, MGMA recommends that the Committee critically consider how practices, both small independent practices and larger health systems, can participate in TCOC models. All practices have a role to play in supporting the value-based care continuum and furnish care to diverse patient populations.

4. What are some options for evaluating and increasing provider readiness to participate in population-based TCOC models?

Each practice's journey exploring value-based payment models is a unique experience, however, there are certain criteria that significantly help practices prepare to participate in TCOC models. TCOC models require providers to assume a certain level of risk for their assigned patient population; not every practice is appropriately prepared to take on such risk, and not every practice has the goal to take on such high levels of risk.

Currently, under the Innovation Center, there are several different types of models practices can participate under that focus on a specific clinical condition or specialty. These targeted models provide clinicians with the opportunity to explore value-based payment arrangements in the context of their clinical specialty and provide critical experience to prepare for participation in a TCOC model. This experience within the value-based care continuum serves as an important steppingstone for practices prior to participation in a TCOC model.

To increase provider readiness to participate in a population-based TCOC model, it is critical for practices to have the tools to fully understand their patient populations. Successful practices within a TCOC arrangement will have the infrastructures in place to continuously evaluate their patient populations, identify who they are providing care to, determine the most appropriate care coordination services for each patient, and determine where opportunities exist to improve care and eliminate duplicative or lower-value unnecessary care.

In addition to understanding a practice's given patient population, it is equally as critical for a practice to be financially resilient to achieve success within a TCOC model. Participation in any model, even with prior experience participating in an alternative payment model (APM), requires significant financial

investment. Within value-based care there are unavoidable uncertainties in the cost of care and, more often than not, there are delays in the return on investment for care coordination, preventive services, and clinical improvement activities that drive value-based payment arrangements. A practice's ability to manage variable costs will significantly support success within a TCOC model.

a. Are there differences in provider readiness by specialty or other factors?

As previously mentioned, there have been different opportunities to participate in APMs based on many different factors, including availability of model types focused on clinically relevant conditions and financial stability for practices. Additionally, the COVID-19 pandemic has stymied some of the expected growth that could have progressed within APMs over the past several years. As PTAC looks ahead at the next phase of APMs and TCOC models, it is important to consider the impact the pandemic has had on practices including financial strain, staffing concerns, and overall readiness to take on new risk within a model.

c. What are some of the provider-level barriers to participating in population-based TCOC models (including barriers for specialists)?

63% of medical group practices indicated they are interested in participating in an APM, however 80% of those interested stated that there isn't a clinically relevant APM available to participate in.[1] MGMA believes that every provider should have the opportunity to participate in value-based payment arrangements, however, every practice has not yet been afforded this opportunity. Without having had previous experience participating in a payment model, practices of certain specialties will likely struggle within a TCOC model that assumes a higher level of risk.

Additionally, population-based TCOC models require significant coordination within the risk bearing entity and participating providers. Primary care providers may have greater insight into patient care coordination and utilization over specialists focusing on a particular patient condition. For successful participation in TCOC models, organizations will require additional communication channels and coordination to ensure practices across specialties have aligned incentives under a population-based TCOC model.

7. What are some options for addressing model overlap and incorporating episode-based payments within population-based TCOC models? a. How might these options vary by differing factors (e.g., ACO ownership type, condition, specialty, type of episode)? b. What are potential issues related to nesting, carve-outs, and other potential approaches?

As PTAC and the Innovation Center continue to develop a greater variety of model participation options for different specialty participation across the risk spectrum, there are several factors that must be considered. Nesting episode models within larger TCOC models may create competing incentives for participating providers. For example, if an episode-based model is carved-out of a TCOC model, the TCOC entity may want to direct certain patients to specific specialty providers that could be participants within the entity. If, however, an episode is nested within a TCOC model, it will be important to consider how the nested models operate in such a way that provides specialists with the opportunity to

[1] Medical Group Management Association (MGMA) Annual Regulatory Burden Report. October 2021. https://www.mgma.com/getattachment/22ca835f-b90e-4b54-ad93-9c77dfed3bcb/MGMA-Annual-Regulatory-Burden-Report-October-2021.pdf.aspx?lang=en-US&ext=.pdf

participate across multiple TCOC entities. This will provide specialty practices with the opportunity to leverage care improvement activities within one TCOC entity, across multiple partnerships and a greater number of patients.

In a shared savings arrangement, it is necessary to determine which entity savings would go to for care provided under an episode-based payment model. There are multiple different mechanisms that could be created to incentivize a TCOC entity to refer patients to the most effective, high-quality, low-cost episode-based provider. Such incentives could include incentives for quality of care achieved or split savings for a specified patient encounter. With any of the proposed options to support specialist participation within a TCOC model, it is critical to ensure that any episode-based model carve-out or nesting explicitly define the episode with distinct diagnoses or treatments defining the onset of an episode and a defined timeframe to determine the end of the episode.

MGMA appreciates the opportunity to provide these comments to the Committee and we look forward to our continued engagement in future PTAC public meetings to discuss TCOC models. If you have any additional questions, please do not hesitate to contact Kelsey Haag, Associate Direct of Government Affairs at khaag@mgma.org or (202) 887-0798.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs
Medical Group Management Association

From: Stellar Health
To: The Physician-Focused Payment Model Technical Advisory Committee (PTAC)
Subject: Population-Based Total Cost of Care (TCOC) Models Request for Input (RFI)

Stellar Health appreciates the opportunity to respond to PTAC's important RFI on Population-Based TCOC Models.

Stellar's mission is to enable success in value-based payment (VBP) arrangements at the ground level of patient-provider interactions. We are a healthcare technology company focused on changing the way payors and providers perform value-based care. Through our point-of-care workflow platform, Stellar prompts and rewards providers on a regular, real-time basis for taking specific high-value actions both during and after visits to improve patient outcomes.

We strongly believe that bringing value-based payment (VBP) to Medicare is a vital part of improving patient care across the continuum and hope that PTAC will find our feedback useful. Based on our experience supporting providers of all sizes across the value-based care continuum, from independent physicians to large health systems, we would like to focus on three particular questions outlined in the RFI.

Question 3b. What are some incentives that can help to improve care coordination and provider accountability for TCOC?

Most VBP models to date retain a traditional fee-for-service delivery model downstream, at the individual practitioner level. As a result, staff are frequently discouraged from engaging in care coordination activities that are not reimbursable through fee-for-service models or, if they are, come with their own onerous billing and administrative requirements. The new ACO REACH model, with its capitated payments, is a step in the right direction by allowing REACH ACOs to employ innovative approaches towards incentivizing their own providers. Nevertheless, many REACH ACOs will likely continue to reimburse their providers on a primarily fee-for-service basis.

Stellar Health's models are based on the concept of rewarding providers and practice staff for completing value-based actions at the point of care. Both actions and incentives are delivered at the point of care, when they are most clinically useful. Providers and their staff act on clear checklists of recommended value-based actions based on patients' historical data and pertinent health information. Instead of receiving risk-based payments on a months (if not years)-long lag, practices can receive timely incentive payments for completing actions that prospectively reduce costs, improve health outcomes, and increase the quality of care.

Care coordination actions, such as appropriate referral, follow-up, and connection to community resources, are all examples of actions that can and should be rewarded at the time of service delivery—not 18 months later during a financial reconciliation. Furthermore, rewards should be available to all staff involved in care delivery, ensuring that incentives are aligned at the individual level.

Question 4. What are some options for evaluating and increasing provider readiness to participate in population-based TCOC models? What are some of the provider-level barriers to participating in population-based TCOC models?

Provider readiness must be achieved not just at the organizational level, but also the level of the clinician and his or her staff. Many independent providers and practices without significant VBP experience are hesitant to enter into TCOC arrangements or join TCOC entities such as Accountable Care Organizations (ACOs), especially once they involve the possibility of downside risk. To participate meaningfully in TCOC, clinicians must be prepared to engage in transformation throughout the practice. Providers who serve a wide range of patients, and therefore have relationships with a correspondingly wide range of payers, often believe in the concepts of value-based care, but do not have the administrative capacity to overhaul their service delivery model.

This is compounded by the financial model of retrospective shared savings, which often means a lack of transparency, prolonged financial uncertainty to account for claims rollout, and the need to make significant investments of capital, time, and effort before there is any payoff for the provider. Providers face uncertainty regarding the tasks required of them to consistently perform on outcomes-based metrics as outlined in complex VBP contract terms. Further, shared annual incentives fail to motivate providers to spend the time needed to complete value-based activities.

Future TCOC models should address these barriers by encouraging real-time incentives and supporting tools that simplify the process for independent providers and practice staff. This would help providers who want to engage in value-based care but who lack the time and administrative capacity to fully engage, including behavioral health and community-based providers.

Question 6. Based on your experience, what payment strategies have been particularly effective for supporting efforts to improve quality and reduce TCOC? Why have these strategies been effective? What have been some challenges and opportunities related to these approaches?

VBP shared savings arrangements are often structured retrospectively, such that they provide payment to the provider only after (a) the total cost of care can be calculated and (b) population-level quality metrics have been reported, typically on an annual basis. As a result, 12-18 months or more can pass between a provider delivering care and receiving a value-based incentive/reward payment. Furthermore, quality measurement is not tied to specific patient-based actions. This makes it difficult to link the actual process of care to the VBP reimbursement model. At the same time, purely process-based quality metrics do not fully address the outcome-oriented goals of VBP initiatives.

In addition, value-based contracts that currently exist are contracted with the aggregate provider entities, who may or may not share that revenue down to the participating practices in

their network. Stellar facilitates timely sharing of value-based care revenue directly with practices in a timely and transparent manner. Furthermore, Stellar ensures that value-based revenue reaches the "doers" of the value-based care delivery work. Stellar supports analytics, reporting, and payment administration within practices to facilitate revenue sharing to clinical care teams and medical staff (including nurses, care coordinators, medical assistants and front desk staffa), such that all members of the care team participate in the value chain and are incentivized to further drive value-based outcomes. This investment and reward for their time allows them to focus on value-based outcomes rather than fee-for-service care delivery.

Future TCOC models should expand on the range of ways to perform quality measurement in VBP. Providers in VBP contracts should be permitted to use supplemental or alternative approaches, such as the Stellar Health approach, which incorporate ongoing and/or intermediate measurements and real-time incentive payments. Full reconciliation can continue to be included later, as necessary.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

April 15, 2022

Paul N. Casale, MD, MPH, Committee Chair, PTAC
New York-Presbyterian, Weill Cornell Medicine and
Columbia University

Lauran Hardin, MSN, FAAN, Vice Chair, PTAC
National Center for Complex Health and Social Needs,
Camden Coalition of Healthcare Providers

[Submitted via PTAC@HHS.gov]

Re: Population-Based Total Cost of Care (TCOC) Models Request for Input (RFI)

Dear Chair Casale and Vice Chair Hardin,

The National Association of Chain Drug Stores (NACDS) writes to offer comments in response to the "Population-Based Total Cost of Care (TCOC) Models Request for Input (RFI)." We applaud PTAC's work and support health care transformation and the movement to value-based care and are pleased to have the opportunity to respond to the RFI.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries.

Below we offer responses to RFI questions 1, 2a, 3a, 3b, 4a, 4b, 6, 8a, 8b, and 14.

1. **The Center for Medicare and Medicaid Innovation (CMMI)'s Strategy Refresh includes a goal that all Medicare beneficiaries with Parts A and B will be in a care relationship with accountability for quality and TCOC by 2030. What should these future population based TCOC models look like?**

NACDS applauds the Innovation Center's goal of having all Medicare beneficiaries in care relationships accountable for the quality and cost of their care by 2030. To achieve this goal, we believe that future models need to include providers across the care continuum who impact patients' experience with care, outcomes, quality of care and influence or drive costs. To this end, we believe that pharmacists, pharmacies, and members of a patient's care team that have historically not been able to participate in Innovation Center models should be considered for inclusion in models developed by the Innovation Center.

We believe increased integration of a patient's entire care team into value-based and total cost of care models is particularly critical as our nation works to consider what health care delivery should encompass in the future, following the COVID-19 pandemic, while also recognizing the need to address long-standing disparities in access to care. Pharmacists and pharmacies are an essential member of a patient's care team and can continue to be a

collaborative partner moving forward. This has been particularly highlighted by the role pharmacies and pharmacists have played in the national COVID-19 response. Notably:

- Pharmacies have administered more than 239 million COVID-19 vaccinations to date[1]
- Today, 2 of every 3 COVID-19 vaccine doses are provided at a pharmacy[2]
- More than 40% of those vaccinated at pharmacies were from racial and ethnic minority groups[3]
- More than 40% of children ages 5 to 11 who received a COVID-19 vaccination did so at a pharmacy[4]
- Half of pharmacy COVID-19 vaccination sites are located in areas with high social vulnerability[5]
- Pharmacies have provided more than 11,000 mobile COVID-19 vaccination clinics across the country[6]
- Pharmacies provide more than 20,000 COVID-19 testing sites nationwide, and 70% of such sites are in areas with moderate to severe social vulnerability[7]
- Pharmacies provide access to COVID-19 antivirals, including test to treat options, at thousands of locations nationwide[8]

TCOC models must include the appropriate team of providers that can deliver accessible, high-quality care that improves outcomes and reduces costs over time. Ensuring models consider and include providers who serve as key touch points for patients and deliver critical services, including pharmacists and pharmacies, will be imperative.

2. What type(s) of entity/entities or provider(s) should be accountable for TCOC in population-based TCOC models? Could the accountable entities look like current Accountable Care Organizations (ACOs) or Medicare Advantage (MA) plans? Could the accountable entities be delivery systems taking on risk, a combination of delivery organizations and payers, or fully integrated systems?

a. Does the ability to manage TCOC vary by certain factors (e.g., type of provider, specialty, condition)?

NACDS believes that responsibility for managing a patient's TCOC depends on a number of factors, including the patient's clinical condition, as well as the setting of care and services included in the total cost of care model. We also believe that a range of providers support management of a patient's total cost of care—including those currently not able to directly participate in the Innovation Center's accountable care organization and advanced primary care models.

NACDS recommends that future models are designed to be more inclusive of the range of providers that contribute to whole-patient care and with the recognition that different providers may impact a patient's health outcomes, quality of care and, ultimately, total cost of care. Moving forward, it is important to design population-based models with the understanding that multiple entities or providers affect total cost of care, including providers whose ability to participate in value-based payment (VBP) models in Medicare and across payers is currently limited, including pharmacists and pharmacies. Pharmacists have extensive clinical training, medication management expertise and

[1]CDC, Federal Retail Pharmacy Program, *available at* https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html. As of April 6, 2022.
[2] White House, *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actionsto-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/
[3] GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, *available at* https://www.gao.gov/assets/gao-22-105079.pdf.
[4] https://www.cdc.gov/mmwr/volumes/71/wr/mm7110a4.htm
[5] GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, *available at* https://www.gao.gov/assets/gao-22-105079.pdf.
[6] Id
[7] White House, *FACT SHEET: Biden Administration Announces Historic $10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities*, *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheetbiden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-andhighest-risk-communities/
[8] https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/article/cdcs-2009-h1n1-vaccine-pharmacy-initiative-in-theunited-states-implications-for-future-public-health-and-pharmacy-collaborations-for-emergency-response/E23689EFE87D7A3ECCCC5F526A24BAC5

are accessible to and integrated into the communities they serve—this well positions them to be meaningfully integrated into and participate in VBP models. Because pharmacists are viewed as one of the most trusted and commonly visited health care professionals, they can serve as a valuable member of the care team responsible for impacting a patient's TCOC.

Additionally, research has shown that pharmacy-based care and care provided by pharmacists can reduce costs and improve quality. For example, a 2014 analysis of the direct medical costs of administering vaccines in different settings found that the direct medical cost per adult vaccination was 11 to 26 percent lower in pharmacies compared to physician offices and other medical settings.[9] Further, a 2018 study that modeled the clinical and economic impacts of using pharmacies to administer influenza vaccinations estimated that including pharmacies in addition to traditional locations for vaccination (e.g., clinics, physician offices, urgent care centers) could prevent up to 16.5 million symptomatic influenza cases and 145,278 deaths at an estimated cost savings of $4.1 to $11.5 billion.[10] Downstream cost savings have been realized across many other pharmacy-led interventions including medication adherence, chronic care, preventive care, and more.[11] Additional examples are included in the Appendix chart.

3. Based on your experience, what are some approaches and best practices for integrating and improving coordination between primary care and specialty care providers within population-based TCOC models?

a. Has provider participation in population-based TCOC models affected innovation with respect to the integration of primary care and specialty care?

To ensure innovation and the development of successful models that reach and meet patients' needs, work to eliminate health disparities, and deliver on quality, and patient-centered care, NACDS urges PTAC, the Innovation Center and others to include and leverage all qualified providers and suppliers across the health care continuum. Leveraging a wider group of providers and settings can help address barriers in care delivery and coordination, and promote equity in health care delivery.

Research has shown that pharmacy-based medication optimization and clinical care services have a demonstrated ability to improve outcomes, enhance quality of care and reduce costs—indicating that pharmacists play an integral role in a patient's team of providers. As such, we believe that pharmacists and pharmacy-based, clinical services should be integrated into VBP models, including population-based TCOC models. This can build on lessons learned from existing pilots and models. For example, a pilot program implemented by the University of Southern California School of Pharmacy and AltaMed Health Services included the provision of comprehensive medication management (CMM) services by pharmacists to patients with poor chronic disease control. Working in collaboration with physicians, pharmacists modified drug therapy, ordered tests for monitoring efficacy and safety and performed follow-up with patients. Evaluations found that these integrated CMM services led to improvements in care management, with 90 percent of patients meeting blood pressure targets, as well as improved outcomes for patients with diabetes and high cholesterol.[12]

NACDS supports the mission of PTAC and applauds the work that it and the Innovation Center have done to

[9] Winegarden W. (2018). Promoting Access and Lowering Costs in Health Care: The Case of Empowering Pharmacists to Increase Adult Vaccination Rates. The Pacific Research Institute.
[10] Bartsch SM et al. (2018). Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. *Vaccine*.
[11] https://www.thecommunityguide.org/sites/default/files/publications/hdsp-ajpm-ecrev-medication-adherence.pdf
[12] "CMMI Project Shows How Comprehensive Medication Management (CMM) Improves Care For High-Risk Patients Initiative Has Expanded Statewide." Accessed April 10, 2022.

advance the movement to value. We also appreciate the role PTAC, and other stakeholders have played in supporting development of models across payers as well as conducting research and identifying best practices and policies. However, no models considered by PTAC or launched by the Innovation Center permit pharmacies or pharmacists to directly participate. NACDS believes that the PTAC, the Innovation Center, payers and stakeholders should work to develop VBP models, including population-based TCOC models, that meaningfully incorporate pharmacist and pharmacies and their ability to provide preventive, chronic care management, medication optimization services, and other interventions.

Pharmacists are also one of the most accessible health care providers—as about 90 percent of Americans live within 5 miles of a pharmacy—well positioning them to advance the reach of VBP initiatives to more beneficiaries and populations, including those previously excluded from models. The reach of pharmacies and pharmacists' role as a trusted provider also point to the ability to use pharmacists and pharmacies to advance health equities and address disparities.

b. What are some incentives that can help to improve care coordination and provider accountability for TCOC?

NACDS believes that population-based TCOC and other VBP models need to include providers with the demonstrated ability to improve outcomes, quality and control costs for the patients being served under these models. As discussed above, in many cases, this may include incorporating essential providers across a patient's care team, including community-based providers, and supporting coordination across those providers.

To support coordination and a whole-patient centered approach to care delivery, NACDS recommends creating opportunities for pharmacies and pharmacists—and other providers who have historically been excluded—to directly participate in value-based care models, including TCOC models. Further, we believe that to improve care coordination and provider accountability, it is important to develop models that include payment approaches that reward providers across the care team for supporting whole-person care that improves health, improves quality, and reduces costs.

4. What are some options for evaluating and increasing provider readiness to participate in population-based TCOC models? *

a. Are there differences in provider readiness by specialty or other factors?

NACDS supports the creation of more opportunities for provider participation in VBP models, including population-based TCOC models, that advance the triple aim and work to support health equity. To achieve these goals, we believe there need to be opportunities for direct participation among providers—such as pharmacists—and other health care entities that have historically been prohibited from participating in VBP models, but have demonstrated the ability to improve outcomes and quality of care and control costs.

In addition to expanding the ability to participate in models to include pharmacists, pharmacies and other previously excluded providers and entities, various mechanisms should be considered to support readiness to participate in population-based TCOC and other VBP models such as the development of a glide path to financial risk—given many providers have had limited experience in risk-based, value-based payment arrangements. Other supports for providers could include technical assistance and funding to allow providers to develop adequate investments in infrastructure, among other operational elements.

b. What are some of the provider-level barriers to participating in population-based TCOC models (including barriers for specialists)?

Historically, especially with relation to Medicare models, many providers have been excluded from directly participating. Pharmacists and pharmacies, in particular, have been unable to participate in Innovation Center models despite the growing body of research demonstrating the positive impact of pharmacy care on patient experience and outcomes and reduced downstream health care costs.

Of note, a significant barrier to direct participation in Medicare alternative payment models for pharmacists has been the fact that they are not currently recognized as Part B providers, despite their ability to provide important clinical care services. NACDS urges PTAC, the Innovation Center and other payers and stakeholders to develop and test models that allow pharmacies and pharmacists to be paid under Part B for preventive care, chronic disease management, and medication management services as well as other services with the potential to improve quality, health outcomes and reduce costs. NACDS presents opportunities for integrating community pharmacy care into value-based programs in our recent paper, "Accelerating the Center for Medicare and Medicaid Innovation's Mission, Integrating Community Pharmacy Care into Value-Based Programs Amid COVID-19 Pandemic Recovery & Beyond." Additional information on the paper is included in our response to question 14.

Despite the inability to directly participate in current Innovation Center models, pharmacists and pharmacies are well positioned to be included in population-based TCOC and other VBP models given the vital role they play in the health care continuum. Pharmacists are able to foster meaningful patient relationships and have shown they are able to improve medication use, deliver accessible clinical care for a range of essential interventions, and facilitate community-based patient centered care. Further, pharmacists and pharmacies have played a critical role in the national response to the COVID-19 pandemic. There is significant opportunity to leverage this role, lessons learned, and the flexibilities granted during the public health emergency (PHE) to incorporate pharmacists and pharmacies into VBP to further drive improved outcomes and quality and reduced costs.

Finally, there are several other barriers to provider participation in value-based payment models that PTAC and other stakeholders should consider as they work to develop models that reach historically underrepresented populations and the providers that serve them. First, providers that have had limited opportunities to participate in value-based payment models to date lack extensive experience assuming risk. Model design must ensure the appropriate providers have the supports necessary to facilitate participation—especially when they have had limited experience in VBPs and with risk—such as design that includes a glide path to risk. Second, providers and suppliers may experience challenges meeting specific models requirements, such as CEHRT requirements. Model design should consider these limitations and leverage, where possible, advancements in health information technology, interoperability and other tools that support coordination across providers, including the bidirectional integration of pharmacy data into broader systems. Other barriers include obstacles to coordination between providers across the care continuum and lack of alignment across payers in terms of quality measures and reporting requirements, among others. As PTAC, the Innovation Center and others work to develop sustainable, population-based TCOC models and other alternative payment models that reach more patients and incorporate the providers that serve them, it will be essential to work to address these barriers.

6. Based on your experience, what payment strategies have been particularly effective for supporting efforts to improve quality and reduce TCOC (e.g., shifting risk downstream to providers)? Why have these strategies been effective? What have been some challenges and opportunities related to these approaches? ***

As discussed above, TCOC and other VBP models do not leverage all the providers and suppliers necessary for managing and coordinating a patient's care across the health care continuum. We recommend that PTAC, the Innovation Center, and other stakeholders working to design and implement models that advance the goals of improved outcomes, enhanced quality and controlled costs, work to expand the ability for more providers to participate in and receive value-based payment for the care they provide under these models.

Pharmacists are already participating in Medicaid and commercial payer models, from which lessons can be learned to support their direct inclusion into population-based TCOC or other models. For example, Minnesota operates the Medication Therapy Management (MTM) Services program for Medicaid and other low-income residents. Under the program, pharmacists provide a range of services including assessing health status, developing medication treatment plans, performing comprehensive medication reviews, documenting care, communicating with patients' primary care providers, and providing patient education. Pharmacists in the program are also able to use telehealth to provide services to certain beneficiaries. Under the model, pharmacies or other providers are reimbursed by the state based on a continuum of patient need and using MTM Current Procedural Terminology (CPT) codes.[13] Further, California's Inland Empire Health Plan created a Pharmacy Pay for Performance (P4P) Program for Medicaid managed care and Medicare Advantage enrollees, which aims to improve member health and reduce costs. As part of the medication safety component of the program, pharmacies receive a payment per prescription claim for certain actions related to drug utilization review (DUR) alerts and are also eligible for bonus payments. Participating pharmacies receive bonus payments for meeting quality measures every 6 months and for certain actions (e.g., pharmacies sending text notifications to plan members).[14]

8. What specific issues should be considered when applying population-based TCOC models to diverse patient populations and care settings? *

a. Are there potential issues related to health equity regarding the implementation of population-based TCOC models?

NACDS believes that expanding the reach of VBP models by including more patients and provider types will help to advance equity, address disparities and expand access to care that aims to improve outcomes and quality to more populations. To this end, we recommend that PTAC, the Innovation Center and others consider ways to include pharmacists and pharmacies in existing and new models, as utilizing these providers could help expand the geographic reach of models and support delivery of care through an accessible provider and setting. As discussed above, pharmacists are one of the most trusted and accessible providers with 90 percent of Americans living within 5 miles of a pharmacy.[15]

Further, NACDS believes that future model development can build on and incorporate lessons learned during the

[13] Doucette, William R, et al.. "Pharmacy performance while providing continuous medication monitoring." *Journal of the American Pharmacists Association*. Volume 57, Issue 6, 692-697. Balick, Rachel. "Adventures in getting paid." *Pharmacy Today*. Volume 27, Issue 2, P22-37, February 01, 2021. Minnesota Department of Human Services, "Medication Therapy Management Services (MTMS).

[14] NACDS, "Comment Letter Re: OIG–0936–AA10–P: Proposed Rule Regarding Fraud and Abuse Revisions to Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements CMP," December 31, 2019. "As Pay For Performance Grows, Health Plans Work With Pharmacies." *Pharmacy Today*. March 2016.

[15] Poll Results: Flu Vaccination. Poll conducted by Morning Consult, August 13-16, 2020. Commissioned by NACDS. NACDS, "NACDS Emphasizes Trust, Accessibility, and Community Presence of Pharmacies and Pharmacists in Joining 'COVID-19 Vaccine Education and Equity Project'," December 2020. NACDS, 2017. https://www.nacds.org/pdfs/about/rximpact-leavebehind.pdf

COVID-19 pandemic, during which health disparities within the United States were further illuminated. Pharmacies and pharmacists played a significant role in the nation's COVID-19 response, and approaches used by pharmacies during the pandemic to expand access to services for hard to reach patients can inform design of models to include pharmacies. For example, during the COVID-19 pandemic response, pharmacies implemented a range of strategies to advance equity, including:

- Leveraging the CDC's Social Vulnerability Index (SVI), information on health professional shortage areas, and medically underserved population measures to help focus efforts in communities facing the greatest challenges.
- Providing COVID-19 vaccinations for homebound individuals, conducting pop-up clinics, and partnering with schools, community centers, places of worship, employers, community leaders, faith-based organizations, and organizations representing racial and ethnic minority groups.
- Collaborating with non-traditional partners like rideshare companies, deploying mobile vaccination units, offering after-hours appointment times, and working to overcome disparities in technology access.[16]

It is imperative that all patients have access to high-quality care, including populations that have historically faced barriers. As models are developed to expand the reach of high-quality care to underserved and underrepresented populations, payment structures should incorporate risk adjustment based on social determinants of health and vulnerability factors. Such approaches will help assure providers are able to deliver care addressing the unique needs of their patients.

b. What are the options for increasing the participation of underrepresented and underserved populations in value-based models, including population-based TCOC models?

NACDS believes that to increase the reach of VBP models to previously underrepresented or underserved populations, it is essential to consider which providers and care settings are most easily accessible to patients who have experienced barriers to access. As noted above, pharmacists and pharmacies are one of the most accessible providers, which well positions them to expand the reach of models. Specifically, research has shown that pharmacies serve as a main point of care for high-risk Medicaid and Medicare patients. One analysis of a pilot program that aimed to improve care coordination for high-risk Medicaid beneficiaries found that these beneficiaries visited their pharmacies an average of 35 times per year – more than the average number of visits to their primary care provider or specialist (4 and 9 times per year, respectively).[17] Another study that examined how frequently Medicare patients visited pharmacies found that visits to pharmacies significantly outnumber primary care encounters (13 and 7 times per year, respectively), with the difference in rural areas being more significant (14 and 5, respectively).[18]

In the development of new care delivery models, the inclusion of providers trusted by patients, and who can develop meaningful patient relationships should be considered, especially in the design of models geared towards underrepresented and underserved populations. Polling shows that pharmacists have high trust ratings, which could be leveraged to expand the reach of VBP models to patients who face barriers to other providers or settings of care. A recent poll found that 3 out of 4 adults report trusting pharmacists to administer a COVID-19

[16] NACDs, "Striving Toward Health Equity in COVID 19, the Role of Pharmacies in a National Response."
[17] Moose J, Branham A, "Pharmacists as Influencers of Patient Adherence," Pharmacy Times; August 21, 2014.
[18] Berenbrok LA, et al. Evaluation of Frequency of Encounters With Primary Care Physicians vs Visits to Community Pharmacies Among Medicare Beneficiaries. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2768247

vaccination.[19]

Notably, pharmacies have administered more than 239 million COVID-19 vaccinations to date,[20] and more than 40 percent of those vaccinated at pharmacies were from racial and ethnic minority groups.[21] Further, approximately half of pharmacy-based COVID-19 vaccination sites are located in areas with high social vulnerability, demonstrating the reach of pharmacies across communities, including those with vulnerable populations.[22]

14. Are there any other important questions that should be considered related to the development of population-based TCOC models and PFPMs?

NACDS commends PTAC's aim to support ideas about how to deliver high-value care for Medicare beneficiaries and others seeking health care services in our nation. To this end, NACDS would like to highlight "Accelerating the Center for Medicare and Medicaid Innovation's Mission, Integrating Community Pharmacy Care into Value-Based Programs Amid COVID-19 Pandemic Recovery & Beyond," a report that examines the essential role that local pharmacies and pharmacists play in providing patient-centered services in their communities and highlights how integrating pharmacies and pharmacists into VBPs and APMs can support the refreshed vision for the Center for Medicare and Medicaid Innovation.

Specifically, the report presents evidence on the value of pharmacy care, including as a key part of the COVID-19 pandemic mitigation and recovery effort, which underscores the imperative to directly integrate pharmacists and pharmacy care services into value-based programs (VBPs), including population-based TCOC models. The report presents five recommendations that aim to serve as a blueprint of actionable solutions for integrating and emphasizing pharmacy care in the Innovation Center's—and other payers'— work to improve health, quality, value, and equity in our system. Key recommendations and actions for policymakers outlined in the report include:

1. Include pharmacists and pharmacies as eligible providers and/or suppliers in existing and future VBPs and APMs. The Centers for Medicare and Medicaid Services (CMS) should implement this change by granting pharmacies supplier status through annual rulemaking and using CMMI to test the impact of an expanded clinical role for pharmacists on outcomes, quality, and costs.
2. Allow pharmacies to be directly paid and/or incentivized for providing care to beneficiaries that improves quality of care, health outcomes, and reduces total cost of care. CMS should allow direct participation by pharmacies in existing population-based models and support establishment of a pharmacy specific model.
3. Develop and implement meaningful measures, including standardized pharmacy-level quality metrics, across all VBPs and APMs, payers and programs. CMS should develop a standard set of performance measures for pharmacies and assess their impact on improving outcomes and quality for beneficiaries and reducing costs in the Medicare program.
4. Support advancements in health information technology, interoperability and other tools that support coordination across providers, including the bidirectional integration of pharmacy data into broader systems. CMS should prioritize expanding interoperability and the sharing of clinical and patient care data to include pharmacies, where feasible

19 NACDS, "NACDS Emphasizes Trust, Accessibility, and Community Presence of Pharmacies and Pharmacists in Joining 'COVID-19 Vaccine Education and Equity Project'," December 2020.
20 CDC, Federal Retail Pharmacy Program, *available at* https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html.
21 GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, *available at* https://www.gao.gov/assets/gao-22-105079.pdf.
22 GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, *available at* https://www.gao.gov/assets/gao-22-105079.pdf.

5. Test a pharmacy value-based program to increase access to evidence-based community pharmacy care for Medicare beneficiaries. CMMI should test the Pharmacy Care Quality Incentive Program (PCQIP) within the Medicare program.

NACDS thanks PTAC for the opportunity to submit these comments. We welcome the chance to serve as a resource to PTAC and would be pleased to discuss further any of the comments outlined above. Please contact NACDS' Sara Roszak, Senior Vice President of Health and Wellness Strategy and Policy at Sroszak@NACDS.org or 703-837-4251.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

APPENDIX

Appendix Chart Examples of Evidence: Value of Pharmacist-Provided Care	
Result of Pharmacist Intervention	**Source**
General Value of Pharmacy Care in Prevention	
This umbrella review included 13 research syntheses, finding that the provision of preventive services at community pharmacies is shown to be effective at **increasing immunization rates, supporting smoking cessation, managing hormonal contraceptive therapies, and identifying patients at high risk for certain diseases.** Community pharmacies offer an ideal venue for the **provision of preventive services** due to their convenient location and extended hours of operation.	San-Juan-Rodriguez A, Newman TV, Hernandez I, et al. Impact of community pharmacist-provided preventive services on clinical, utilization, and economic outcomes: An umbrella review. Preventive Medicine. 2018. https://www.ncbi.nlm.nih.gov/pubmed/30145351
Pharmacist-provided Annual Medicare Wellness Visits are comparable to those provided by physicians and offer an **additional access point for valuable services for Medicare beneficiaries.**	Sewell, Mary Jean. Et. al. Comparison of Pharmacist and Physician Managed Annual Medicare Wellness Services. J Manag Care Spec Pharm. 2016;22(12):1412-16, available at: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2016.22.12.1412
Pharmacists have demonstrated their value in the community setting by providing high-quality and accessible care but are faced with barriers. This article discussed ways to optimize access to care in communities and implementation strategies to further improve population health outcomes while minimizing downstream healthcare costs.	Newman TV, Hernandez I, Keyser D, et al. Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations. J Manag Care Spec Pharm. 2019. https://www.jmcp.org/doi/10.18553/jmcp.2019.25.9.995
This article emphasizes **the need for collaboration between practices, patients, and payers to improve healthcare outcomes and reduce costs** by moving towards value-based payment models.	Armistead LT, Ferreri SP. Improving Value Through Community Pharmacy Partnerships. Population Health Management. 2018. https://www.liebertpub.com/doi/abs/10.1089/pop.2018.0040?journalCode=pop
Evidence suggests **pharmacists can prescribe to the same standards as other providers of care**, including the ability to better adhere to dosing guidelines when prescribing by protocol.	Poh EW, McArthur A, et al. Effects of pharmacist prescribing on patient outcomes in the hospital setting. JBI Database of Systematic Reviews and Implementation Reports. September 2018. https://journals.lww.com/jbisrir/Abstract/2018/09000/Effects_of_pharmacist_prescribing_on_patient.9.aspx
As hospitals and other care sites continue to close, especially in underserved areas, it is necessary for patients to have alternative locations to receive coordinated, high-quality care including chronic care management, and preventive care. Community pharmacies are well-positioned to serve as care sites to support the rest of the care continuum.	Heath S. How Pharmacists Can Drive Patient Engagement, Value-Based Care. March 2019. https://patientengagementhit.com/news/how-pharmacists-can-drive-_p atient-engagement-value-based-care
Preventive screenings	
This systematic search determined significant heterogeneity for all included outcomes, however, determined that **pharmacies are feasible sites for screening for diabetes and cardiovascular disease risk.**	Willis A, Rivers P, Gray LJ, Davies M, Khunti K. The effectiveness of screening for diabetes and cardiovascular disease risk factors in a community pharmacy setting. PLoS One. April 2014 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3972156/
A literature review showed that community pharmacy conducted and analyzed point-of-care tests had satisfactory analytical quality. This review further supports that **community pharmacies are well positioned to deliver a wide range of point-of-care tests** and will allow for patients to have increased access to various screenings.	Buss V.H., Naunton M. (May 2019). Analytical quality and effectiveness of point of care testing in community pharmacies: A systematic literature review. Res. Soc. Adm. Pharm. 2019;15:483–495. doi: 10.1016/j.sapharm.2018.07.013. https://www.ncbi.nlm.nih.gov/pubmed/30057328
The Centers for Disease Control and Prevention's (CDC's) Community Preventive Services Task Force (CPSTF) recognized the importance of pharmacy-based prevention by issuing	CDC. (2016). Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A

a **strong recommendation for a pharmacy-based adherence intervention for cardiovascular disease prevention**, with its guidance based on its comprehensive literature review of 48 cases.	Resource Guide for Pharmacists. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. https://www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdfhttps://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf
This retrospective analysis studied community pharmacies providing flu and group A streptococcus (GAS) testing. Participating pharmacies reported 661 visits for adult (age 18 and over) patients tested for influenza and for GAS pharyngitis. For the GAS patients, 91 (16.9%) tested positive. For the Influenza patients, 22.9% tested positive and 64 (77.1%) tested negative. **Access to care was improved** as patients presented to the visit outside normal clinic hours for 38% of the pharmacy visits, and **53.7% did not have a primary care provider.**	Klepser D, et al. (2018). Utilization of influenza and streptococcal pharyngitis point-of- care testing in the community pharmacy practice setting. Research in Social Administrative Pharmacy. https://www.ncbi.nlm.nih.gov/pubmed/28479019
Pharmacist-initiated HCV screening in community pharmacy **assists with identifying patients at risk for HCV** infection and provide patients with **linkage to care**.	Isho N, et al. (March 2017). "Pharmacist-initiated hepatitis C virus screening in a community pharmacy to increase awareness and link to care at the medical center."; *Journal of the American Pharmacists Association*. https://www.japha.org/article/S1544-3191(17)30136-X/pdf
Between September 2015 and February 2016, 1298 individuals consented to HCV community-based antibody testing. Two patients withdrew consent after testing. In all, 8% (103/1296) were HCV antibody–positive; of them, 91 (88%) were contacted by an HCV management specialist. During the 21- to 28-day follow-up, 56 individuals (62%; 56/91) were reached by an HCV management specialist, and 29 (52%; 29/56) confirmed that an HCV RNA test was ordered. The authors conclude: **supportive results of point-of-care HCV screening in retail pharmacies for at-risk individuals** in the United States.	Kugelmas M, Pedicone LD, Lio I, Simon S, Pietrandoni G. Hepatitis C Point-of-Care Screening in Retail Pharmacies in the United States. *Gastroenterol Hepatol (N Y)*. 2017;13(2):98–104. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5402690/
Pharmacists provided 606 TB tests administered to 578 patients; 70.9% women, median age 31 years (4–93 years). Employment and school were the main reasons for obtaining a TB test. A total of 578 of 623 (92.8%) patients followed up to have their TSTs read. A total of **18 positive tests (3.1% positivity rate) were identified and appropriate referrals were made**. The authors conclude that pharmacist-performed TB testing had a **valuable public health benefit**. TB testing follow-up rates at community pharmacies in New Mexico were high, most likely due to convenient hours, accessible locations, and no required appointments.	B Jakeman, et al. Evaluation of a pharmacist-performed tuberculosis testing initiative in New Mexico. Journal of the American Pharmacists Association. Volume 55, Issue 3, May–June 2015, Pages 307-312. https://www.sciencedirect.com/science/article/pii/S1544319115300650?via%3Dihub
In Michigan, a pharmacist-provided HIV testing model, which incorporated rapid HIV testing, counseling, and linkage to confirmatory HIV testing demonstrated the acceptability and feasibility of pharmacist-provided rapid HIV testing and increased access to care. Approximately **42% of the participants stated it was their first HIV test, many of whom reported high-risk behaviors in prior 6 months.**	Darin KM, et al. (February 2015). "Pharmacist-provided rapid HIV testing in two community pharmacies;" *Journal of the American Pharmacists Association*. https://www.japha.org/article/S1544-3191(15)30015-7/pdf
A partnership between the Virginia Department of Public Health and community **pharmacies provided HIV tests to more than 3,600 individuals over 2 years.** Approximately half of these patients had never been tested for HIV before, and those who tested positive were linked to appropriate care with the assistance of a pharmacist.	Collin B, et al. The "No Wrong Door" Approach to HIV Testing: Results From a Statewide Retail Pharmacy–Based HIV Testing Program in Virginia, 2014-2016. 2018. Public Health Rep. https://journals.sagepub.com/doi/full/10.1177/0033354918801026
Pharmacies are increasingly providing a wide range of point-of-care tests including COVID-19, flu, strep throat, A1c screening, and more. Importantly, pharmacies throughout the country have also **partnered with local health departments to develop HIV and hepatitis C pharmacy-based screening programs that include linkage to care** if a test is positive.	Hoth A, Shafer C, et al. Iowa TelePrEP: A Public-Health-Partnered Telehealth Model for HIV Pre-Exposure Prophylaxis (PrEP) Delivery in a Rural State. Sexually Transmitted Diseases. May 2019. https://www.ncbi.nlm.nih.gov/pubmed/31157732 Dong BJ, et al. Pharmacists performing hepatitis C antibody point-of-care screening in a community

	pharmacy: A pilot project. Journal of the American Pharmacists Association. Volume 57, Issue 4, July–August 2017, Pages 510-515. https://www.sciencedirect.com/science/article/pii/S1544319117306660?via%3Dihub
This pilot project established HIV testing in several community pharmacies and retail clinics to offer rapid, point-of-care HIV testing. It demonstrated the **willingness and ability of staff at community pharmacies and retail clinics to provide confidential HIV testing to patients**. Expanding this model to additional sites and evaluating its feasibility and effectiveness may **serve unmet needs in urban and rural settings.**	Weidle, P, Lecher, S, Botts, L, et al. (2014). HIV testing in community pharmacies and retail clinics: A model to expand access to screening for HIV infection. Journal of the American Pharmacist Association, 54(5), 486-492. https://www.ncbi.nlm.nih.gov/pubmed/25216878
To help combat challenges in HIV PrEP and PEP access to care, more and more states are looking to pharmacists to help fill care gaps. For example, states including New Mexico, Iowa, and Washington, have piloted studies that show **pharmacist-run, or pharmacist-involved, PrEP clinics are an effective way to increase uptake of the medication**, which can then lead to decreased HIV transmission.	Ryan K, Lewis J, Sanchez D, et al. The Next Step in PrEP: Evaluating Outcomes of a Pharmacist-Run HIV Pre-Exposure Prophylaxis (PrEP) Clinic. ID Week 2018 Poster Abstract Session. Oct 2018. https://idsa.confex.com/idsa/2018/webprogram/Paper72194.html Tung EL, Thomas A, Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. Sex Health. Nov 2018. https://www.ncbi.nlm.nih.gov/pubmed/30401342
Chronic disease management	
This 2010 systematic review of pharmacist interventions concluded that such programs improve therapeutic and safety outcomes, and the results of various meta-analyses conducted for hemoglobin A1c, cholesterol levels, and blood pressure demonstrate the significant benefits of pharmacist care—**favoring pharmacists' direct patient care impact over comparative services**	Chisholm-Burns AM, et al. US Pharmacists' Effect as Team Members on Patient Care: Systematic Review and Meta-Analyses. Medical Care: October 2010 - Volume 48 - Issue 10 - p 923-933 https://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US_Pharmacists__Effect_as_Team_Members_on_Patient.10.aspx
Notable agencies within the healthcare system, such as the Department of Veterans Affairs, Department of Defense, Public Health Service, CDC, and the U.S. Surgeon General **recognize the value of pharmacists in improving quality and healthcare outcomes through services such as transitions of care and chronic disease management**, for example. By providing these important services in a convenient, easily accessible location, patients in underserved areas can benefit from expanded access to care and improved health outcomes.	A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. CDC. August 2012. https://www.cdc.gov/dhdsp/programs/spha/docs/pharmacist_guide.pdf Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011. https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf Surgeon General supports USPHS report on pharmacists as providers. APhA. January 2012. https://www.pharmacist.com/CEOBlog/surgeon-general-supports-usphs-report-pharmacists-providers?is_sso_called=1
A study examining pharmacist-led diabetes education, including individual consultations, point of care testing, and care coordination with other providers, led to **significant reductions in HbA1C, cholesterol, and blood pressure levels.**	Guide to Community Preventive Services. (April 2019). Cardiovascular Disease: Tailored Pharmacy-based Interventions to Improve Medication Adherence. https://www.thecommunityguide.org/findings/cardiovascular-disease-tailored-pharmacy-based-interventions-improve-medication-adherence

A review of 22 studies showed that community pharmacist-led interventions **improve patients' adherence** and contribute to **improved blood pressure control, cholesterol management, and chronic obstructive pulmonary disease and asthma control.**	Milosavljevic A, Aspden T, Harrison J. (June 2018). Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. International Journal of Pharmacy Practice. 26(5). https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462
The pharmacy intervention group had **statistically significantly higher improvements in the individual areas of A1c, blood pressure, and statin goal attainment**. In this study, 40% of patients in the pharmacist intervention group achieved all 3 clinical goals after intervention, compared with only 12% of patients in the usual care group.	Prudencio J, Cutler T, Roberts S, Marin S, Wilson M. (May 2018). The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home. JMCP. 2018;24(5):423-429. https://www.ncbi.nlm.nih.gov/pubmed/29694290
A study assessing pharmacy-based medication synchronization programs for Medicaid FFS beneficiaries with certain conditions (e.g., hypertension, hyperlipidemia and diabetes) found **improved adherence to cardiovascular medications, cardiovascular clinical outcomes and significantly lower rates of hospitalization and emergency department visits**, compared to a control group.	Krumme A. Glynn, R., Schneeweiss, S. et al. (January 2018). Medication Synchronization Programs Improve Adherence to Cardiovascular Medications and Health Care Use. Health Affairs 37(1)125-133. https://www.ncbi.nlm.nih.gov/pubmed/29309231
The results for 6-month **systolic blood pressure** reading showed **significantly decreased rates** for the pharmacist group versus the control group (-11.8mmHg vs - 6.2mmHg) and slightly smaller, but observable changes of diastolic blood pressure in the intervention group versus the control group (-8.4 vs -6.2mmHg). Percentage of patients achieving **good refill adherence** was larger for the intervention group compared to the control group (59.7% vs 36.1%).	Shireman TI, et al. (March 2016). "Cost-effectiveness of Wisconsin TEAM model for improving adherence and hypertension control in black patients;" *Journal of the American Pharmacists Association*. https://www.ncbi.nlm.nih.gov/pubmed/27184784
A review by the Department of Veterans Affairs of over 60 research studies found that patients receiving chronic care management from a pharmacist had a **higher likelihood of meeting blood pressure, cholesterol and blood glucose goals**, compared to those receiving usual care	Greer N, Bolduc J, Geurkink E et al. (April 2016). Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care. Ann Intern Med. Epub ahead of print.
CDC, CMS, and other public health leaders have noted the **robust ability for pharmacists to play an important role in smoking cessation**.	Centers for Disease Control and Prevention, Pharmacists: Help Your Patients Quit Smoking, April 22, 2019. https://www.cdc.gov/tobacco/campaign/tips/partners/health/pharmacist/index.html Department of Health and Human Services, Centers for Medicare & Medicaid Services; CMCS Informational Bulletin, State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf Tobacco Control Network, Access to Tobacco Cessation Medication Through Pharmacists, Feb 8, 2017, *available at* http://www.astho.org/Prevention/Tobacco/Tobacco-Cessation-Via-Pharmacists/
Pharmacy care program for elderly patients led to increases in medication adherence, medication persistence, and clinically meaningful reductions in blood pressure. After 6 months of intervention, **medication adherence increased from baseline of 61.2% to 96.9%** and associated with significant **improvements in systolic blood pressure** (133.2 to 129.9) and **LDL-C levels** (91.7 to 86.8).	Lee JK, et al. (December 2006). "Effect of a Pharmacy Care Program on Medication Adherence And Persistence, Blood Pressure, and Low-Density Lipoprotein Cholesterol: A Randomized Controlled Trial;" Journal of the American Medical Association; Available at https://jamanetwork.com/journals/jama/fullarticle/204402.

This systematic review evaluated the role of community pharmacists in the provision of screening with and without subsequent management of undiagnosed COPD and asthma. The literature review identified that community pharmacists can play an effective role in **screening of people with poorly controlled asthma and undiagnosed COPD along with delivering management interventions.**	Fathima, M et al. (October 2013). The role of community pharmacists in screening and subsequent management of chronic respiratory diseases: a systematic review. Pharmacy Practice, 11(4), 228-245. https://www.ncbi.nlm.nih.gov/pubmed/24367463
Several states authorize pharmacies to play an elevated role in initiation of prescription and over the counter products to support patients in smoking cessation. In fact, Colorado, Idaho, Indiana, and New Mexico **authorize pharmacists to initiate all medications approved by the U.S. Food and Drug Administration for smoking cessation**.	Adams AJ, Hudmon KS. Pharmacist prescriptive authority for smoking cessation medications in the United States. J Am Pharm Assoc (2003). 2018. doi: 10.1016/j.japh.2017.12.015.
Medication adherence and optimization	
This project evaluated the impact of medication adherence on five chronic medication classes. The study involved 283 pharmacists who screened 29,042 patients for poor adherence risk and provided brief interventions to patients with increased risks. The intervention group experienced **statistically significant improvements in adherence across all medication classes**. Further, the intervention demonstrated a significant reduction in per patient annual healthcare spending for patients taking statins ($241) and oral diabetes medications ($341). Based on these findings, the study concluded that such pharmacy adherence programs would **reduce costs for a plan with 10,000 members by $1.4 million each year** and could also be expected to increase the plan's star rating.	Pringle JL, et al., "The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs," Health Affairs (Aug. 2014), available at https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.1398
Patients receiving the pharmacist **adherence intervention for antihypertensives** increased between baseline and the end of the study **(86.0% vs 96.5%)** whereas the control group did not have a significant change (86.5% vs 85.4%). The odds of adherence to antihypertensive drug therapy in the pharmacist group was three times higher than the control group.	Fikri-Benbrahim N, et al. (December 2013). Impact of a community pharmacists' hypertension-care service on medication adherence."; *The AFenPA study. Research in Social and Administrative Pharmacy*. Available at https://www.ncbi.nlm.nih.gov/pubmed/23391845 . Last Accessed June 13, 2018.
Another relevant example includes a program designed to leverage the clinical expertise of pharmacists for Medicare and Medicaid beneficiaries, which led to **improved medication adherence** among patients in the pharmacist intervention group **by 46% compared to the control group**, who received usual care from their doctors and nurses.	Ameer H, Jain SH. How Pharmacists Can Help Ensure That Patients Take Their Medicines. Harvard Business Review. Jan 2019. https://hbr.org/2019/01/how-pharmacists-can-help-ensure-that-patients-take-their-medicines
This retrospective chart review included 728 medication therapy management encounters by pharmacists in a family medicine clinic. Patients were an average of 53.6 years old and took 11.9 medications to treat 5.7 medical conditions. A total of **3057 drug therapy problems were identified** in the **728 encounters**, of which 1303 were resolved the same day as the visit. This resulted in an average of 4.2 drug therapy problems identified and 2.0 resolved per visit per patient. The most common category identified in this study was the need for additional drug therapy (41.6%).	MacDonald D, Chang H, et al. Drug Therapy Problem Identification and Resolution by Clinical Pharmacists in a Family Medicine Residency Clinic. 2018. https://pubs.lib.umn.edu/index.php/innovations/article/view/971
In this retrospective review of 408 comprehensive medication management visits with a pharmacist, and an average of **2.5 drug therapy problems** were found **per patient visit** following hospital discharge. The most common problems were "needs additional therapy" and "dose too low."	Westberg SM, Derr SK, et al. Drug Therapy Problems Identified by Pharmacists Through Comprehensive Medication Management Following Hospital Discharge. Journal of Pharmacy Technology. June 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5998417/
This retrospective chart review included patients seen by a geriatric pharmacist during a one-year period. During this time, a total of **3100 drug therapy problems were identified during 3309 patient–pharmacist** encounters for 452 patients (mean age, 81.4 years).Pharmacists provided **4921 interventions**, often more than 1 intervention per drug therapy problem, for 275 different medications with an estimated **annual financial savings between $268,690 and $270,591.**	Campbell AM, Corbo JM, et al. Pharmacist-Led Drug Therapy Problem Management in an Interprofessional Geriatric Care Continuum: A subset of the PIVOTS Group. American Health and Drug Benefits. December 2018. http://www.ahdbonline.com/issues/2018/december-2018-vol-11-no-9/2678-pharmacist-led-drug-therapy-problem-management-in-an-

	interprofessional-geriatric-care-continuum-a-subset-of-the-pivots-group
Another pharmacy-led chronic care management program includes a $12 million CMMI grant to the University of Southern California and AltaMed, aimed to optimize patient health, reduce avoidable hospitalizations and emergency visits by integrating pharmacists into safety-net clinics in Southern California. This collaborative program resulted in **reduced rates of uncontrolled blood sugar** by nearly a quarter (23%), **improvements in elevated LDL** with 14% more patients controlled, **and improvements in blood pressure** with 9% more patients controlled at 6 months in the intervention group (collaborative care model with pharmacists as leads) versus the control group (primary care physicians only). The program resulted in a **33% reduction in readmissions** per patient per year primarily attributed to medications estimated at 6 months. Through this project, pharmacists identified **67,169 medication-related problem in 5,775 patients**. The top actions made by pharmacists to resolve these problems included: 14,981 dose change/drug interval, 5,554 medications added, 4,230 tests ordered, 3,847 medications discontinued, and 2,665 medication substituted. Further, 100% of program physicians either "strongly agreed" or "agreed" that having pharmacists in their clinics improves their patients' care, and that pharmacists are knowledgeable. And, 92% of patients rated the program very highly, rating scores of 9 or 10 out of 10.	Chen SW, Hochman M, Olayiwola JN, Rubin A. Integration of Pharmacy Teams into Primary Care. The Center for Excellence in Primary Care and the Center for Care Innovations May 2015. https://www.careinnovations.org/wp-content/uploads/2017/10/USC.CEPC_.pharm_webinar_FinalV.pdf Chen SW. Comprehensive Medication Management (CMM) for Hypertension Patients: Driving Value and Sustainability. University of Southern California. http://betheresandiego.org/storage/files/cmm-for-htn-usc-steven-chen-condensed-slide-deck.pdf
Through a brief pharmacist-to-provider intervention, a **significant gap closure in statin therapy was seen in patients with diabetes**. The number of statins prescribed was statistically significant between intervention group (n = 221) versus control group (n = 199) with 46 statins versus 17 statins, respectively (P <0.001).	Pharmacist-to-prescriber intervention to close therapeutic gaps for statin use in patients with diabetes: A randomized controlled trial. Journal of the American Pharmacists Association Volume 57, Issue 3, Supplement, May–June 2017, Pages S236-S242.e1. https://www.sciencedirect.com/science/article/pii/S1544319117301553?via%3Dihub
A clinical pharmacist and pharmacy resident evaluated clinical appropriateness and cost of statin therapy, provided recommendations to physicians, facilitated statin prescribing, and provided patient education. After implementation, 375 (82.6%) patients were on statins (P < .0001), compared to 343 before. **Recommendations were well received** (90.2% accepted) and no significant adverse effects were reported. Pharmacist implementation of a collaborative, patient-centered initiative **increased statin prescribing in diabetic patients**, most of which were black and had hypertension, in an internal medicine resident clinic.	Vincent R, Kim J, Ahmed T, Patel V. Pharmacist Statin Prescribing Initiative in Diabetic Patients at an Internal Medicine Resident Clinic. J Pharm Pract. 2019 Jan 29:897190018824820. https://www.ncbi.nlm.nih.gov/pubmed/30696337
Mental and Behavioral Health	
Community pharmacists have the capacity to **identify patients at risk for misuse of opioid medications**. Of the 164 patients who completed the survey, 14.3% screened positive for prescription opioid misuse risk, 7.3% for illicit drug use, 21.4% for hazardous alcohol use, 25.8% for depression, and 17.1% for post-traumatic stress disorder (PTSD).	Cochran G, Rubinstein J, Bacci JL, Ylioja T, Tarter R. Screening Community Pharmacy Patients for Risk of Prescription Opioid Misuse. J Addict Med. 2015 Sep-Oct;9(5):411-6. https://www.ncbi.nlm.nih.gov/pubmed/26291546
In Rhode Island, a grant from the National Institute on Drug Abuse is being used to allow patients to **receive addiction care at a community pharmacy**. Through this program, patients receive their initial prescription from a physician and, when stable, a pharmacist will take over their care, including conducting toxicology swabs to determine adherence and providing motivational counseling. Participants report **increased convenience and comfort** with receiving addiction care at their local pharmacy.	Freyer F. In Rhode Island, Some Get Addiction Care at the Pharmacy. Boston Globe. March 2019. https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVILRXX1W9X3WdeOP/story.html
In this pharmacist-physician collaborative care model, pharmacists conducted intake assessments and follow-up appointments with patients taking buprenorphine in order to **further expand access to treatment**. This program demonstrated 100% 6-month retention rates and 73% 12-month retention rates with an **estimated cost savings of**	DiPaula BA, Menachery E. Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients. J Am Pharm Assoc (2003). 2015 Mar-Apr;55(2):187-92. https://www.ncbi.nlm.nih.gov/pubmed/25749264

$22,000. Data from this pilot was then used to develop a permanent program utilizing this model.	
During the study period, 3,726 patients were screened for depression by pharmacists. Of the patients who completed the PHQ-9, approximately 25% met the criteria for consideration of diagnosis and were referred to their physician. Five patients presented with suicidal thoughts and were referred for urgent treatment. Approximately **60% of patients with a positive PHQ-9 had initiated or modified treatment at the time of follow-up**. The author concluded that a screening program for depression can be successfully developed and implemented in the community pharmacy setting. Using the PHQ, **pharmacists were able to quickly identify undiagnosed patients with symptoms of depression**. The majority of patients with apositive screening had initiated or modified treatment at the time of follow-up.	Rosser S, Frede S, Conrad WF, Heaton PC. Development, implementation, and evaluation of a pharmacist-conducted screening program for depression. J Am Pharm Assoc. 2013 Jan-Feb;53(1):22-9. doi: 10.1331/JAPhA.2013.11176. https://www.ncbi.nlm.nih.gov/pubmed/23636152
Twenty-six percent of individuals (n = 107) receiving opioid prescriptions were **identified as at some risk of misuse** and 30% at **risk of an accidental overdose**. Participating pharmacists preferred the value of having an **objective measurement of potential of opioid misuse**, to relying only on professional judgment. They also reported the value of the toolkit elements in enhancing conversations with patients.	Strand MA, Eukel H, Burck S. Moving opioid misuse prevention upstream: A pilot study of community pharmacists screening for opioid misuse risk. Res Social Adm Pharm. 2019 Aug;15(8):1032-1036. https://www.ncbi.nlm.nih.gov/pubmed/30031696
Pharmacists are increasingly being trained in mental health first aid. Research to date has demonstrated effectiveness and positive public perceptions.	Witry MJ, Fadare O, Pudlo A. Pharmacy professionals' preparedness to use Mental Health First Aid (MHFA) behaviors. Pharm Pract (Granada). 2020 Oct-Dec;18(4):2102. doi: 10.18549/PharmPract.2020.4.2102. Epub 2020 Nov 14. PMID: 33294061; PMCID: PMC7699831. Mospan CM, Gilletee C, Mckee J, et al. Community Pharmacists as Partners in Reducing Suicide Risk. The Journal of the American Board of Family Medicine. Nov 2019. DOI: 10.3122/jabfm.2019.06.190021 Dollar KJ, Ruisinger JF, Graham EE, Prohaska ES, Melton BL. Public awareness of Mental Health First Aid and perception of community pharmacists as Mental Health First Aid providers. J Am Pharm Assoc. March 2020. doi: 10.1016/j.japh.2020.01.017.
This study found large and **statistically significant decreases for almost every measure of substance use** in patients who received SBIRT method screening services, including decreases in alcohol use, heavy drinking, and illicit drug use. Greater intervention intensity was also associated with larger decrease in substance use.	Aldridge A, Linford R, Bray J. Substance use outcomes of patients served by a large US implementation of Screening, Brief Intervention and Referral to Treatment (SBIRT). Addiction. 2017 Feb;112 Suppl 2:43-53.https://www.ncbi.nlm.nih.gov/pubmed/28074561
An Australian study examined the impact of community pharmacists performing screenings and risk assessments for depression and found that pharmacists were able to provide screening and risk assessment services and make referrals as needed – which could facilitate **early intervention** and **reduce the overall burden of disease** associated with depression	O'Reilly CL, Wong E, Chen TF. A feasibility study of community pharmacists performing depression screening services. Res Social Adm Pharm. 2015 May-Jun;11(3):364-81.. https://www.ncbi.nlm.nih.gov/pubmed/25438728
Immunizations	
A 2019 study found that a community pharmacy vaccination program demonstrated an **increase of immunization rates for influenza, herpes zoster, and pertussis vaccination rates by 37%, 12%, and 74%, respectively**.	NK Wehbi, JR Wani, DG Klepser, J Murry, AS Khan. Impact of a Technology Platform to Increase Rates of Adult Immunization in Pharmacies. Vaccine. Volume 37, Issue 1, 3 January 2019, Pages 56-60. https://www.ncbi.nlm.nih.gov/pubmed/30471954

A 2018 study that modeled the clinical and economic impacts of using pharmacies to administer influenza vaccinations estimated that including pharmacies in addition to other locations for vaccination (e.g. clinics, physician offices, urgent care centers) could **prevent up to 16.5 million symptomatic influenza cases and 145,278 deaths** at an estimated **cost savings of $4.1 to $11.5 billion.**	Bartsch SM et al. Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. Vaccine. November 2018. https://www.ncbi.nlm.nih.gov/pubmed/30340884
Pharmacy-based immunization services increased the likelihood of immunization for influenza and pneumococcal diseases, resulting in millions of additional immunizations in the United States. Five years after national implementation, it is estimated that **6.2 million additional influenza immunizations and 3.5 million additional pneumococcal immunizations** are attributable to pharmacy-delivered immunization services each year	Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. Journal of the American Pharmacists Association. August 2018. https://www.ncbi.nlm.nih.gov/pubmed/30076098
In a CDC-funded, adult immunization initiative, more than 300 pharmacies across four states explored and developed approaches aimed at incentivizing community pharmacies and other stakeholders to improve rates for influenza, pneumococcal, pertussis, and herpes zoster vaccine. This effort resulted in 304,405 immunizations administered and **significant improvements in routinely recommended adult vaccination rates** with the most consistent increases across all sites seen for influenza (20-45%) and pertussis (13-74%) vaccines.	NACDS. (2018). CDC Project – Immunization Rates and VBM.
Policy changes permitting pharmacist immunization resulted in influenza **immunization administration rates rising** from 32.2% in 2003 to 40.3% in 2013.	Drozd EM, Miller L, Johnsrud M. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States. Clinical Therapeutics. 2017 Aug;39(8):1563-1580.e17. https://www.ncbi.nlm.nih.gov/pubmed/28781217
A 2016 review of 36 different studies found that **pharmacist involvement** in the immunization process, whether as educators, facilitators, or administrators, always resulted in an **increase in immunization coverage**.	Isenor JE, Edwards NT, Alia TA, Slayter KL, MacDougall DM, McNeil SA, Bowles SK. Impact of pharmacists as immunizers on vaccination rates: A systematic review and meta-analysis. Vaccine. 2016 Nov 11;34(47):5708-5723.https://www.ncbi.nlm.nih.gov/pubmed/27765379
A large proportion of adults being vaccinated receive their vaccines during evening, weekend, and holiday hours at the pharmacy, when traditional vaccine providers are likely unavailable. Of the nearly 6.3 million vaccinations administered during the study period, 30.5% were given during off-clinic hours. Younger, working- aged, healthy adults, in particular, received a variety of immunizations during off-clinic hours. With the low rates of adult and adolescent vaccination in the United States, **community pharmacies are creating new opportunities for vaccination** that expand access and convenience.	Goad JA, Taitel MS, Fensterheim LE, Cannon AE. Vaccinations administered during off-clinic hours at a national community pharmacy: implications for increasing patient access and convenience. Annals of Family Medicine. 2013 Sep-Oct;11(5):429-36. https://www.ncbi.nlm.nih.gov/pubmed/24019274
Social Determinants of Health & Health Disparities	
This example of pharmacists' ability to improve chronic care reached rural, underserved patients, and included a collaboration between A&B Pharmacy and Emporia Medical Associates, yielding significant patient outcomes. Through this program, pharmacists provided chronic care management (CCM) services for Emporia Medical Associates' Medicare patients. Pharmacists supported patients by providing medication reconciliation/ synchronization services, educating on how to self-monitor blood glucose and blood pressure, and answering questions about chronic disease management during monthly CCM appointments. Pharmacists also worked collaboratively with the physician to develop an appropriate care plan. The program resulted in an 8% increase in **medication reconciliation**, an 11% increase in use of **tobacco cessation services**, and a 6% increase in the **number of patients receiving chronic care management** through the provision of pharmacist-led services. All participating patients also reported **improvements in health outcomes** related to healthy eating and exercise.	A Team-based Care Approach to Reach Rural, Underserved Virginia Patients. WWCDPC. 2018. https://chronicdisease.host/WWCDPC/admin/dompdf/SuccessStories.php?id=712 Health Quality Innovators. A Partnership in Chronic Care Management. http://qin.hqi.solutions/wp-content/uploads/2018/05/CCM-poster-with-3-video-QR-link.pdf

This study describes the result of a pharmacist-driven, type 2 diabetes targeted, collaborative practice within an urban, underserved federally qualified health center. Pharmacists, within a primary care team, managed patients with chronic illnesses utilizing a collaborative practice agreement. Pharmacists had a **significant impact on improving the health outcomes of patients with Type 2 diabetes**, with significant improvements in patient attainment of A1c <9%, ACE inhibitor/angiotensin receptor blocker and statin use, and tobacco cessation at follow-up.	Ray S, Lokken J, Whyte C, Baumann A, Oldani M. The impact of a pharmacist-driven, collaborative practice on diabetes management in an Urban underserved population: a mixed method assessment. Journal of Interprofessional Care. 2020 Jan-Feb;34(1):27-35. https://www.ncbi.nlm.nih.gov/pubmed/31381470
Pharmacist-provided MTM can improve chronic disease intermediate outcomes for medically underserved patients in FQHCs. This pilot study displayed **improvement in diabetes and hypertension clinical markers** associated with pharmacist provision of MTM. A1c goal achievement occurred in 52.84% of patients and hypertension control was reported in 65.21%. Pharmacists identified and resolved more than **1400 medication- related problems** and addressed multiple adverse drug event issues.	Rodis JL, et al. (2017). Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers. Journal of Primary Care & Community Health. https://www.ncbi.nlm.nih.gov/pubmed/28381095
This survey analyzes Oregon pharmacy practices in the provision of hormonal contraception (HC) and evaluates if pharmacists' motivation to prescribe HC changed after 6 and 12 months of experience. The survey results demonstrated that pharmacist prescribing of HC continues to grow with almost 50% of pharmacists billing insurance for the visit. Visits take <30 minutes and the top 3 motivators continue to be **enhanced access to care**, reducing unintended pregnancy, and expanding pharmacists' scope of practice.	Rodriguez MI et al. Pharmacists' experience with prescribing hormonal contraception in Oregon. Journal of the American Pharmacists Association. December 2018. https://www.ncbi.nlm.nih.gov/pubmed/30190201
Socioeconomic challenges might influence education about interventions and lifestyle decisions, access to support activities, access to nutrition/health and wellness services, and access to screenings and services which would emphasize the need for well-positioned care. Community pharmacists are located where many patients facing socioeconomic challenges live and work, offering accessible preventive care opportunities.	Tucker M, Barclay L. What's the Effect of Diabetes Prevention Services? Medscape. July 2019. https://www.medscape.org/viewarticle/915077
Among black male barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in larger blood-pressure reduction when coupled with medication management in barbershops by specialty- trained pharmacists. The **mean reductions in systolic and diastolic blood pressure were 21.6 and 14.9 mmHg greater, respectively, in participants assigned to the pharmacist-led intervention** than in those assigned to the active control. In the intervention group, the rate of cohort retention was 95%, there were few adverse events, and self-rated health and patient engagement increased.	Victor RG, et al. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops. The New England Journal of Medicine. April 2018. https://www.nejm.org/doi/full/10.1056/NEJMoa1717250
This article highlights three health systems – Yale-New Haven Health, Ascension, and the University of Illinois Hospital and Health Sciences System – that are **utilizing pharmacists to provide healthcare services to underserved patients.**	Wild D. ASHP Intersections. June 2018. https://www.ashpintersections.org/2018/06/underserved-patients-rely-on-pharmacists-to-fill-care-gap/

April 15, 2022

Physician-Focused Payment Model Technical Advisory Committee
Assistant Secretary for Planning and Evaluation, Room 415F
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted electronically at PTAC@HHS.GOV

Re: Population-Based Total Cost of Care (TCOC) Models Request for Input

To Whom It May Concern:

On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association appreciates the opportunity to submit comments in response to the Physician-Focused Payment Model Technical Advisory Committee's Population-Based Total Cost of Care (TCOC) Models Request for Input. APTA is dedicated to building a community that advances the physical therapy profession to improve the health of society. As experts in rehabilitation, prehabilitation, and habilitation, physical therapists play a unique role in society in prevention, wellness, fitness, health promotion, and management of disease and disability for individuals across the age span, helping individuals improve overall health and prevent the need for avoidable health care services. Physical therapists' roles include education, direct intervention, research, advocacy, and collaborative consultation. These roles are essential to the profession's vision of transforming society by optimizing movement to improve the human experience.

APTA supports value-based payment programs that focus on improving quality of care by allowing physical therapists to meaningfully participate in and contribute to advancing high-value care across the health care continuum. We support efforts by PTAC, the Innovation Center and other stakeholders to advance the movement to value-based payment that rewards for the delivery of high-quality, patient-centered care. While we applaud the progress that has been made since the creation of the Innovation Center and with the support of PTAC, we urge policy makers to ensure that the continued trend toward value-based care is inclusive of physical therapists as well as other providers participating in advancing patient-centered care. To support PTAC's future work, we offer the following comments in response to questions 2a, 3a, 3b, 4a, 4b, 6a, 8a and 8b included in the RFI. Moving forward, we welcome the opportunity to serve as a resource to PTAC to help support the Committee's work.

2. **What type(s) of entity/entities or provider(s) should be accountable for TCOC in population-based TCOC models? Could the accountable entities look like current Accountable Care Organizations (ACOs) or Medicare Advantage (MA) plans? Could the accountable entities be delivery systems taking on risk, a combination of delivery organizations and payers, or fully integrated systems?**

    a. **Does the ability to manage TCOC vary by certain factors (e.g., type of provider, specialty, condition)?**

Physical therapists are well positioned to participate in value-based payment models, including TCOC models, given the demonstratable value of physical therapy services– including advancing improved function and mobility, creating a positive impact on co-morbidities and helping to lower downstream costs. Unfortunately, to date, few value-based quality payment programs have attempted to fully measure the impact of physical therapy. Too often, physical therapy is considered a downstream component of care and the benefits of physical therapy are either not measured, measured inaccurately or not attributed to the therapist. The largest quality payment program currently available to physical therapists, Medicare's Merit-Based Incentive Program (MIPs), only scores physical therapy on two of the four categories—quality and improvement activities—leaving cost and promoting interoperability unmeasurable by physical therapists. Omitting the impact of physical therapists on cost is a serious flaw in any system designed to measure value.

To this end, APTA believes that various factors impact management of a patients' TCOC—as well as their health outcomes and the quality of care received—including a patient's functional and physical performance, health status, the presence of chronic conditions or diseases, use of health care services and the settings in which the patient receives care, among other factors. Given the many contributing factors to TCOC, APTA supports the notion that a range of health care providers have the ability to significantly influence a patient's TCOC. However, existing Medicare accountable care organization and advanced primary care models do not have a clear pathway for many types of providers, including physical therapists, to participate in value-based payment arrangements. And, as noted above, while physical therapists may participate in MIPs, scoring capabilities are limited.

Notably, physical therapists are critical providers that are poised to influence outcomes, quality and TCOC. One study that analyzed the impact of PT services delivered in the emergency department (ED) to patients who came in after a fall found that PT was associated with a significantly lower probability of a fall-related return to the ED within 30 and 60 days. This is particularly notable, given it is estimated that falls led to $31.9 billion in direct medical costs to Medicare in 2015.[1] Another example of physical therapists' value comes in the context of total knee arthroplasty. Approximately 600,000 total knee replacements are performed in the United States each year and the average cost per knee is $30,000. The Osteoarthritis Initiative of the National Institutes of Health (OIA) has been tracking osteoarthritis specific to total knees for 11 years[2] and estimates that 34% of total knees are deemed inappropriate for surgery and could have been managed conservatively.[3] If the 204,000 patients (34%) in any given year had been referred to physical therapy instead of to total knee surgery at $30,000 cost each, physical therapists could potentially save the health care system $6 billion per year.

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[1] Lesser, Adriane, et al, Association Between Physical Therapy in the Emergency Department and Emergency Department Revisits for Older Adult Fallers: A Nationally Representative Analysis, The Journal of the American Geriatrics Society, 2018

[2] See https://nda.nih.gov/oai/; see generally https://www.nature.com/articles/s41598-020-63395-9

[3] See https://onlinelibrary.wiley.com/doi/abs/10.1002/art.38685. "The prevalence rates for classification of the procedure as appropriate, inconclusive, and inappropriate were 44.0% (95% confidence interval [95% CI] 37–51%), 21.7% (95% CI 16–28%), and 34.3% (95% CI 27–41%), respectively."

Moving forward, APTA urges PTAC, the Innovation Center and other stakeholders working to develop value-based payment models to identify the providers influencing TCOC and compare the impact of inclusion and/or exclusion of certain provide types in these models on TCOC. These types of analyses can support the movement of more providers to value-based payment and potentially expand the reach of models that incentivize delivery of high-value care to more patients.

3. Based on your experience, what are some approaches and best practices for integrating and improving coordination between primary care and specialty care providers within population-based TCOC models? **

a. Has provider participation in population-based TCOC models affected innovation with respect to the integration of primary care and specialty care?

APTA believes that to truly advance innovation with respect to value-based payment models—including TCOC models—new models need to be developed. Further, select, current models need to be expanded to include more patients and providers. Currently, for certain providers—including physical therapists—and especially for patients with functional limitations, participation in Innovation Center models could be expanded.

As discussed earlier, evidence shows the positive impact PT services can have on outcomes, quality and costs, pointing to the imperative to integrate these providers and services into models. For example, one study that aimed to assess the impact of the amount of outpatient PT received by Medicare FFS beneficiaries within one year of being diagnosed with low back pain on Medicare Parts A/B spending found that patients who used PT as the initial treatment had average Medicare Parts A and B spending that was 36% lower than those who used injection as the initial treatment and 66% lower than those who used surgery as the first treatment.[4] Another study that assessed the impact of services delivered during a 60-day Medicare-certified home health care episode following discharge on rehospitalization found that as PT visit intensity increased, the risk of rehospitalization decreased, ranging from a 41% decrease for 1.36 visits per week to an 82% decrease for 2.30 visits per week.[5]

To continue to advance innovation, PTAC, the Innovation Center, payers and other stakeholders need to consider opportunities via existing and new models to leverage integrated care teams across primary and specialty care. Currently, physical therapists are playing meaningful roles in providing care and controlling costs under the Comprehensive Care for Joint Replacement (CJR) model and within the Bundled Payments for Care Improvement Advanced (BPCI-Advanced) model. Moving forward, we urge PTAC, the Innovation Center and other stakeholders to consider the demonstrated impact preventive and chronic disease management PT services have had on improving outcomes and lowering longer-terms costs and to develop programs to advance their potential in TCOC models. One way to better integrate PTs and PT

[4] The Moran Company, Physical Therapy Episodes for Low Back Pain: Medicare Spending and Intensity of Physical Therapy Services. Prepared for APTQI, October 2017.
[5] Jinjiao Wang et al, Inverse Dose-Response Relationship Between Home Health Care Services and Rehospitalization in Older Adults, JAMA, 2019.

services into care delivery could entail creation of an algorithm to support diversion of patients to the most appropriate provider when presenting to primary care or seeking a primary care provider.

b. What are some incentives that can help to improve care coordination and provider accountability for TCOC?

For TCOC models to fully realize their potential, it is important for them to meaningfully integrate care providers with a demonstrated ability to influence a patient's health outcomes and costs. Further, TCOC models should be designed to support care coordination across appropriate providers and settings. To drive providers to coordinate care and manage patient outcomes and costs, including provider incentives (e.g., shared savings or risk, performance-based payments, etc.) tied to their components of a patient's care within a model's payment structure is critical. Allowing more providers to realize and share accountability for a patient's care can support quality of care across more providers within the care team. To this end, we strongly recommend PTAC, the Innovation Center, payers and other stakeholder that are developing models prioritize opportunities to integrate physical therapists into value-based payment models.

We also recommend that models include waivers of certain requirements to assess the implications of removing access barriers to providers on health, outcomes and reduce costs. For example, many payers require some form of a physician referral to access physical therapist services for evaluation and/or treatment. This is in contrast to the fact that every state, the District of Columbia, and the US Virgin Islands allow for evaluation and physical therapy treatment without physician referral. Further, when a physical therapist develops a plan of care for a Medicare patient—even if the patient was given a written order for therapy—it must be certified and periodically reviewed by a physician or non-physician practitioner to approve PT reimbursement. Waiving such types of requirements for patients with certain functional status or conditions (e.g., those with lower back plan, at risk of falls) to allow for direct access or implementation of a plan of care without certification or recertification could result in improved patient-centered care and more timely access to clinically appropriate care delivered in a lower-cost setting. Such a model has the potential to improve health, quality and reduce costs and administrative waste.

4. What are some options for evaluating and increasing provider readiness to participate in population-based TCOC models? *

a. Are there differences in provider readiness by specialty or other factors?

APTA supports development of new models or enhancements to existing models that create opportunities for more providers to participate in value-based payment arrangements, including TCOC models. While our members have successfully participated in value-based payment models in the commercial and employer markets, direct participation in Innovation Center models has been limited for physical therapists as well as many other providers. Moving forward, it is important that the Innovation Center's model designers consider including a broader range of providers, supporting their readiness for participation, and leveraging

learnings from models implemented by other payers. This could include waivers that enhance care delivery and coordination, technical assistance, and upfront funding to support providers or practices working to meet participation requirements (e.g., staffing, technology, education, and training, etc.).

b. What are some of the provider-level barriers to participating in population-based TCOC models (including barriers for specialists)?

As discussed above, many providers have been unable to directly participate in Medicare models. To support delivery of patient-centered care and help drive the health system towards value, APTA urges PTAC, the Innovation Center, payers and stakeholders working to design models to consider options to expand opportunities for more providers to participate in TCOC models. Further, even when providers are part of the team delivering care under a model, transparency in many models is lacking regarding appropriate incentives to drive high-value care while controlling costs and improving quality across all members of the care team. For example, while physical therapists have been integrated into care teams providing services under CJR and certain BPCI and BPCI-Advanced episodes, their impact on quality, outcomes and costs under these models has not been adequately evaluated despite research demonstrating that integrating physical therapists into care teams has the potential to improve health outcomes and reduce costs. Moving forward, model evaluations should be expanded to assess the impact of the range of providers and services critical to patients under the model as this can support refinements to care delivery and the future evolution of models.

More specifically, there are a number of significant barriers to leveraging the ability of physical therapists to provide preventive and chronic care management services, including limits on direct access, plan of care certification requirements, and challenges with interoperability. First, as discussed above, many payers require some form of a physician referral to access physical therapist services for evaluation and/or treatment. This can prevent access to preventive, high-quality services that have the ability to lower a patient's total costs of care. Second, when a physical therapist develops a plan of care for a Medicare patient, even if the patient was given a written order for therapy, it must be certified and periodically reviewed by a physician or non-physician practitioner in order for the PT to be reimbursed for care. These approaches can create barriers to both the delivery of and timeliness of care. Finally, a significant barrier to non-physician provider participation in quality payment programs concerns health IT and interoperability.

In 2011, CMS established the Medicare and Medicaid EHR Incentive Programs (now known as the Medicare Promoting Interoperability Program or commonly referred to as meaningful use) to encourage adoption, implementation, and demonstration of meaningful use of certified electronic health record technology (CEHRT). Financial incentives were given to certain providers to adopt CEHRT, however, the vast majority of healthcare providers were not included. Physical therapists have been excluded from the Meaningful Use program and, as such, they have not received any financial or technical assistance to adopt and implement CEHRT. Given that the 2015 Base Electronic Health Record definition and several of the 2015 Edition certification criteria are not applicable to physical therapists, vendors that develop and

offer EHRs for physical therapists are not attempting to certify their products because their EHRs do not encompass the necessary components to satisfy the CEHRT definition. Accordingly, physical therapists—and many, if not most non-physician clinicians—do not have the same standard of EHR technology as available to physicians. This leads to barriers to entry into quality payment models, like the MIPs promoting interoperability category, as well as barriers to contracting with other healthcare providers who have incompatible EHR programs, or who would lose their status under meaningful use should they integrate with a practice that is not compliant with the program. Last, until recently, the anti-kickback statute prevented many healthcare providers in value-based care models from including their downstream partners in their risk and/reward. Fortunately, a 2021 update to the physician self-referral regulations and the anti-kickback statute safe harbors finally allowed for value-based arrangements between providers. However, more should be done to encourage providers participating in value-based care models to include downstream clinicians in a meaningful way that transitions providers across the care team away to value-based payments.

~~6~~. Based on your experience, what payment strategies have been particularly effective for supporting efforts to improve quality and reduce TCOC (e.g., shifting risk downstream to providers)? Why have these strategies been effective? What have been some challenges and opportunities related to these approaches? ***

a. What are the pros and cons of using payment methodologies that rely on a fee-for-service (FFS) architecture with upside and downside risk versus payment methodologies that involve global budgets or capitated payments?

APTA's members have experience participating in a number of commercial and employer value-based payment models that entail a range of arrangements including shared savings and risk to bundled payments. While physical therapists are playing an important role in Innovation Center models focusing on post-acute care (e.g., CJR and BPCI/BPCI-Advanced), opportunities for physical therapists to participate in other Innovation Center models is currently limited. PTAC, the Innovation Center, payers and other stakeholders can leverage learnings and strategies from the commercial and employer markets to design models that meaningfully integrate physical therapists and support the movement to value-based payments.

As outlined above, although physical therapists have been integrated into care teams providing services under CJR and certain BPCI and BPCI-Advanced episodes, their impact on quality, outcomes and costs under these models has not been evaluated despite research demonstrating the ability of these providers and services to improve health outcomes and reduce costs. A better understanding of the impact of physical therapists and other providers participating in models on cost, quality and care will support future design of models that more effectively meet the triple aim.

8. What specific issues should be considered when applying population-based TCOC models to diverse patient populations and care settings? *

a. Are there potential issues related to health equity regarding the implementation of population-based TCOC models?

APTA believes that there are significant opportunities to leverage value-based payment models to extend high-quality care that improves health and controls costs to historically underserved or vulnerable populations. To deliver whole person care, model design must consider the roles of a range of providers and specialists in helping to advance equity and address disparities. For example, research has shown that disparities exist in activity limitations among adults with arthritis as the prevalence of activity limitations is higher among African America/Black, non-Hispanic adults (48.6%), Hispanic/Latino adults (44.3%), multi-race/non-Hispanic adults (50.5%), and American Indian/Alaska Natives (51.6%), than white non-Hispanic adults (40.1%). Given the impact activity limitations have on long-term health and outcomes, improving access to physical therapists could help to address these disparities.[6]

b. What are the options for increasing the participation of underrepresented and underserved populations in value-based models, including population-based TCOC models?

As discussed above, APTA believes that for value-based payment models, including TCOC models, to reach historically underrepresented and underserved populations, it is essential to consider the range of health care needs and challenges faced by these populations—including addressing functional and mobility issues for Medicare beneficiares. Models must be designed to meet patient populations where they are and deliver care that is accessible and in the appropriate care setting. This includes supporting access to providers that are able to treat patients in a variety of settings, such as clinics as well as in the community or home. More specifically, PTs are well positioned to deliver care across a range of settings, including inpatient and outpatient as well as in a patient's home. PTs' training and expertise also allows them to identify and support access to interventions and opportunities for physical activity as well as gaps in community resources that need to be addressed. This well positions physical therapists to meet the needs of patients that are more vulnerable or have historically faced barriers to care and health-related services.

By removing barriers to access and care, models can support delivery of high-quality, cost-effective care to more patients, including historically vulnerable populations. To this end, models must be designed to support access to needed providers, such as physical therapists, that have the ability to improve health and influence total cost of care for under-represented populations.

Conclusion

APTA thanks PTAC for the opportunity to offer feedback on its Population-Based Total Cost of Care (TCOC) Models Request for Input. Should you have any questions regarding our comments, please contact Kate W. Gilliard, JD, director, health policy and payment, at kategilliard@apta.org or 703-706-8549.

[6] CDC, Health Disparity Statistics, Arthritis Data and Statistics. Accessed January 20, 2022.

April 15, 2022

Paul N. Casale, MD, MPH
Chair, Physician-Focused Payment Model Technical Advisory Committee
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Avenue, S.W., Room 415F
Washington, DC 20201

Re: Population-Based Total Cost of Care Models Request for Input

Dear Chairman Casale:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments in response to the request for input (RFI) on key issues and options related to the development and implementation of population-based total cost of care (TCOC) models as published on the Physician-Focused Payment Model Technical Advisory Committee (PTAC) webpage in conjunction with the March public meeting on March 7–8, 2022. This RFI provides an important opportunity for stakeholders to provide committee members with information about current perspectives on the role that population-based TCOC models can play in optimizing health care delivery and value-based transformation in the context of alternative payment models (APMs) and physician-focused payment models (PFPMs).

NAACOS is the largest association of accountable care organizations (ACOs) and Direct Contracting Entities (DCEs) representing more than 12 million beneficiary lives through hundreds of Medicare Shared Savings Program (MSSP), Global and Professional Direct Contracting Model (GPDC), and commercial ACOs. NAACOS is a member-led and member-owned nonprofit that works on behalf of ACOs and DCEs across the nation to improve the quality of Medicare delivery, population health, patient outcomes, and healthcare cost efficiency.

NAACOS is committed to advancing the value-based care movement, and our members want to see an effective, coordinated, patient-centric healthcare system that focuses on keeping all individuals healthy. Strengthening the ACO model and other TCOC models provides an important opportunity to improve clinical quality and reduce health inequities while controlling rising healthcare costs. We are pleased to provide feedback on the following topics, which respond to the indicated groups of questions noted below.

Future population-based TCOC model design and implementation

Questions: 1. The Center for Medicare and Medicaid Innovation (CMMI)'s Strategy Refresh includes a goal that all Medicare beneficiaries with Parts A and B will be in a care relationship with accountability for quality and TCOC by 2030. What should these future population-based TCOC models look like?

2. What type(s) of entity/entities or provider(s) should be accountable for TCOC in population-based TCOC models? Could the accountable entities look like current ACOs or Medicare Advantage (MA) plans? Could the accountable entities be delivery systems taking on risk, a combination of delivery organizations and payers, or fully integrated systems?
    a. Does the ability to manage TCOC vary by certain factors (e.g., type of provider, specialty, condition)?
7. What are some options for addressing model overlap and incorporating episode-based payments within population-based TCOC models?
    a. How might these options vary by differing factors (e.g., ACO ownership type, condition, specialty, type of episode)?
    b. What are potential issues related to nesting, carve-outs, and other potential approaches?
13. What types of services should be included in calculating TCOC in the context of APMs, PFPMs, and population-based TCOC models? To what extent do definitions of TCOC differ across specialties, models, payers, and other factors?
    a. Should there be a single definition of TCOC in future population-based TCOC models? Are there considerations regarding why the definition of TCOC should potentially be allowed to differ by certain factors (e.g., payer type)?

Response:

NAACOS strongly supports the Centers for Medicare and Medicaid Services (CMS)'s stated goal of having all Medicare beneficiaries with Parts A and B in a care relationship with accountability for quality and TCOC by 2030, and we look forward to working with the agency to realize this goal by achieving the strategic objectives outlined by CMMI. The MSSP is the most established value-based care program in Medicare, currently serving 11 million Medicare beneficiaries, which is nearly one-third of traditional Medicare patients. Medicare data show that the success of TCOC, population-health models such as Medicare ACOs far outpaces the performance of narrowly focused APMs and therefore should be considered as the best path forward for implementing healthcare payment reform. Medicare ACOs such as the MSSP, the Pioneer ACO Model, the Next Generation ACO Model (NextGen), GPDC, and the recently-announced ACO Realizing Equity, Access, and Community Health (REACH) Model are designed to incentivize all providers to work together to provide coordinated, whole-person care, functioning as a cohesive system. This has been described as akin to operating a farm versus an individual part, like a silo, on that farm. Historically, our health system has been siloed, with primary care providers, specialists, hospitals, and post-acute care all working discretely and often without the full-patient picture.

In a population-based model, the focus is not solely about caring for individual patient needs at a given time, but about managing and improving the overall health of that patient and of a broader population. Therefore, full accountability should not be placed on individual providers, but spread across the team. It is most appropriate to have the ACO act as the accountable entity and to provide the ACO with the flexibility to work collaboratively with the ACO's providers to determine the amount of risk that individual provider types take on. This incentivizes a team-based approach without holding providers accountable for factors outside of their control and provides additional support for managing health-related social needs (HRSNs) and social determinants of health (SDOH). The ACO model has been successful because it allows local healthcare providers to determine who to collaborate with and come together voluntarily with those who share common goals. This provides the flexibility to form partnerships with shared accountability to support innovation and collaboration without forcing it, which allows ACOs to meet differing needs of differing communities.

In recent years, specialty-focused and episode-based bundled payment models have proliferated in the healthcare industry which has had negative consequences on TCOC models. Overlapping

models create confusion for patients served by multiple models as well as the clinicians participating in such models, and these issues have become increasingly complex due to the overlap of multiple models. NAACOS has encouraged CMS to work collaboratively with stakeholders to establish transparent and consistent overlap policies that protect and support TCOC models and, specifically, to exclude ACO patients from these models unless a collaborative agreement between the bundler and the ACO is in place. Fair and appropriate model overlap policies should give deference to TCOC models such as ACOs, which have outperformed other models to date and should, therefore, be prioritized when incorporating episode-based payments within population-based TCOC models.

As discussed in the PTAC March 2022 public meeting, there are many considerations to account for when defining and calculating TCOC in the context of a population health model. For example, payer type can impact what data are available to facilitate management of TCOC. Given the barriers created by the separation of Part D in Medicare, Medicare TCOC models should remain inclusive of only Parts A and B. If CMS were exploring adding accountability for costs outside of Parts A and B, it would be important that the agency do so very thoughtfully, offering an optional ACO test for those ready to take accountability beyond Parts A and B. Further, CMS should not move forward with such an approach until the systems within Medicare are equipped to provide the data necessary to successfully manage those additional costs.

Definitions of TCOC may also vary based on the needs of the given population or other factors, which is why an accountable entity, such as an ACO, should be provided flexibilities to collaborate with providers in ways that meet their needs. For example, allowing ACO participation at the Tax ID Number-National Provider Identifier (TIN-NPI) level would ensure that all providers in the ACO are voluntarily participating and share the goals of the ACO and a commitment to value-based care.

Payment structure and financial incentives needed to support population-based TCOC models

Questions: 6. Based on your experience, what payment strategies have been particularly effective for supporting efforts to improve quality and reduce TCOC (e.g., shifting risk downstream to providers)? Why have these strategies been effective? What have been some challenges and opportunities related to these approaches?

a. What are the pros and cons of using payment methodologies that rely on a fee-for-service (FFS) architecture with upside and downside risk versus payment methodologies that involve global budgets or capitated payments?

10. Based on your experience, what are different methodologies for developing benchmarks used to determine payment under population-based TCOC models? What are the pros and cons of these approaches? How can approaches for developing benchmarks be improved?
11. Based on your experience, what are different methodologies for risk adjusting measures used to determine payment under population-based TCOC models? What are the pros and cons of these approaches from a beneficiary, physician, or program perspective? Are there any unintended consequences of applying risk adjustment methodologies?

Response:

When considering payment strategies most effective in supporting quality improvement and cost control, there are a variety of factors at play, including practice type, resource allocation, and provider experience with value-based payment initiatives and population health models. Imposing downside risk on practices that aren't prepared will limit program participation and growth, as was shown by the decline in MSSP participation following implementation of the Pathways to Success Rule, which included significant changes to mandatory downside risk and

other program elements. An appropriate balance of risk and reward is necessary to ensure broad and successful participation in a population-based TCOC model.

It is important to distinguish between risk and value, as there has been some misconception that value in healthcare requires downside risk. Shifting downside risk to providers is not the main answer to improving quality and reducing costs, and mandating downside risk or predicating the availability of payment waivers or other participation incentives on the level of risk that an ACO has assumed is detrimental to the value transformation and ignores the fact that shared savings only or one-sided risk arrangements produce significant savings for the Medicare program. ACOs in both shared savings-only and risk-based models have shown reductions in spending per beneficiary relative to their benchmarks, and risk-based ACOs are not necessarily successful because of the assumed risk but because of other aspects of value transformation that have taken root. It can take years for the clinical and cultural changes necessary to succeed in value-based care to develop, and allowing providers ample time in one-sided arrangements allows those changes to progress. In many cases, one-sided risk arrangements mature to risk-bearing arrangements over time, which conforms with evidence showing that ACO performance improves over time, with length of participation associated with increases in both quality improvement and savings generated.

Appropriate incentives are necessary to ensure success when shifting risk downstream to providers, which is why Congress established a 5 percent bonus payment for providers participating in Advanced APMs through the Medicare and CHIP Reauthorization Act (MACRA). These bonuses have been instrumental in incentivizing providers to participate in high-risk models, but due to implementation challenges, participation in such models has not yet grown to the levels Congress envisioned when enacting MACRA in 2015. Currently, the opportunity to qualify for the Advanced APM bonus is set to expire on December 31, 2022, leaving minimal incentive for providers to remain in or join Advanced APMs. ACOs have reported using the bonuses to invest in ACO initiatives such as care coordination or data analytics and to support the ACO's move to a risk-based model. If the bonus is not extended, it will be important to consider alternative incentives to promote increased participation in high-risk APMs.

Offering optional capitation payments within a population-based TCOC model can be an effective strategy in the value transformation. Implementing optional capitation payments helps to break the FFS "wheel" that providers are accustomed to and allows the flexibility to transform care delivery. CMS has already been granted the statutory authority to implement partial capitation within the MSSP, and NAACOS has encouraged the agency to develop a new full risk option for ACOs in the MSSP, which could include 100 percent shared savings and loss rates, participation at the TIN-NPI level, options for capitated payments, and more advanced waivers such as those tested under CMMI's NextGen Model. Due to diversity among providers and varying levels of experience with non-FFS payment structures, some providers may find it easier to manage capitation than others and, therefore, capitation payments should be an optional component of model design. Ultimately, payment strategies within a population-based TCOC model should include appropriate flexibilities for providers to select risk and capitation options that meet their needs and recognize their ability to manage risk and administer capitation at that time.

NAACOS has long advocated for the creation of fair and accurate financial benchmarks and risk adjustment policies for ACOs. These benchmarks should create realistic opportunities for ACOs to generate and keep shared savings when they successfully lower patients' total cost of care. TCOC models have been successful in Medicare and should be widely encouraged because of their

ability to both encourage care coordination among providers that leads to higher quality care, and generate savings for Medicare that prolong the fiscal sustainability of the program. Both are contingent upon sound financial benchmarking and risk adjustment policies, which are at the heart of fairly holding providers accountable for cost and quality.

While Medicare TCOC models differ in their financial methodologies, all follow the same basic pattern. They are based upon per capita expenditures for Parts A and B services under traditional Medicare. Benchmarks include beneficiaries who would have been assigned to the ACO in each of three previous calendar years used in the model. They are trended forward based on national growth rates in Medicare spending. There is also some sort of regional adjustment so that efficient providers are rewarded and inefficient providers aren't unfairly rewarded. Spending is also risk adjusted to account for an aging population and sicker groups of patients ACOs may care for. These calculations are done across four beneficiary types – aged, non-disabled, disabled, dually eligible for Medicaid, and end-stage renal disease patients.

In the past, NAACOS has generally supported ACO benchmarking policies that more closely resemble those used in Medicare Advantage (MA). These are based more on spending for a particular county or region and are adjusted based on quality and risk scores. They are also administratively adjusted on an annual basis. If Medicare were to move to such policies for TCOC models, that could create more predictable benchmarks for ACOs. We encourage PTAC and CMS to further explore this approach and to make robust data publicly available for researchers to model the effects of such a revised approach.

In the meantime, NAACOS calls on CMS to fix the existing ACO benchmarking and risk adjustment policies by correcting longstanding flaws that unfairly penalize ACOs and stymie the growth of the Medicare ACO program. For example, as we detailed in our comments in response to the proposed 2022 Medicare Physician Fee Schedule, CMS should refine the current benchmarking and risk adjustment policies employed in MSSP to create fairer, more equitable financial methodologies for ACOs. For starters, CMS should remove ACO-assigned beneficiaries from the regional reference population. This is often referred to as the "rural glitch" and systematically penalizes an ACO when it reduces costs. Because of the rural glitch, when an ACO lowers the TCOC for its assigned population, it also reduces the average regional costs and diminishes the positive effect of the regional adjustment. This defeats the purpose of a benchmark that is based in part on regional expenditure data, which CMS has acknowledged is fair and necessary for a viable ACO program long-term. Specifically, to correct this CMS should remove ACO beneficiaries from calculation of the regional risk-adjusted per member per year (PMPY). Research conducted by the Institute for Accountable Care has found that 90 percent of MSSP ACOs would benefit to some degree by this correction.

To help create fair policies that account for the sickness of ACO patients, CMS employs a number of policies to limit so-called "upcoding." Most recently in GPDC and ACO REACH, CMS uses a Coding Intensity Factor, which limits risk score growth across the entire model by effectively normalizing risk scores for all patients in the model. In the MSSP, CMS caps risk scores at growing no more than 3 percent over a five-year period. In contrast to traditional Medicare's accountable care programs which have multiple controls in place used to limit risk score increases, there are fewer such controls in MA. As a result, the Medicare Payment Advisory Commission reported in March 2021 that higher coding intensity resulted in MA risk scores that were more than 9 percent higher than scores for similar FFS beneficiaries.

These policies create an inherently uneven playing field for providers operating in APMs within traditional Medicare. NAACOS urges CMS to align risk adjustment policies across all of its programs, including traditional Medicare and MA to avoid arbitrage and profit seeking based solely on risk scores**.** NAACOS is very concerned about the growing imbalance in risk adjustment policies between MA and various ACO programs that operate within traditional Medicare. CMS estimates that risk scores in MA will increase by an average of 3.5 percent in 2023. Risk adjustment policies in MSSP, by comparison, can only increase by 3 percent over a five-year agreement period. Sound program fundamentals around benchmarking and risk adjustment methodologies, as well as a reasonable glide path to taking on downside risk and an appropriate balance of risk and reward, are necessary to attract participants and ensure long-term financial sustainability in a population-based TCOC model.

Care delivery strategies for population-based TCOC models

Questions: 3. Based on your experience, what are some approaches and best practices for integrating and improving coordination between primary care and specialty care providers within population-based TCOC models?

a. Has provider participation in population-based TCOC models affected innovation with respect to the integration of primary care and specialty care?
b. What are some incentives that can help to improve care coordination and provider accountability for TCOC?

5. Based on your experience, what kinds of care delivery strategies (e.g., patient-centered medical homes, telehealth, and care coordination; addressing social determinants of health, addressing behavioral health needs, and focusing on seriously ill patients) have been particularly effective for improving quality and reducing TCOC? Why have these strategies been effective? What have been some challenges and opportunities related to these approaches?
    a. What are options for incorporating these strategies when developing care delivery models for future population-based TCOC models?
    b. What are some best practices for improving the affordability of care for beneficiaries (e.g., copayments, prescription drugs) within population-based models?

Response:

Care innovations are often developed and implemented within the context of a specific population's needs and, therefore, it is important that population-based TCOC models such as ACOs have the flexibility to tailor care innovations to the communities they serve. In order to enable ACOs to identify and target the greatest opportunities to improve gaps in health outcomes and tackle unnecessary spending, they need access to timely and accurate data.

Providing timely data allows ACOs to deliver the kind of patient-centered, well-coordinated care necessary to improve health outcomes and reduce inequities, with emphasis on providing the right care in the right setting and preventing avoidable and costly complications or hospital readmissions. CMS provides some data, but it is delayed by weeks or months and is therefore not always actionable. The data available in the HIPAA (Health Insurance Portability and Accountability Act) Eligibility Transaction System (HETS) is very meaningful and should be provided in real time to ACOs for their beneficiaries. This would allow ACO providers to communicate with treating providers at the hospital and to work with the beneficiary upon their release to ensure optimal treatment, medication adherence, and follow up care. NAACOS has repeatedly urged CMS to develop a mechanism to share more robust health data, including that from HETS, with ACOs in real time to enhance care coordination, improve outcomes and reduce costs. As PTAC evaluates strategies to improve value-based care modes, we request that robust, timely, and actionable data be a priority.

Another data challenge is that ACOs lack access to substance use disorder (SUD) data despite the fact that Section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act helped to align 42 CFR Part 2 (Part 2) with HIPAA. ACOs still lack access to vital SUD-related data on their patients due to the fact that under current regulations, care coordination is not considered by CMS to fall under treatment, payment, and health care operations. Design of any population-based TCOC model should ensure that accountable entities have access to whole-person data on their patient populations to facilitate care coordination and other strategies to improve patient care and outcomes.

Primary care versus specialty participation and levels of integration in ACOs can vary by different factors such as organizational structure or geography. Many ACOs include specialists as a strategy to reduce TCOC, and in 2018 nearly two-thirds of physicians participating in the MSSP were specialists. While the Affordable Care Act (ACA) provided CMS and the U.S. Health & Human Services Department (HHS) Office of Inspector General (OIG) broad statutory physician waivers of the physician self-referral law (the "Stark" law) and anti-kickback statute (AKS) for ACOs participating in MSSP, ACO participants continue to have questions about the application and scope of the agency-issued waivers. In order to encourage and enable collaboration and integration among primary care providers and specialists in ACOs, the agencies should address remaining uncertainty concerning whether, as well as the extent to which, an incentive program offered to a physician with respect to assigned MSSP patients may, without creating potential Stark Law issues, also be offered to the same physician for non-MSSP patients. This can create confusion for providers and limit uptake of such incentive programs. NAACOS has provided recommendations on modifications to Stark Law and AKS waivers that could provide participants with certainty and stability, and we also called for the expansion of waivers for non-risk bearing ACOs. These entities' accountability for TCOC promotes self-regulation, and key safeguards in waivers ensure appropriate use. Clarifying remaining uncertainty regarding current Stark and AKS waivers and flexibilities in place would allow ACOs and other TCOC model participants to more easily create relationships to deliver coordinated, integrated care.

A variety of care delivery strategies have been implemented by ACOs across the country, but specific strategies with the greatest efficacy vary based on the needs of the population being served and the capabilities of the individual ACO. ACOs should have the flexibility to develop and implement care delivery strategies that work within the organizations' resources and the patient populations' needs. An ACO in its evolution to value may be able to deploy different strategies in the beginning and later advance them, and readiness for different strategies depends on where the providers are on the continuum, so it is important that TCOC model design not be overly prescriptive of care delivery methods.

For example, ACOs that are immature or underfunded often approach innovations within value-based care in stages, initially tackling obvious opportunities that require minimal overhead. This can be as simple as implementing workflow changes for staff to include additional care management or pharmacy staff or creating a manual process to test the effectiveness of a new care model before purchasing more costly services such as data platforms or artificial intelligence (AI) to facilitate provider data, referrals, or consults. ACOs that are more experienced and have proven success in their model are often better-equipped to pursue additional innovation and the investments required to create the best outcomes, which often come at a financial or staffing disruption cost. Some examples of innovation for a mature ACO could include adding technology that has bidirectional communication between participant electronic medical records (EMRs), network consulting platforms, or sharing services for patient care such as paramedics or nurses

for home care. Regardless of an ACO's maturity, provider engagement in care delivery innovation takes time and proof of concept. Primary and specialty care providers have worked in silos for decades and changing cultural patterns take time, persistence, and flexibility to meet providers where they are today, while allowing them to implement value-based care in a way that fits their practice to create better patient outcomes.

There are other "wraparound" strategies that facilitate innovative care delivery and improved outcomes, such health information technology (IT) infrastructure and data analytics that are important to consider. Appropriate infrastructure for closed-loop referrals within and outside of the ACO can support transitions of care and help to manage HRSNs and other factors impacting health outcomes that may be outside of the primary care provider's control. Waivers and payment support should be made available where appropriate to enable accountable entities to implement such wraparound strategies. Smaller and/or under-resourced entities may require additional support in order to implement and sustain these strategies. For this reason, NAACOS has recommended providing upfront funding and other financial supports to enable the development of ACOs in underserved communities. This could be accomplished through a program analogous to the ACO Investment Model (AIM), which encouraged ACO development in rural and underserved areas by offering pre-payment of shared savings in both upfront and ongoing per beneficiary per month payments and is considered to be one of the most successful CMMI models to date.

Population-based TCOC models such as ACOs are incentivized to deliver the right care at the right time and in the right setting for a given patient. Copays and cost sharing should never be an impediment to this. A patient, who cannot afford the copay for a primary care visit at the onset of symptoms, may end up with a much higher bill from an emergency department visit later on. ACOs should have the flexibility to waive cost sharing for certain beneficiaries in order to encourage patients not to delay needed care. While the Beneficiary Incentive Program in the MSSP was intended to help eliminate financial barriers to accessing care, the current program requires an ACO to offer any beneficiary incentive payment to all beneficiaries equally, regardless of financial need or particular condition. This requirement makes the program cost-prohibitive and has significantly limited uptake. Under GPDC and ACO REACH, CMMI is testing a beneficiary engagement incentive that allows the accountable entity (DCE/ACO) to provide cost sharing support for an identified subset of beneficiaries, types of Part B services, or both. NAACOS supports this type of flexibility, which allows accountable care entities to allocate resources in the most appropriate and effective manner for the needs of their patient populations.

NAACOS has also recommended that such waivers be extended to ACOs in shared savings-only arrangements to allow those activities to develop and grow. All ACOs, regardless of risk level, require substantial startup and ongoing operational costs. Therefore, the use of waivers and other tools to enable success should be seen as a necessary precursor for long-term program participation and the path to assuming downside risk.

Health equity and clinical quality considerations for population-based TCOC models

Questions: 8. What specific issues should be considered when applying population-based TCOC models to diverse patient populations and care settings?

a. Are there potential unintended consequences associated with implementing population-based models (for patients, primary care providers, specialty providers, and others)?
b. Are there potential issues related to health equity regarding the implementation of population-based TCOC models?

c. What are the options for increasing the participation of underrepresented and underserved populations in value-based models, including population-based TCOC models?

9. Based on your experience, what are the best performance metrics for evaluating population-based TCOC models, and their impact on the quality and cost of care?

Response:

There are vast differences in care needs and priorities across communities and even across populations within those communities. Therefore, careful consideration of potential unintended consequences is essential when designing and implementing any population-based TCOC model. When models include mandatory downside risk, this creates barriers that can prevent providers treating greater proportions of historically-disadvantaged patients from being able to participate and will result in ACOs only forming in areas with financially secure health care providers, which is a detriment to health equity. An equitable TCOC model should include sound program fundamentals around benchmarking and risk adjustment methodologies to meet providers where they are at and avoid unintentionally penalizing those serving historically under-resourced communities. As mentioned previously, the rural glitch is a prime example of how benchmarking methodologies, when not designed carefully, can have negative consequences on certain communities.

Additionally, model design and implementation should consider the upfront costs and resources required to stand up an ACO or other population-based TCOC model. In order to be successful in these models, accountable entities need access to sufficient health IT infrastructure and data analytics, as well as appropriate staff such as community health workers (CHWs), care navigators, and peer support specialists. Providers working in under-resourced communities with significant unmet need likely will not have access to the necessary capital to participate in such models without upfront funding and a reasonable glide path to taking on risk. NAACOS has provided several recommendations of strategies to both enhance existing ACOs' ability to identify and address health inequities and to enable and encourage the formation of ACOs in historically under-resourced communities with more vulnerable populations. These recommendations include upfront funding, adjusted financial benchmarks, and development of a "chronic social determinant management" service (akin to chronic care management codes) that would allow ACOs to deliver and bill for certain supplemental benefits that address social determinants, improve health equity, and meet social needs.

Careful consideration needs to be taken when designing policies that address health equity as to avoid unintentionally penalizing those treating underserved populations or creating winners and losers as a result of a given policy. Those working to design and implement equitable population-based TCOC models must recognize that there is considerable unmet need and significant health disparities in many populations due to a variety of compounding systemic factors that are largely outside the control of a healthcare provider. Some policies that may seem to support health equity may actually be detrimental. For example, stratifying quality measures by race/ethnicity can help to identify health disparities so that they can be targeted for improvements. However, some have suggested adjusting quality benchmarks for race and ethnicity. NAACOS strongly opposes this, as doing so would endorse and accept that for an underserved population it is acceptable to have lower quality or poor outcomes. Instead, policies that enable ACOs to identify and eliminate gaps in health equity should be pursued. Health equity initiatives should include rewards for reducing gaps in health equity but should not penalize ACOs for existing gaps or suggest that said gaps are acceptable or immutable.

CMMI's recently-announced ACO REACH Model exemplifies how a population-based TCOC model can be intentionally designed to promote health equity through various provisions, including a health equity benchmark adjustment to provide additional financial support to ACOs serving a disproportionate number of underserved beneficiaries and demographic data collection requirements to help with model monitoring and evaluation. While this model seems promising, NAACOS was disappointed to learn that the health equity benchmark adjustment will be budget neutral, and any upwards adjustments to support ACOs serving higher proportions of underserved beneficiaries will come at the expense of other ACOs in the model. This limits the amount of funding available and creates other challenges given the fact that beneficiaries are defined as "underserved" in relation to other beneficiaries in the model, not based on a standard definition. Given the significant unmet need experienced by historically-underserved populations, models designed to support health equity should include additional funding for these populations, which is long overdue.

CMMI has also acknowledged the need for additional collaboration with external stakeholders, such as beneficiaries, community based-organizations (CBOs), and patient advocacy groups, in designing models that advance health equity. In order to increase the participation of underrepresented and underserved populations in value-based models, diverse stakeholder input is needed at every stage of design, implementation, and evaluation. Feedback from those working with these populations, including local health care providers and CBOs, will be necessary to understand the barriers and enablers to participation.

In evaluating population-based TCOC models, the historical focus has been on a model's ability to generate savings. However, recent remarks from leadership at CMS indicate that there will be an increased focus on quality improvement and health equity in future model evaluations. This is critical given the significant unmet need being experienced by underserved populations. In the short term, it may not be feasible to achieve cost savings while improving quality and reducing health inequities but achieving high quality, equitable outcomes will be necessary for the long-term success and sustainability of our health care system. When evaluating cost savings, comprehensive difference-in-difference (DID) analysis should be used in addition to comparing benchmarks to performance, as DID can provide a more sophisticated estimate of the model's impact. It is also important to note that actuarial evaluations may not capture care delivery transformation and the effect it has on patients. Therefore, it is important that model evaluation leverage a multifaceted approach with both quantitative and qualitative data to ensure a full picture of the model's impact on quality, equity, and cost is being assessed.

Impacts on quality can be difficult to measure. To date, CMS has used a variety of quality measures and measurement approaches across APMs. In some TCOC models, there are few if any clinical quality measures, and instead the focus is on administrative claims measures that assess hospitalization and readmission rates. In other TCOC models, CMS has aligned quality measurement approaches with the FFS program, the Merit-Based Incentive Payment System (MIPS). This misaligned approach creates uncertainty for participants and does not allow CMS to appropriately evaluate model impact on quality.

Further, there is little room for stakeholder input on APM quality measures. Most CMS programs must involve stakeholder input through the Measure Applications Partnership (MAP), which makes annual recommendations to CMS on Measures Under Consideration for various CMS programs. However, to date, no CMMI models have engaged in the MAP process, leaving stakeholders no way to provide input and no transparency regarding the process for measure

selection, as well as no way to question the validity of a certain measure or provide other critical input. CMS should be focused on advancing quality evaluations for APMs, and TCOC models in particular, in an aligned and transparent manner that involves stakeholder input. In particular, CMS's recent actions to move MSSP ACO quality assessments to the FFS MIPS methodology is a step in the wrong direction and has the potential to erode participation in that model.

Specifically in the Final 2021 Medicare Physician Fee Schedule Rule, CMS created a new APM Performance Pathway (APP) within the MIPS program to evaluate APMs who are, despite their participation in an APM, subject to MIPS. At the same time, CMS also removed the previous MSSP quality assessment methodology to replace it with the new APP methods. Aligning ACO quality assessments with MIPS assessments is a step backward for value-based care. Instead, CMS should look for ways to align the quality approach for value-based payment models, which are the future of healthcare delivery.

While CMS has taken the approach of removing all clinical quality measures from certain population health models, such as the Direct Contracting Model, NAACOS believes there continues to be utility in maintaining some high value process measures focused on prevention, such as cancer screenings and immunizations. Further, while CMS often cites that measure performance is topped out on these process measures, when stratified by race/ethnicity and other factors, there is indeed still room for improvement. NAACOS believes TCOC models like ACO models provide an opportunity to look across a population served to identify inequities in quality so that they may be addressed appropriately. We have provided a detailed list of recommendations and considerations when addressing health equity in quality measurement for TCOC models, and we recommend PTAC and CMS consider these approaches when moving forward. When these issues are not addressed, there may be unintended consequences. For example, in moving the MSSP to the APP quality assessment structure, CMS has inadvertently established a policy which will punish ACOs serving under-resourced communities as their quality scores will appear lower, and, as a consequence, they may not be eligible for shared savings or even owe losses to CMS.

Finally, while hospitalization and readmission rates can be a good indicator of reducing costs and maintaining health for a beneficiary by avoiding a hospital stay, to solely focus on these measures is missing the broader picture of quality improvement efforts ACOs engage in. Additionally, there are certain quality measures that lend themselves to a TCOC model or program, such as measures focused on screening for SDOH. CMS should begin to think more strategically about how to evaluate quality for APMs, and TCOC models in particular, gathering stakeholder input throughout the process, such as using the established MAP process.

Issues related to provider readiness, participation incentives, and administrative burden associated with population-based TCOC models

Questions: 4. What are some options for evaluating and increasing provider readiness to participate in population-based TCOC models?

a. Are there differences in provider readiness by specialty or other factors?
b. To what extent can provider participation in models with some upside and downside risk help to increase provider readiness to participate in population-based TCOC models? If so, what are some options for improving provider readiness to take on risk?
c. What are some of the provider-level barriers to participating in population-based TCOC models (including barriers for specialists)?

12. Are there opportunities to improve multi-payer alignment and increase multi-payer participation in population-based TCOC models? What are the most important model design components related to increasing multi-payer alignment (e.g., clinical tools, outcome measures, payment)?

Response:
There are a variety of factors that may impact a given provider's readiness to participate in population-based TCOC models such as practice size and sophistication, staffing issues, culture, financial backing, or serving rural or underserved communities. Providers need to share the values and goals of the accountable care entity in order to achieve the necessary level of buy-in to be successful. Without this, providers will not be motivated to change clinical practice and workflows to deliver high quality, high value care. Past experience with APMs or value-based care strategies outside of the traditional FFS system may impact providers' interest in and readiness to participate in a population-based TCOC model. As previously mentioned, a reasonable glide path to taking on downside risk is necessary to ensure that different types of practices and providers are able to participate and succeed in population-based TCOC models. NAACOS has previously advocated for no fewer than four years before an ACO be required to take on financial risk. It is important to recognize that not all providers are in the same position on the path to value and model design should be flexible enough to meet providers where they are at and provide sufficient time to demonstrate positive results.

Model design should also avoid overly complex administrative burdens. Certain program requirements are associated with considerable costs, time, and resources. While meeting one specific program requirement, like securing a repayment mechanism or ensuring adherence with compliance requirements, may seem reasonable, the totality of administrative burdens on providers in APMs is rarely considered. Taken together, meeting these requirements takes away from staff time and resources that would otherwise go to direct patient care or quality improvement initiatives. We recognize that not all administrative burdens can be eliminated, but we encourage PTAC and CMS to consider and limit these growing burdens as models are developed and updated.

NAACOS has provided detailed recommendations on strategies to reduce administrative burdens and allow more time and resources to be dedicated to care transformation efforts, such as reforming beneficiary notification requirements, addressing model overlap, providing ACOs with actionable and timely data, and other improvements to program elements. NAACOS has also provided recommendations to CMS on strategies to encourage MSSP participation and bolster ACO program growth including changes to quality assessments, benchmarking and risk adjustment methodologies, and shared savings rates.

In addition, finding ways to align certain methodologies and program design elements across payers would go a long way in reducing burdens for providers wishing to participate in multiple models across multiple payers. This would not necessarily require a new model, but rather is a recommendation for efforts to align TCOC model building blocks and methodologies such as quality measurement approaches, risk adjustment methodologies, and payment rule waivers. Alignment across models would allow ACOs to reduce the significant administrative burden associated with participating in multiple models, each relying on their own unique methodologies and program design elements. We recommend that HHS play an active role in collaborating with provider stakeholders and payers outside of Medicare to generate consensus and support for an ideal set of standard TCOC model elements.

Other considerations and next steps

Question: 14. Are there any other important questions that should be considered related to the development of population-based TCOC models and PFPMs?

Response:

In developing population-based TCOC models, it is important to leverage lessons learned from past models in order to structure models in a way that is attractive enough for providers to voluntarily participate. This includes recognizing the burdens of startup and ongoing operational costs, balancing risk and reward to encourage provider buy-in and prevent attrition, addressing issues of model overlap, and providing ample data and technical assistance for accountable entities to succeed in population-based TCOC models. NAACOS encourages diverse stakeholder collaboration in model development with ample provider input throughout each stage of model design, implementation, and evaluation. This will increase transparency, predictability, and fairness which will foster a higher level of trust between providers and payers entering into these value-based agreements, thus leading to a successful transition to value-based care.

Conclusion:

Thank you for the opportunity to provide comments on the PTAC RFI on key issues and options related to the development and implementation of population-based TCOC models. Should you have any questions about our comments, please contact Allison Brennan, SVP, Government Affairs, at abrennan@naacos.com.

Sincerely,

Clif Gaus, Sc.D.
President and CEO
NAACOS

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April 25, 2022

Paul N. Casale, MD, MPH
Chair, Physician-Focused Payment Model Technical Advisory Committee
c/o U.S. DHHS Assistant Secretary of Planning and Evaluation Office of Health Policy
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted electronically: PTAC@HHS.gov

Re: Population-Based Total Cost of Care (TCOC) Models Request for Input

Dear Dr. Casale,

The American Society for Radiation Oncology[1] (ASTRO) appreciates the opportunity to provide written comments on the "Population-Based Total Cost of Care (TCOC) Models Request for Input" (RFI). ASTRO has appreciated the opportunity to engage with PTAC over the years, most recently as a virtual participant during the March 7-8th public meeting on TCOC. The dialogue that took place during that meeting echoed our own sentiments about payment models.

We were pleased to hear that PTAC members, as well as several of the distinguished speakers, recognize the value of episode-based payment models and the need to nest episode-based payment within broader TCOC models. This is particularly important when considering TCOC or ACO concepts that involve cancer care, which involves multiple modalities of treatment with very distinct costs and care delivery requirements.

It was also reassuring to hear several speakers point to the need for incentives and payment constructs that recognize the cost of entering into and participating in value-based payment models. Cancer care is complex and expensive. Without the necessary supports for upfront investments in equipment and systems to deliver the most efficient and high-quality treatments, payment models run the risk of jeopardizing access to care for

[1] ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists, and social workers. They treat more than one million patients with cancer each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

some of our most vulnerable populations, particularly those who experience healthcare disparities.

ASTRO has significant experience with the development of episode-based payment models, specific to radiation therapy. We appreciate the opportunity to provide our perspective in response to the various questions posed in the RFI that was issued at the conclusion of the March 7-8 public meeting. Rather than respond to each of the key questions, we are sharing observations based on our experience with the CMS Radiation Oncology Model (RO Model) that apply to the various scenarios described in the RFI.

The Shift toward TCOC & the Role of Episode Based Payment Models

While ASTRO appreciates the need to shift towards TCOC models, we urge PTAC and CMS to consider the appropriateness of episode-based payment within broader TCOC models. One of the tenets of value-based care is the development of alternative payment models that allow physicians to manage the costs that they can control. Episode-based models are appropriate for distinct segments of care that are delivered within a specific period. We believe that radiation therapy is an appropriate candidate for episode-based payment since it is a distinct component of care within the broader cancer care continuum. It involves a unique treatment, delivered over a specific period of time, that involves expensive capital resources that are not found elsewhere in medicine.

Types of TCOCs

The PTAC RFP seeks comment on the type of entities that may be able to operationalize TCOC models. We believe that TCOC models can be established through a variety of entities: ACOs, MA plans, healthcare systems, etc. For cancer care, this may include multi-disciplinary cancer treatment centers, free-standing single modality clinics, and hospital-based settings. Regardless of the location of the TCOC setting, a radiation oncology episode can be successfully nested within any one of these settings to ensure that the radiation oncologist can participate in overall TCOC coordination, but also take responsibility for those radiation therapy services they provide to ensure they are appropriately delivered to patients.

Integrating Care

Care integration is particularly critical for patients with cancer. One of the best practices for integrating and improving coordination of care between primary care and oncology care providers is to require consultation with a broad range of providers representing surgical oncology, medical oncology and radiation oncology once a cancer care diagnosis has been made. Too often, referring physicians solely rely on previous experience in making referrals, which can lead to siloed care that does not recognize the latest techniques or advances in treatment and therefore does not result in the best care for the patient. When a patient is diagnosed with cancer, there should be a referral to a coordinated group of oncology specialists to ensure the patient not only has a variety of treatment options to select, but also, with the assistance of their treatment team, can choose the course of treatment that best aligns with their personal needs and leads to the best possible outcome.

Additionally, TCOC models must find ways to better align incentives that take into consideration the providers and costs involved in downstream services. For many existing models, these are usually the greatest generator of savings, yet the initiating provider gets all the risk and reward for participation,

whereas there is no risk or reward for the downstream provider. For instance, post-acute care spending accounts for 43% of a Comprehensive Joint Replacement episode, 30% of a BPCI COPD episode, and 23% of a Hospital Readmission Reduction episode[2]. The savings generated from each of these models is based on reducing the cost of these post-acute services. While the initiating provider, in these cases the hospital, has plenty of incentive to reduce cost, the providers associated with these services do not, thus creating misaligned incentives. This misalignment can potentially harm patient care, particularly in the most acute cases in which a downstream provider may believe that a patient warrants additional care and clinical interventions, but the initiating provider is more concerned about meeting a spending target.

ASTRO believes this demonstrates the need for more discrete bundles within broader TCOC models. As has been previously mentioned, the significant costs of cancer care must be considered based on modality of treatment to ensure that the various providers involved in care can ensure that the patient is getting the best treatment based on their diagnosis and has control over the cost of the therapy that he or she is delivering.

Benchmarks

The RO Model approach included a blend between national base rates and participant specific historical payments. The blend weighted historical payments at 90% and national base rates at 10%. While not perfect, it was a reasonable approach to bringing more expensive providers closer to the national mean. However, the policy fell short in several ways. First, it disadvantaged those radiation oncology practices that had already achieved high levels of efficiency because their historical rates were significantly lower than non-efficient providers. Additionally, the blend established a policy by which weights for inefficient practices would be modified over the five-year duration of the model, without giving consideration to appropriate use of more expensive modalities of treatment that automatically characterized a practice as inefficient due to their higher cost. This created a situation in which efficiency wasn't really based on high-quality, high-value care, but rather just on cost, which is inappropriate given the expense associated with cancer care.

Evaluation

CMS established the following evaluation and monitoring requirements associated with the RO Model:

1) discuss goals of care with each Medicare beneficiary before initiating treatment and communicate to the beneficiary whether the treatment intent is curative or palliative;

2) adhere to nationally recognized, evidence-based treatment guidelines when appropriate in treating Medicare beneficiaries or document in the medical record the rationale for the departure from these guidelines;

3) assess the Medicare beneficiaries' tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnosis;

[2] Westhead, Monica. "Influence Downstream Provider Behavior: Key strategies to achieve success in an era of risk." Advisory Board. Post Acute Collaborative. 2017.

4) assess the Medicare beneficiaries' performance status as a quantitative measure determined by the physician;

5) send a treatment summary to each Medicare beneficiary's referring physician within three months of the end of treatment to coordinate care;

6) discuss with each Medicare beneficiary prior to treatment delivery his or her inclusion in and cost-sharing responsibilities; and

7) perform and document Peer Review for 50 percent of new patients in performance year 1, 55 percent of new patients in performance year 2, 60 percent of new patients in performance year 3, 65 percent of patients in performance year 4, and 70 percent of patients in performance year 5, preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within two weeks of starting treatment.

ASTRO pointed out that unless these measures could be incorporated into an Electronic Health Record (EHR) system, they will require a significant commitment to manual input and additional staff resources to ensure compliance. We recommended a more simplified approach to these monitoring requirements by establishing an accreditation requirement as part of the RO Model. Accreditation standards include each of these components as part of the assessment. ASTRO's APEx standards identify systematic quality and safety approaches that build on and reinforce regulatory requirements to add value for practitioners and health care consumers. The ASTRO standards translate the goals outlined in the *Safety is No Accident* framework into objective, verifiable expectations for performance in radiation oncology practice[3].

As previously mentioned, incorporating this type of information into EHRs is really the most reasonable way to collect valuable clinical information without placing additional burden on practices. ASTRO is working closely with CodeX, a member driven HL7 FHIR accelerator to enable FHIR-based interoperability that will drive improvements for the most important challenges in patient healthcare. CodeX members are integrating and testing the mCODE (minimal Common Oncology Data Elements) FHIR implementation guide within use cases to create new workflows to support better cancer care. ASTRO has urged CMS to support standards development work like this for all of medicine, but mostly for specialties that are not covered by large initiatives that are frequently focused on primary care medicine. CMS should also provide funding opportunities for organizations that are working in this area to support data availability and liquidity throughout healthcare. This will allow for the seamless collection of data relevant to care coordination, patient safety and shared decision making.

Finally, we are concerned that one of the reasons CMS has failed to implement the RO Model is due to an overemphasis on model savings. We would argue that the shift to value-based payment should focus heavily on quality and practice transformation. As has been previously mentioned, the delivery of radiation therapy relies heavily on significant capital investments, there are limited variable costs from which to generate significant savings. However, there is a critical opportunity to improve the quality of

[3] *Safety is No Accident: A Framework for Quality Radiation Oncology Care*. American Society for Radiation Oncology. 2012.

care and achieve practice transformation, with subsequent incremental savings, through the adoption of shorter course treatments, which are guideline concordant.

Cost of Participation in Value Based Payment

Radiation oncology clinics are an example of a medical specialty in which the ratio of fixed costs far exceeds variable costs. The total capital required to open a single linear accelerator freestanding radiation oncology center is approximately $5.5 million, plus an additional $2 million in annual operating and personnel expenses. These significant fixed investments far outweigh the variable costs of operating a radiation oncology clinic and should be given consideration as part of any alternative payment model. While it is important to reduce the cost of care and drive value in healthcare, it is also important to ensure that efforts to generate savings do not cause financial hardship and access to care issues for those specialties with high fixed costs and the complex patients they treat. This is particularly important for practices operating in rural and underserved areas.

Radiation oncologists that provide care in rural communities or to underserved populations experience several challenges related to participation in any type of payment model, whether it be episode based or TCOC. Clinics in rural or underserved communities serve patients who are more likely to be covered by Medicare or Medicaid programs, rather than privately funded employer-based health plans. Due to this payer mix, this group of physicians typically has more limited financial resources than their peers in other areas. This makes it difficult to invest in the resources necessary to participate in value-based payment programs.

A lack of capital funding puts these practices at a disadvantage when it comes to investing in newer, more efficient technology, as well as the upgrades in EHR systems for quality measures reporting, both of which are necessary for successful participation. The limitation on financial resources also limits their ability to hire staff to perform the administrative services associated with participation. Frequently, in clinics that provide care to rural communities or medically underserved areas, the radiation oncologist wears more than just the physician's hat, they are also billing and claims adjudication professionals and practice administrators.

Strategies for Achieving Health Equity

Up until recently, very little attention has been paid to the impact of payment models on healthcare inequity. A recent Health Affairs article points to the fact that many of the existing policies are "color blind" and do not recognize the unequal social structures that exist. This puts providers who serve populations experiencing higher rates of healthcare inequity at greater risk for penalties associated with payment models[4].

A Mayo Clinic analysis of the RO Model indicated that practices caring for socioeconomically disadvantaged populations would face significant revenue reductions, resulting in access to care issues

[4] Yearby, Ruqaiijah; Clark, and Fiqueroa. "Structural Racism in Historical and Modern US Health Policy." Health Affairs. February 2022, 41:22 p. 187-194.

for the communities they serve.[5] According to the analysis, late-stage disease was historically reimbursed higher than the RO Model base rates. The result would be a dramatic reduction in reimbursement for practices that treat patients with advanced disease, which disproportionally impacts minority and rural populations.

Decades of research has demonstrated that minority and rural populations frequently present with advanced stage disease due to limited access to preventative services. African Americans (12.3%) and Hispanics (10.5%) present with clinically advanced-stage prostate cancer more frequently than whites (6.3%)[6]. Additionally, African American women are more likely than white women to receive a breast cancer diagnosis at an advanced stage of disease[7].

Frequently, patients with advanced stage disease receive palliative radiation therapy, which reduces pain and improves quality of life for patients with metastatic cancer. Despite this benefit, African American patients with prostate cancer are 20% less likely to receive palliative radiation therapy and, for colorectal cancer, 28% less likely to receive palliative radiation therapy when compared to white patients.[8] The RO Model could potentially exacerbate these disparities because the 90-day bundle only recognizes and reimburses for one disease site.[9] There is no recognition or payment adjustment in the model that accounts for patients with advanced stage cancer that will likely present with a primary diagnosis to one part of the anatomy that also requires treatment of metastatic disease that has spread to another part of the anatomy.

ASTRO's own analysis of the RO Model's National Base Rates for cervical cancer indicated a significant reduction in payment when compared to the cost of guideline concordant care. Studies have demonstrated that the rates of cervical cancer are almost 40% higher for African American women compared to white women, with a corresponding 61% increase in the mortality rate.[10],[11] The payment

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[10] Adams, Swann Arp et al. "Racial disparities in cervical cancer mortality in an African American and European American cohort in South Carolina." *Journal of the South Carolina Medical Association (1975)* vol. 105,7 (2009): 237-44.

[11] Thevenot, Laura. "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures – Proposed Rule Comment Letter." American Society for Radiation Oncology. September 16, 2019. https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/ASTRO-ROModelFinalCommentLetter.pdf

rate set by CMS did not recognize guideline concordant care, which is critical to patient survival rates.[12],[13]

In addition to limited access to preventative care resulting in advanced stage disease, minority populations also struggle with access to care once diagnosed. Preliminary analysis of Medicare data shows that minority patients are nearly 1/3 more likely than white patients to not even begin their radiation therapy treatments, despite having completed the treatment planning process. While it is unclear, we are exploring what prevents some minority patients from beginning radiation therapy treatment, evidence points to lack of transportation, lower socioeconomic status, lack of childcare, inability to take the necessary time off work, underinsured/uninsured, and limited social supports (housing, access to fresh food, etc.) as key barriers. By stripping resources from practices required to participate in the model, instead of capitalizing on the opportunity to address the social determinants of health leading to this gap, payment models run the risk of worsening disparities care.

ASTRO recommended that CMS consider the application of a Health Equity Achievement in Radiation Therapy (HEART) payment to provide wrap around services for patients who are at risk for experiencing social inequities that may prevent them from initiating or completing treatment. This concept is very similar to the Monthly Enhanced Oncology Services (MEOS) payment that is applied in the Oncology Care Model. HEART payments could support services, not currently billable, such as:

- Triage patient needs 24/7;
- Provide patient care navigation, including patient education and symptom management, as well as financial support;
- Assess and address patient's nutrition, transportation and lodging needs, personal support system and identify resources to address barriers to accessing treatment and compliance with treatment care plan;
- Coordination of care and communication of information following evaluation and treatment with other care providers engaged in the patient's treatment;
- Established care plan that contains 13 components of the Institute of Medicine Care Management Plan that is documented and reviewed during each patient visit; and
- Documented survivorship plan that are developed in coordination with the patient, as well as other care providers and issued upon completion of treatment.

Symptom management clinics or triage units established in oncology settings have proven to be successful at reducing costs and ensuring patients have access to resources that improve their quality of

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life during their treatment. These units are typically run by nurse care managers that meet with patients during regular clinic visits to assess symptoms associated with radiation therapy and provide guidance regarding self-management, as well as treatment follow up. A 2017 UNC Chapel Hill study demonstrated significant savings associated with the implementation of a symptom management program leading to reduced unnecessary emergency department visits and inpatient admissions[14]. Programs such as this are currently not reimbursable -- and therefore difficult for smaller practices to establish -- yet have a significant impact on the patient's quality of life and the cost of care.

Radiation oncologists typically report that transportation barriers disproportionately impact underserved populations, leading to interrupted and incomplete treatments that lower outcomes. It is possible that RO Model participants would need waivers from Medicare to provide transportation services to eligible patients, with protections against abuse similar to the safe harbor for local transportation for rural beneficiaries issued by the HHS OIG[15].

Data associated with those episodes with a HEART payment could be collected and used to determine the effectiveness of HEART interventions. By learning more about what causes these disparities and understanding what interventions are most effective and are closing gaps, the model could test measures to ensure participants are accountable for reducing disparities. Over time, measures could potentially involve treatment refusals, interruptions, and completion of the RT episode of care, and duration of treatments.

ASTRO appreciates the opportunity to comment on the PTAC RFP. We look forward to continued dialogue with PTAC regarding opportunities to achieve improved care integration through the establishment of TCOC payment models that allow discrete episodes of care that are focused on health equity, quality and of high value. If the Committee has any questions, please contact Anne Hubbard, Director of Health Policy at 703-839-7394 or Anne.Hubbard@ASTRO.org.

Sincerely,

Laura I. Thevenot
Chief Executive Officer

Laura Dawson, MD
Chair of the Board of Directors

[14] Chera, Bhishamjit S., Reducing Emergency Room Visits and Unplanned Admissions in Patients with Head and Neck Cancer, University of North Carolina Cancer Hospital Lineberger Comprehensive Cancer Center, Clinical Journal of Oncology Nursing – June 2017.

[15] https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the