

Improving Care Delivery and Integrating Specialty Care in Population-Based Models Request for Input (RFI) Responses

On March 3, 2023, the Physician Focused Payment Model Technical Advisory Committee (PTAC) requested input from the public on information that could describe current perspectives on specialty integration in population based total cost of care (TCOC) models and PFPMs. PTAC received nine responses from the following stakeholders that are listed below in the order in which their responses were received:

1. [Oncology Nursing Society \(ONS\)](#)
2. [Healthcare Transformation Task Force](#)
3. [American Society of Retina Specialists \(ASRS\)](#)
4. [Alliance of Specialty Medicine](#)
5. [National Association of ACOs \(NAACOS\)](#)
6. [American Society for Radiation Oncology \(ASTRO\)](#)
7. [American College of Emergency Physicians \(ACEP\)](#)
8. [American Medical Association \(AMA\)](#)
9. [American Vein & Lymphatic Society \(AVLS\)](#)

For additional information about PTAC's request, see [PTAC's solicitation of public input](#).

From: Emily Graham <egraham@hhs.com>
Sent: Wednesday, March 29, 2023 8:02 AM
To: PTAC (OS/ASPE) <PTAC@hhs.gov>
Cc: Alec Stone <astone@ons.org>
Subject: Comments from ONS on PTACs Specialty Integration RFI

Good morning,

Please find attached comments from the Oncology Nursing Society (ONS) on PTAC's Improving Care Delivery and Integrating Specialty Care in Population-Based Models Request for Input. Thank you for considering this feedback as you prepare feedback for the Secretary of HHS. Should you have any questions, please let us know.

Best,

Emily

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March 29, 2023

Miranda Lynch-Smith
Deputy Assistance Secretary, Office of Human Services Policy
Assistant Secretary for Planning and Evaluation, Room 415F
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201
Submitted electronically via: PTAC@HHS.gov

RE: Improving Care Delivery and Integrating Specialty Care in Population-Based Models Request for Input (RFI)

Dear Ms. Lynch-Smith,

The Oncology Nursing Society (ONS) appreciates the opportunity to provide feedback to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) on its aforementioned RFI.

General Comments

We are concerned that PTAC's model evaluation process – including its *Quality and Cost* and *Integration and Care Coordination* criteria – does not meaningfully factor in the role of nurses, including advanced practice registered nurses (APRNs). As PTAC is requesting information on specialty integration in population-based models – models that are likely to include patients with cancer or a history of cancer – the role of oncology nurses must be substantively considered.

Specialty Designation for Advance Practice Registered Nurses (APRNs)

ONS remains concerned that all APRNs are “lumped” into a single “specialty,” which hinders appropriate attribution of quality and resource use to specialized nurse practitioners, including oncology nurses, delivering care to Medicare beneficiaries. As a result, it is difficult to achieve the desired characteristics of population-based models as outlined in the RFI, namely the following:

- *Primary and specialty care provider roles and responsibilities are clearly delineated throughout the care journey for a given condition or episode of care.*
- *Specialist care includes a continuum of responsibilities for a patient or condition, including, but not limited to, single consultation, co-management, and primary management.*
- *Primary and specialty care providers coordinate to provide patient-centered care using bidirectional, synchronous, and asynchronous communication.*
- *Specialists provide consultations and/or ongoing care via multiple modes in a timely manner.*

Without specialty designations for APRNs, distinguishing the pivotal role oncology nurses play in delivering comprehensive care to Medicare beneficiaries receiving care in population-based models challenging. Beyond population-based models, the lack of specialty designation for APRNs limits the availability of

objective Medicare claims and other administrative data, thus preventing ONS and other public and private stakeholders from conducting important analysis on the impact of oncology nurses on cancer care. This does the Medicare program, its beneficiaries, and the oncology nursing profession, a great disservice. Robust analysis and evaluations, including comparisons to other provider types, is essential for oncology nurses to continue raising the bar and improving cancer care and outcomes, especially in the context of value-based models.

We urge PTAC to include a recommendation that CMS develop specialty designation codes that APRNs can self-select upon enrollment in the Medicare program as part of its report to the Secretary.

We appreciate the opportunity to comment on this proposed rule. ONS looks forward to continuing dialogue on these important issues. If you have any questions about our comments, please contact Alec Stone, MA, MPA, ONS Director of Health Policy, at astone@ons.org.

Sincerely,

The Oncology Nursing Society

About ONS

The Oncology Nursing Society (ONS) is a professional organization of over 39,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.

From: Joshua Traylor <Joshua.Traylor@hcttf.org>
Sent: Wednesday, March 29, 2023 9:39 PM
To: [PTAC \(OS/ASPE\) <PTAC@hhs.gov>](mailto:PTAC(OS/ASPE)<PTAC@hhs.gov>)
Cc: Jeff Micklos <Jeff.micklos@hcttf.org>
Subject: Public Comment - Improving Care Delivery and Integrating Specialty Care in Population-Based Models RFI

Dear PTAC members,

I am writing on behalf of the Health Care Transformation Task Force (HCTTF) in response to your Request for Information (RFI) titled Improving Care Delivery and Integrating Specialty Care in Population-Based Models. Please find attached the letter that HCTTF submitted to CMMI on this topic.

Our letter provides feedback on several of the topics raised in the RFI, including strategies for promoting cross-model alignment, criteria for addressing overlap and attribution issues, and recommendations for payment policies to encourage specialist engagement, either as participants in total cost of care (TCOC) models or by nesting specialty-focused models within TCOC models. We hope you find this useful as you prepare for your discussion of this topic at upcoming meetings.

As you review this paper, please keep in mind that the Task Force is continuing to work with our members to further refine these recommendations and identify additional ways to promote innovative and effective ways to integrate specialty and population-based models. We will pass along additional resources on this issue as they become available.

Thank you for considering our submission. If you have any questions or require further information, please do not hesitate to contact us.

Sincerely,
Joshua Traylor

Health Care Transformation Task Force

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Partners in promoting value



April 5, 2022

VIA ELECTRONIC MAIL

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Re: APM Alignment Recommendations

Dear Directors Seshamani and Fowler:

The Health Care Transformation Task Force (HCTTF or Task Force¹) writes to offer recommendations for how the Center for Medicare & Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI) can advance the goal of streamlining the alternative payment model (APM) portfolio. A recent [study](#) found that the mean number of specialist visits for Medicare beneficiaries has increased 20 percent between 2009 and 2019, with 30 percent of beneficiaries seeing five or more specialists per year. Given the increasing role of specialists in caring for the Medicare population, it is imperative that CMS devise a way to align APM designs to promote better coordination between primary care providers (PCPs) and specialists to effectively deliver high quality and cost-effective care.

The model overlap policies CMMI has implemented to avoid duplicate shared savings payments have resulted in unintended consequences, including confusion over which provider has responsibility for managing the financial risk of a patient, limited incentives for effective care coordination, and diminished opportunities for financial savings for both the Medicare Trust Fund

¹ Founded in 2014, the Task Force is an industry consortium representing a diverse set of health care stakeholders – including providers, payers, purchasers, and patient advocacy organizations – all committed to adopting payment reforms that encourage health care organizations to move from a system that incentivizes the volume of services to one that rewards the value of care delivered. The Task Force strives to provide a critical mass of policy, operational, and technical support from the private sector that, when combined with the work being done by the CMS and others, can increase the pace of delivery system transformation.

and providers. Our recommendations focus on defining the barriers to improving alignment between primary care and specialty focused models and offering a strategy for promoting alignment through the design of future models.

EXECUTIVE SUMMARY

The comments offered in this letter reflect our desire to support CMMI's effort to meet the vision offered in the CMMI's Strategy Refresh. Our recommendations for advancing APM alignment efforts are organized into four main areas: barriers to APM alignment, design elements for future APMs, cross model alignment strategies, and approaches for promoting equity. Key points from these sections are summarized below.

1. **Addressing Barriers:** There are a number of actions that CMS can take to address structural barriers in the current APM landscape that interfere with alignment efforts. These include:
 - Addressing unnecessary complexity caused by overlapping model timelines by aligning new model launch schedules and application requirements so participants can compare APM opportunities side-by-side.
 - Allowing model participants greater flexibility to create high quality provider networks by extending the TIN-NPI participant selection approach to MSSP and future APMs.
 - Creating aligned incentives for quality improvement across model types by collaborating with stakeholders and using existing measure sets to develop outcome-oriented measure sets that can apply to primary care and specialist models. The quality measurement strategy should balance efforts to minimize provider reporting burden with the goal of selecting clinically meaningful and actionable measures.

2. **Future Model Design Elements:** Task Force members identified several elements of model design that CMS should consider as it refines the APM portfolio and develops new models within CMMI. These include:
 - Designing benchmarking methodologies that align across models and establish clear incentives for population-based model participants and bundled payment providers to partner. In the event that this alignment cannot be achieved, CMS should limit the potential for the benchmarks it set in one model to harm the financial performance of participants in another model.
 - Gaining broad and sustainable model adoption among a critical mass of providers with the goal of improving quality while achieving predictable and sustainable health care cost growth. To accomplish this CMS should provider on-ramps for providers new to APMs, create benchmarking options that address the ratcheting effect to reward and retain efficient providers, and explore options for alternative benchmarking approaches that do not rely on current FFS spending to promote long term sustainability.
 - Playing an active role in the design and operation of models targeting specific service lines and conditions. These efforts should focus on two areas: 1) procedural episodes where a beneficiary has a time limited relationship with a provider to address a specific issue, and 2) Chronic Condition-Specific Models built around a limited set of chronic health conditions where specialists play a predominant role in managing care longitudinally or for discrete periods of time as the condition is in an acute phase.

3. **Strategies for Cross-Model Alignment:** HCTTF recommends that CMS pursue a hierarchical model alignment strategy. This strategy should set a clear, consistent, and predictable beneficiary attribution policy supported by financial arrangements that: 1) allows providers delivering complimentary care to mutually benefit under their respective models, and 2) strives to minimize cross-model gaming opportunities that drive adverse incentives such as participant selection bias or freeriding. To do this we recommend that CMS:
- Allow high-risk ACOs the flexibility to either:
 - i. Participate in bundled payment models designed and operated by CMS. Under this option the ACO would identify a set of bundled payment arrangements and a list of participating specialists for CMS to apply the bundled payment arrangement to. The ACO would retain beneficiary attribution, CMS would make direct payments to providers under the bundled payment model, and all bundled payment spending would be reconciled against the ACO TCOC benchmark.
 - ii. Opt-out of CMS designed bundles. Under this option ACO aligned beneficiaries would not be eligible for any other payment models. Instead, ACOs may choose to contract directly with specialists, receive funds from CMS, and manage downstream payments. ACOs would have the latitude to design these contracts and would retain responsibility for TCOC. ACOs would also have the discretion to not enter into any downstream contracts.
 - Establish model alignment policies for low and moderate risk ACOs that preferences models based on the nature of the clinical condition covered by the model and the degree of responsibility the provider is accepting for beneficiary care coordination, cost, and quality. Under this policy, beneficiary attribution would work as follows:
 - When a beneficiary with a chronic condition receives care under both a low or moderate risk ACO and a relevant chronic-condition model, alignment preference would go to the chronic condition model provider when the specialist serves as the central coordinating point of care for beneficiaries (such as ESRD) and is willing to accept greater risk for the total cost of care and quality.
 - When a beneficiary is receiving care from a low or moderate risk ACO model and receiving treatment from a provider participating in a procedural episode, beneficiary alignment would remain with the ACO model.
 - When a beneficiary is not receiving care from any ACO provider but is receiving care from a provider in another APM, then attribution would default to the other APM (with chronic-condition models taking precedence over procedural episodes).
 - Leverage model participation requirements to promote alignment by requiring applicants to chronic-condition models and procedural episodes to have explicit contractual relationships, defined referral pathways, and clear coordination plans with primary care providers in population-based APMs.

4. **Advancing Equity:** HCTTF fully supports the emphasis on health equity that CMS has placed at the core of new payment model design efforts. We urge CMMI to continue leveraging a multi-faceted approach to incorporating equity considerations into models. This should include:
- Participant requirements for formal health equity plans.
 - Benchmarking and risk adjustment strategies that account for beneficiary and community level equity and are designed for providers working in underserved communities.
 - Demographic data collection standards and quality measurement strategies that encourage the closing of health equity gaps.

DETAILED COMMENTS

HCTTF member organizations have considerable experience with CMS-designed APMs and believe these models are critical for improving quality and reducing health care costs. The Task Force has consistently supported CMS efforts to develop advanced risk models that promote accountability for spending and outcomes for Medicare beneficiaries. We appreciate CMS' vision for accountable healthcare as set forth in the [CMMI Strategy Refresh](#). The goal of having all Medicare fee-for-service beneficiaries in an accountable care relationship by 2030 sends a clear signal to stakeholders about the future direction of delivery system reform. To achieve this goal, CMS will need to expand opportunities for APM participation and implement models that drive alignment between primary care providers and specialists. The comments offered in this letter reflect our desire to support CMMI's effort to meet the vision offered in the Strategy Refresh.

A. Barriers to APM Alignment

HCTTF members identified several barriers that hamper the ability to drive alignment between primary care and specialists. While we focus on issues that are within the purview of CMS to address, we also note key barriers that require Congressional action. We mention these broader issues to offer a more holistic view of our members' experiences and perspectives.

1. Misaligned Model Timelines

HCTTF has previously commented on the considerable time and resource investments providers and organizations make evaluating and participating in CMS APMs. These challenges are compounded by the fact that many Medicare APMs operate on independent timelines for model applications and key elements of model operations such as provider list submissions and financial reconciliation. Misaligned model timelines unnecessarily complicate APM participation and increase the likelihood that participants will default to the fee-for-service (FFS) status quo rather than taking on new models. **To address these issues, CMS should align new model launch schedules and application requirements so participants can compare APM opportunities side-by-side. CMS should simplify the application and operational timelines for ACOs by leveraging the Medicare Shared Savings Program (MSSP) as a standard operating platform for aligning all future ACO models.** The Task Force detailed this concept in a [letter](#) to CMS on strategies for improving MSSP.

2. TIN Only Provider Selection

MSSP requires that accountable care organization (ACOs) be defined by their Medicare billing tax identification number (TIN). In contrast, CMMI models have allowed ACOs to define

participating providers using a combination of TIN and national provider identifier (NPI). TIN-only selection limits ACOs to including all specialist providers within a TIN regardless of how well they align with the care delivery priorities of the ACO.

With TIN-only provider selection, ACOs are more likely to exclude entire specialist provider groups, and even multi-specialty groups that include primary care providers, due to the potential impact of the specialists on their underlying model performance. This also creates an incentive for TIN-splitting, creating new separate TINs for primary care and specialists, which adds an unnecessary administrative burden for providers and CMS. The Pioneer and Next Generation ACO models allowed ACOs to use a TIN-NPI combination to identify providers which enabled them to create more focused high-performing provider networks. **We recommend that CMS extend the TIN-NPI participation approach to MSSP and future APMs to allow greater flexibility for engaging high quality specialists.**

3. Lack of Shared Accountability in Quality Measurement

Reliable and valid accountability measures that align quality and financial performance are central to APM expansion and the incorporation of specialists. While we appreciate past efforts to streamline the total number of performance measures, the resulting measure sets are often so narrow they exclude specialty providers. This further disincentivizes specialist participation in APMs because their work cannot be clearly tied to representative quality measures that reflect their specialty (e.g., functional outcomes for patients who undergo orthopedic surgery). **The Task Force recommends CMS collaborate with stakeholders and use existing measure sets to develop systems based on outcome-oriented measures.** This refined measure strategy should include domains focused on improving care delivery, improving health, and lowering costs while avoiding excessive process-based measures that increase provider burden. CMS should also make focused efforts to align measures across payers. Inclusion of patient-reported outcome measures (PROMs) with lessons learned from Blue Cross and Blue Shield of Massachusetts (BCBSMA) in their systematic adoption of PROMs can aid in the shift to person centered care.

4. Current Model Overlap Policies

Task Force Members identified clarity with respect to patient attribution as a significant barrier to model alignment. Current CMS model overlap policies often preclude a beneficiary from being aligned to more than one model at a time. While this is an effective strategy to prevent duplicate shared savings payments, these policies create clear financial disincentives for coordination across providers when such coordination could result in one provider losing attribution. The complexity of model overlap policies negatively impacts a healthcare organization's ability to prioritize care redesign efforts and dilutes potential impacts on the quality and cost of care. In the future model design section below, we offer recommendations for designing models intended to minimize overlap issues and maximize the potential for alignment between primary care providers and specialists.

5. APM Alignment Barriers Requiring Congressional Action

The bullets below highlight key barriers to APM alignment that generally require Congressional action to address. We highlight where we believe there is opportunity for CMS to take actions alongside Congress to help address these issues.

- **Fee-For-Service to APM Payment Policy Transition:** HCTTF believes that efforts to expand APM opportunities should be paired with actions that make APMs a more

attractive option for providers. Changing the current Medicare fee schedule is critical to incentivizing provider participation in APMs and increasing the number of Medicare beneficiaries in accountable care relationships. To date, specialist participation in ACOs has been low. The Task Force believes the low participation rates are due to a combination of APM model design issues highlighted throughout this letter and insufficient pressure on the fee-for-service (FFS) environment to spur change. We have urged Congress to build on the policies in MACRA to create long-term momentum to transition to APMs. **The Task Force also calls upon CMS to leverage its regulatory authority over FFS policies and the MIPS program to align future FFS policy changes with the long-term goal of incentivizing APM adoption.**

It is important that these FFS adjustments be paired with increased APM opportunities for specialists and primary care providers, reasonable timelines for these providers to successfully transition into APMs, and strong incentives for accepting greater accountability for cost and quality. The increasing complexity of new APMs favors well-resourced providers with capacity to accept risk over providers with fewer resources or prior experience with APMs. While several market solutions exist to help aggregate physicians and enable their success in performance-based risk models, we acknowledge that the APM movement is still leaving behind a cohort of providers and the beneficiaries they serve.

CMS can play a key role in addressing this issue by expanding access to existing models and reviving earlier model concepts that provided an on-ramp for providers interested in adopting APMs. **Specifically, we recommend that CMS encourage broader participation in MSSP as the largest permanent APM program in the country.** HCTTF offered several recommendations to improve MSSP in an earlier [comment letter](#) submitted to CMS. **We also encourage CMS to create targeted model opportunities for regions that lack APM availability and providers that have historically faced major headwinds in APM participation.** These models should: 1) support for providers that lack the capital to invest in the necessary infrastructure to form and operate ACOs (e.g., a new version of the CMMI ACO Investment Model), and 2) offer primary care providers without APM experience technical assistance and opportunities to engage in care transformation while gaining experience by accepting a more manageable level of risk.

- **MACRA (AAPM Incentive and Qualified Participant Threshold):** The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created incentives for providers to transition to APMs. Under the Advanced Alternative Payment Models (AAPM) track, MACRA offers a five percent incentive payment, in addition to the normal Medicare payments providers receive through their AAPM and exempts these providers from otherwise applicable reporting requirements. This policy appropriately incentivizes providers to accept greater accountability of care and higher levels of risk. However, the five percent bonus effectively expires with the 2022 performance year, and its lack of availability in future years is likely to have a detrimental impact on the desire of both PCPs and specialists to engage in AAPMs. Task Force members have cited the incentive payments as a key part of their recruitment efforts for both bundled payment models and ACOs and are concerned about the implications if Congress does not extend this bonus payment. **HCTTF has called upon Congress to extend the incentive payment to**

keep up momentum on value-based transformation, and we strongly urge CMS to join us in supporting efforts to extend the availability of the AAPM bonus.

Another barrier to AAPM adoption and alignment is the current Qualifying APM Participant (QP) threshold policy physicians must meet to receive AAPM incentive payments. Our members note that the current QP threshold is too high, creating a disincentive for ACOs to recruit specialists who often see patients referred from non-APM providers struggling to meet the QP threshold requirements. ACOs working to maintain performance in an AAPM are more likely to drop specialists as the QP threshold becomes more difficult to meet. Additionally, ACOs would benefit from greater transparency than is currently available regarding the QP Threshold and AAPM bonus. Specifically, ACOs need the ability to verify who of their participating providers met the QP threshold and earned the AAPM bonus. **The Task Force supports a call for Congress to take action to address the QP threshold as proposed in the Value in Health Care Act. Specifically, that CMS should be granted the authority to set the thresholds providers must meet to qualify for bonus payments under the AAPM.**

B. Future Model Design Recommendations

The Task Force agrees with recent CMMI remarks signaling a preference for population-based models to function as the core chassis for patient alignment, although we note there are cases where this will not be feasible. We recommend that CMS continue to refine a targeted set of bundled payment arrangements and implement a hierarchical model strategy to promote the nesting of specialty care models within population-based total cost of care (TCOC) models. Properly designed, this approach would create strong incentives for improved coordination between primary care providers and specialists and encourage more ACOs to take on greater levels of accountability to better manage risk. Our recommendations are divided into two broad areas: (1) design elements for future bundled payment and population-based payment models, and (2) strategies for alignment across models based on the relationship between the Medicare beneficiary and the provider – i.e., beneficiaries aligned to high-risk ACO models vs. beneficiaries aligned to low or moderate risk ACO models.

1. Design Elements for Future Models

HCTTF believes CMS should continue to play an active role in designing specialist focused bundled payment arrangements informed by collaboration with specialty specific stakeholder representatives. As discussed below, CMMI-designed bundled payment models will play a key role in a hierarchical alignment strategy and will be necessary in cases where no provider has TCOC accountability for a beneficiary. CMMI's ability to design, test, and evaluate models is critical to informing further refinement of APMs and offers a framework that less sophisticated organizations participating in population-based TCOC models could use to guide their efforts to contract with specialists.

Furthermore, without sufficient APM options to engage specialists, it will be challenging to achieve CMMI's goal of having all Medicare beneficiaries in an accountable care relationship by 2030. There are several conditions where a specialist or team of specialists play a predominant role in managing a patient's care, such as end stage renal disease or cancer care – which may involve a surgeon, medical oncologist and radiation oncologist. In the event that a specialist is not contracted with an ACO, CMMI has an interest in designing APMs focused on these providers and

beneficiaries. CMMI should consider the following elements when designing future bundled payment and population-based models:

- **Benchmarking Alignment:** Addressing the misalignment of benchmarking methodologies between ACO and bundled payment models is a critical prerequisite for successful model alignment. Model design and efforts to avoid double-counting of shared savings payments can create headwinds or tailwinds for one APM participant or the other, and potentially adverse incentives such as participant selection bias, risk selection, or gaming opportunity. For example, when beneficiaries overlap, episode target prices set based on regional averages could serve as a disincentive for ACOs already performing better than their region, while the episode provider may receive an outsized benefit from the ACO's prior improvement efforts. In short, HCTTF members have highlighted the challenges posed by bundled payment model benchmarks that are set too high – or alternatively ACO benchmarks that are set too low – to allow for mutually successful partnerships.

To address this challenge CMS should co-design benchmarking methodologies across models with a focus on setting payment levels at a point where population-based model participants and bundled payment providers have a clear financial incentive to partner. The goal of this approach should be to encourage appropriate referrals so primary care providers and specialists are delivering the right care, in the right setting, and at the right time to promote efficiency and quality. The Task Force recognizes how challenging it is to set appropriate benchmarks. In the event that CMS is unable to successfully address the pricing misalignment across ACOs and bundled payment model benchmarks, we encourage CMS to establish policies to limit the financial harm to ACOs. This could include benchmark exclusion or stop-loss criteria that would limit the financial risk an ACO is exposed to as the result of benchmark price misalignment.

- **Benchmark Adjustments:** The Task Force recognizes CMS has an interest in adjusting models to reflect changing market trends. The approach to accomplishing this has typically relied on annual adjustments that rebase the model benchmark to account for broader changes in utilization and costs. Task Force members, The Medicare Payment Advisory Commission (MedPAC), and independent researchers have all identified benchmarking and frequent rebasing as a disincentive to long term model participation because it creates a ratcheting effect on benchmarks making them increasingly difficult to meet. This strategy can also hamper investment in and utilization of beneficial advancements in technology because benchmarking methodologies do not adjust for the cost of these types of investments.

At this stage in the evolution of APMs, we believe CMS should focus on gaining broad and sustainable model adoption among a critical mass of providers with the goal of improving quality while achieving predictable and sustainable health care cost growth. To do this, we recommend that CMS:

- A. **Create a sustainable on-ramp for providers entering models.** To succeed in APMs, organizations must invest in care delivery reforms and technology to manage risk while keeping providers engaged in the model concept. This requires resources and time to develop. We support the approach CMS has used in some recent models (including ACO REACH) to maintain fixed baseline years and eliminate rebasing. We recommend that CMS continue this approach

for future models. If CMS determines that rebasing is essential to the design of a model, we recommend eliminating rebasing at least in the initial years of a model (example: years 1-3 of a five-year model) and holding benchmark adjustments to later model years (years 4-5 of a five-year model) to offer participants greater predictability in benchmarking and avoid penalizing participants for early success.

- B. **Reward and retain efficient providers.** Historical benchmarking methodologies create a long-term structural disadvantage for experienced and efficient APM providers and disincentivizes maximizing efficiency. To address this, CMS should shift providers that deliver high-quality, cost-effective care to a regional benchmarking methodology. The beneficiaries assigned to these providers would need to be excluded from the regional benchmark calculation to ensure the efficient providers are not penalized for the savings they achieve for their assigned populations.
- C. **Transition to predictable and sustainable benchmarks.** We believe a key long-term goal of APM reform efforts should be achieving health care spending growth that is predictable and sustainable for payers, providers, and patients. Both historical and regional benchmarking as a basis for shared savings models will become increasingly untenable if efforts to transition the majority of the health care system to APMs are successful. While this issue is not a central concern at the moment, we believe CMS should start preparing for this eventuality. Specifically, we urge CMS to explore options for designing and testing alternative benchmarking approaches that do not rely on current FFS spending. This could include the exploration of administratively set benchmarking strategies as raised in recent MedPAC committee discussions.

These proposals would allow participants additional flexibility to invest in the people, technology, and equipment necessary to achieve greater efficiencies and improved patient outcomes and would provide incentives to remain in models for the long term. Implementing these strategies might result in CMS forgoing some potential savings at the level of individual model participants but we believe this would be offset by transitioning a wider range of participants into models and increasing the number and retention rate of efficient providers.

- **Cross-Model Quality Measures:** As noted in the Barriers to APM Alignment section above, quality measures are an important lever for driving coordination across provider types. **CMS should focus on balancing efforts to minimize provider reporting burden with the selection of clinically meaningful and actionable measures.** One explicit goal of this quality measurement strategy should be to promote measure sets that encourage shared accountability across primary care providers and specialists to create incentives for partnership and efficient referrals.

CMS should engage in continued public-private partnerships to develop and align performance measures leveraging existing collaboration including the Core Quality Measures Collaborative (CQMC) or the Measure Applications Partnership (MAP). Specialty providers should be included throughout the measure development process. Finally, while continuing to create and pressure test the next generation of

performance measures, the multitude of data infrastructure challenges that limit the success and scalability of these measures should be addressed.

Finally, Health IT interoperability – or lack thereof – is a significant factor in the feasibility of quality measure alignment. **CMS should collaborate with the Office of the National Coordinator of Health IT (ONC) to strengthen certified EHR technology.** Specifically, CMS and ONC should focus on ensuring EHRs are equipped with the appropriate level of quality measure specifications, data validation requirements, and active data dashboards needed for aligned quality reporting that is valid, reliable, and mitigates reporting burden and costs for providers and APM entities.

- **CMS Role in Episode-Based and Condition-Specific Models:** As noted earlier, we believe CMS should continue playing an active role in the design and operation of models targeting specific service lines and conditions. Whenever possible, these models should be nested within more comprehensive models – as we detail in the following section – to ensure chronically ill beneficiaries receive coordinated and person-centered care. In addition to further refining ACO models, we recommend CMS leverage the lessons learned from the past decade of model design alongside knowledge from APM stakeholders to develop models focused on two areas:
 - A. **Procedural Episodes:** Episodic models built around procedures with variable cost and quality outcomes that are amenable to bundled payment arrangements. These bundled payment arrangements would focus on procedures (e.g., total hip/knee arthroplasty, spinal fusion, stroke/transient ischemic attack) where a beneficiary has a time limited relationship with a provider to address a specific issue. The bundle’s principal goal would be to improve quality and address unexplained variations in cost, and efficiency. Participants in these models would be responsible for managing costs and quality within the bundle – or total cost of care for that patient for the duration of the episode – but would not be eligible to serve as accountable entities for overall beneficiary care.
 - B. **Chronic Condition-Specific Models:** Payment models built around a limited set of chronic health conditions where specialists play a predominant role in managing care longitudinally or for discrete periods of time as the condition is in an acute phase. If a beneficiary is not aligned to a high-risk ACO model, providers in these condition-specific models would be eligible to serve as the accountable entity for beneficiary costs and quality. This concept is discussed in more detail below in the Alignment Across Models section below.

HCTTF recognizes that there are conditions that do not fit neatly into either of these categories. For some conditions, the nature of the beneficiary and provider relationship – time-limited or longitudinal – can only be determined after the initiation of treatment. Cancer care is a good example of this challenge. For these cases, we urge CMMI to:

- Continue engaging with stakeholders to inform approaches to developing effective payment models that recognize the distinct – and often complimentary – components of cancer treatment: surgery, medical oncology, and radiation oncology, and

- Explore alternative APM strategies for improving quality and controlling costs for these conditions such as the [Cancer Care ACO](#) concept proposed by Third Way.

2. Alignment Across Models

HCTTF members highlighted CMMI model overlap policies that impact beneficiary attribution as the principal challenge for APM alignment. Current overlap policies – where one model participant may lose attribution when a beneficiary receives care from providers participating in another model – disincentivize cross-model partnership even when such partnerships make clinical sense. CMS should focus on setting a clear, consistent, and predictable beneficiary attribution policy supported by financial arrangements that: 1) allows providers delivering complimentary care to mutually benefit under their respective models, and 2) strives to minimize cross-model gaming opportunities that drive adverse incentives such as participant selection bias or freeriding.

The Task Force believes that CMS efforts to align ACOs and specialty focused bundled payment models should favor providers willing to accept greater levels of responsibility for the cost, quality, and coordination of a beneficiary’s care. To accomplish this, we urge CMS to implement a hierarchical model alignment policy using the following approach.

- **Beneficiaries Aligned to high-risk ACO Models (i.e., MSSP Track E, Enhanced Track, and ACO-REACH):** Under a hierarchical model arrangement, when a beneficiary is aligned to a high-risk ACO– such as those in MSSP Enhanced or ACO-REACH – that relationship would take precedence over any other payment model. The ACO would retain beneficiary attribution, and the responsibility for the cost of care would be reconciled under the ACO benchmark. **To encourage provider alignment, CMS should allow high-risk ACOs two options for engaging with specialists.**
 - **Option 1:** ACOs could elect to participate in bundled payment models designed and operated by CMS. In this scenario, the ACO would identify a set of bundled payment arrangements and a list of participating specialists for CMS to apply the bundled payment arrangement to. The ACO would retain beneficiary attribution, CMS would make direct payments to providers under the bundled payment model, and all bundled payment spending would be reconciled against the ACO TCOC benchmark.
 - **Option 2:** ACOs could opt-out of CMS designed episodes. ACO aligned beneficiaries would not be eligible for any other payment models. Instead, ACOs may choose to contract directly with specialists, receive funds from CMS, and manage downstream payments. ACOs would have the latitude to design these contracts giving them full flexibility to negotiate the details of the payment arrangement (e.g., electing to design bundled payment models or enter into sub capitation agreements). ACOs would also have the discretion to not enter into any downstream contracts.

Under both options, the ACO would keep responsibility for the TCOC of all attributed patients whether they received care from a specialist contracted with the ACO or an outside provider. This approach would allow more advanced ACOs to fully align specialists through contracting and support less advanced ACOs by allowing them to outsource the complexity of designing a custom model for specialists to CMS. ACOs would

have an incentive to coordinate care as the TCOC risk bearing entity and duplicate shared savings issues would be avoided by virtue of all beneficiary spending being reconciled against the ACO's TCOC benchmark under both options.

- **Beneficiaries Aligned to low and moderate risk ACO Models (i.e., MSSP Tracks A-D):** In situations where a beneficiary is receiving care from a provider under a low or moderate risk ACO model, CMS should advance APM alignment by establishing a model overlap policy that preferences models based on the nature of the clinical condition covered by the model and the degree of responsibility the provider is accepting for beneficiary care coordination, cost, and quality. The goal of this policy should be to limit the potential for gaming opportunities across models, align patients to providers best suited to address their clinical needs, encourage care coordination, and incentivize providers to transition to higher-risk arrangements over time. Under this policy, beneficiary attribution would work as follows:
 - **Beneficiary with Chronic Condition:** When a beneficiary with a chronic condition receives care under both a low or moderate risk ACO and a relevant chronic-condition model, alignment preference would go to the chronic condition model provider when the specialist serves as the central coordinating point of care for beneficiaries (such as ESRD) and is willing to accept greater risk for the total cost of care and quality. The goal of this policy would be to encourage specialists in chronic-condition models to take accountability for beneficiaries with conditions that could most benefit from their expertise. CMS would need to establish a threshold to preclude alignment of low-acuity beneficiaries to chronic-condition models due to on-off or intermittent consultations. Additionally, because beneficiaries often have multiple chronic conditions, CMS would need a process for determining the most appropriate accountable provider when a beneficiary could qualify for alignment to an ACO and multiple chronic-condition model.
 - **Beneficiary with Condition that Aligns to Procedural Episode:** When a beneficiary is receiving care from a low or moderate risk ACO model and receiving treatment from a provider participating in a procedure focused episode, beneficiary alignment would remain with the ACO model.
- **Beneficiaries not Aligned to any ACO:** When a beneficiary is not receiving care from any ACO provider but is receiving care from a provider in another APM, then attribution would default to the other APM (with chronic-condition models taking precedence over procedural episodes).

To further incentivize alignment across provider types, **CMMI could leverage model participation requirements by requiring applicants to chronic-condition models and procedural episodes to have explicit contractual relationships, defined referral pathways, and clear coordination plans with primary care providers in population-based APMs (unless no such providers exist within a specified geographic region).** These requirements in combination with the aligned quality measures and benchmarking methodologies mentioned above could be designed to: (1) encourage specialists to refer lower acuity patients to population-based models and (2) encourage population-based models to transition to higher-risk payment arrangements and accept greater accountability for the costs and quality of care for the beneficiaries they serve.

c. Advancing Health Equity

HCTTF fully supports the emphasis on health equity that CMS has placed at the core of new payment model design efforts. We commend CMMI's efforts to address this issue through the health equity plan requirements and benchmark adjustments in the new Accountable Care Organization Realizing Equity, Access, and Community Health (REACH) Model. In previous letters to CMS, the Task Force highlighted issues with APM design that negatively impact the ability of models to address equity and have offered recommendations to address them. Many of those recommendations are directly applicable to CMMI efforts to align APMs.

Specifically, we note that the providers most often caring for communities impacted by inequity (rural practices/hospitals, safety net practices/hospitals, critical access hospitals, federally qualified health centers, community clinics, and small practices) lack the investment resources and risk tolerance for most APMs. Additionally, current benchmarking approaches generally fail to adequately account for equity in that they rely to some degree on historic spending and utilization as a proxy for appropriate levels of care. This is not a realistic expectation for individuals and communities that are underserved by the health care system and further entrenches historic inequities.

We urge CMMI to continue leveraging a multi-faceted approach to advancing equity including: equity plan requirements, benchmarking strategies that adjust for beneficiary and community level equity, risk adjustment methodologies tailored to providers working in underserved communities, demographic data collection, and quality measurement strategies that encourage the closing of health equity gaps. These efforts must be grounded on the establishment of reasonable expectations for the cost of providing efficient and high-quality care in a manner that adjusts for the historic underinvestment in some communities and demographic groups. To improve equity in relation to APM alignment and specialist care, CMMI could target models to communities with shortages of primary care providers and specialists and develop measures to monitor equity issues in the treatment modalities that beneficiaries receive, patient experience, and outcomes.

D. Multi-Payer Alignment

Improving multi-payer alignment is critical to spreading and sustaining APM adoption. HCTTF is supportive of the HCP-LAN efforts to convene state collaboratives and view states as key players in alignment efforts. The Task Force Board has made this issue a priority for 2022. Several HCTTF members have experience engaging specialists in APMs and working to align specialists and primary care providers. This includes examples of APM arrangements implemented in coordination with [states](#), and [purchasers](#), as well as commercial payer efforts to address the issue of model overlaps and duplicate payments. We would welcome the opportunity to share lessons from our members and continue the dialogue on how to achieve alignment between CMS and private sector APM efforts.

The HCTTF is eager to work with CMS to achieve sustainable change in value-based payment and care delivery, a goal that requires alignment between the private and public sectors and engagement with payers, providers, purchasers, and patients. Please contact Joshua Traylor (Joshua.Traylor@hcttf.org | 202.556.0339) with any questions or comments on this letter.

Sincerely,

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Aetna, A CVS Health Company

Claire Mulhearn
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Sean Cavanaugh
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From: Allison Madson <allison.madson@asrs.org>

Sent: Wednesday, April 5, 2023 1:29 PM

To: PTAC (OS/ASPE) <PTAC@hhs.gov>

Subject: ASRS Response to Specialty Care in Population-Based Models RFI

Good afternoon,

Attached, please find a response to the Improving Care Delivery and Integrating Specialty Care in Population-Based Models Request for Input (RFI) from the American Society of Retina Specialists.

Please don't hesitate to contact me if you need additional information.

Thanks,

Allison

Allison Madson
Vice President of Health Policy
American Society of Retina Specialists
571-213-8578

April 7, 2023

Miranda Lynch-Smith
Deputy Assistant Secretary, Office of Human Services Policy (HSP)
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
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Submitted electronically via: PTAC@HHS.gov

RE: Improving Care Delivery and Integrating Specialty Care in Population-Based Models Request for Input (RFI)

Dear Ms. Lynch-Smith,

Thank you for the opportunity to provide input as the Physician-Focused Payment Model Technical Advisory Committee (PTAC) considers strategies to improve specialty participation in alternative payment models (APMs), such as population-based total cost of care models (PB-TOCs).

The American Society of Retina Specialists (ASRS) is the largest retina organization in the world, representing over 3,500 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

ASRS recommends PTAC focus on the following items:

- Address primary care-led models', such as accountable care organizations (ACOs), disincentive to include retina specialists due to the high cost of Part B drugs required to treat retinal diseases.
- Incentivize clinicians participating in models to refer patients to specialists and sub-specialists earlier in their treatment to ensure better clinical outcomes and more cost-effective care.
- Include specialty-specific quality measures in PB-TOCs.
- Address inequitable access minority and low-income populations have to retinal care to improve outcomes, particularly for diabetic eye disease.
- Incentivize health IT innovations to facilitate the exchange of electronic health data for patients in BP-TOCs.

BACKGROUND

Retina specialists are board-certified ophthalmologists who have completed an additional two-year fellowship in the surgical and medical management of vitreoretinal disease. They treat chronic retinal

diseases such as age-related macular degeneration (AMD), diabetic retinopathy, diabetic macular edema and retinal vein occlusion, which are among the most common causes of blindness in the United States. In addition, they provide surgical care to repair retinal detachments and tears, macular holes, and many other potentially-blinding conditions.

With the advent of anti-vascular endothelial growth factor (anti-VEGF) drugs in the last two decades, retina specialists have revolutionized care for patients with chronic disease. With regular intravitreal injections of anti-VEGF drugs, retina specialists are now slowing the progression of disease—and in many cases improving vision—in patients who would have otherwise gone completely blind.

But these treatments come with a cost. Bevacizumab (Avastin) is available off-label and must be repackaged for ocular use. While it is relatively inexpensive, most retina specialists and their patients find that FDA-approved treatments—such as aflibercept (Eylea), ranibizumab (Lucentis), and faricimab (Vabysmo)—lead to better outcomes, but are much more expensive. Newly available ranibizumab biosimilars are less expensive than the originator products, but still far more costly than repackaged Avastin. Given that a patient could require injections in both eyes every four to six weeks, treatment for retinal disease is a significant cost for the Medicare program.

Because of the high cost of these products—which is out of the physician’s control—retina specialists have not been able to join ACOs or other APMs in any significant number. APM entities that bear financial risk have not been willing to invite retina specialists in for fear of what the cost of the Part B drugs they use would do to their cost metrics. ASRS has even heard from retina practices who have been intimidated by local ACOs, of which they are not members, who threaten to withhold referrals to the practice if they use the higher-cost, FDA-approved treatments, rather than the cheaper repackaged Avastin.

Medicare Advantage and commercial plans have attempted to address the cost of chronic retinal disease treatment in the form of utilization management tactics, such as step therapy and prior authorization. Nearly all non-original Medicare patients with chronic retinal disease are currently forced to begin treatment with Avastin and “fail” with it before their plan will cover the FDA-approved treatments, including biosimilars. These short-sighted policies achieve limited savings for the plan in the very near-term, but inflict patients with treatments their retina specialist knows are not as effective, and often make them come back for more visits or more frequent treatments. Patients that are forced to wait for the physician’s originally prescribed treatment can have their vision worsen or experience complications. These policies are generally instituted across-the-board by pharmacists or physicians who lack expertise in the management of retinal diseases and offer very few opportunities for exceptions or appeals. Managing prior authorization and step therapy is also a labor-intensive task that generally requires retina specialists to employ several dedicated staff to work solely on obtaining them—injecting still more unnecessary costs into the healthcare system.

The intransigence of both existing APMs in the Medicare program, and of private payers requiring step therapy, to move away from their current stances has meant that the status quo prevails. There have been no large-scale efforts to improve care coordination for patients with chronic disease, such as diabetes, and no incentives for retina specialists to work toward new and innovative care delivery models.

Because of the barriers the cost of Part B drugs create in integrating retina specialists—and other specialists who directly administer drugs to beneficiaries—into APMs, PTAC should explore ways to exclude their cost from total cost of care models. This position to exclude drug costs is consistent with recommendations from the American Medical Association (AMA). Physicians do not set prices for drugs and other efforts, including price negotiation authorized under the Inflation Reduction Act, are underway to address their high costs. The cost of the drugs have nothing to do with the performance of the physician or the clinical outcomes of the patients. These models should look at whether care was provided in an efficient, clinically appropriate manner that ensures the beneficiary can remain functional and not need additional, avoidable care. In the case of retinal disease, patients should receive the most appropriate treatment that will prevent them from losing vision or suffering known co-morbidities, such as depression and falls.

RETINA-SPECIFIC QUALITY MEASURES

Another key factor that prevents retina specialists from being asked to join ACOs is the lack of quality measures relevant to retinal care. In an effort to reduce burden and maintain a “parsimonious” list of quality measures, the Medicare Shared Savings Program has drastically scaled back the number and variety of measures ACOs have to report. The diabetic eye exam measure was previously included in the measure set, but was removed several years ago. Since Medicare is not basing ACO scores on this or other measures relevant to retina specialists, there is no incentive for these entities to include retina specialists, or seek to improve outcomes for attributed beneficiaries who suffer from retinal disease.

ASRS acknowledges that simply adding more measures could be difficult. The society has worked for several years to develop new measures for the MIPS program and hopes they will be in use for 2024. However, it was a labor-intensive and expensive process to develop them and identifying reasonable clinical endpoints in chronic disease to create outcome measures was nearly impossible. Furthermore, including surgical outcome measures for retina may also be difficult because the volume of episodes—particularly limited to just Part B beneficiaries—may be too small to measure reliably.

To incorporate more specialty-specific measurement, PTAC could explore options such as limiting the scores to, or sub-scoring, only the practitioners who provide that type of care.

CARE-COORDINATION EFFORTS

Despite the lack of system-wide initiatives to innovate care delivery for retinal disease, ASRS and its members recognize the importance of working toward better outcomes and access for patients. Retina specialists recognize that their treatments can be burdensome for patients, requiring visits roughly every four to six weeks. The patient must also be accompanied by a family member or care-giver, who may need to miss work. Bearing this in mind, retina specialists are always seeking new options and researching new treatments, including longer lasting agents.

To complement that, ASRS is working with its coalition partners to facilitate better outcomes for patients. For example, ASRS has recently been engaged in a project led by the American Diabetes Association (ADA) to develop an “Eye Care Interprofessional Communication Protocol” to improve

communication among professionals involved in diabetes-related eye care. The goal is to adopt a protocol that assists the provider managing the patient's overall diabetic care to better understand and act on the information coming from the retina specialist about the care the patient received for his or her retinal disease. This project was conceived when it became clear that non-ophthalmic specialists, such as endocrinologists, had no knowledge of the way retina specialists documented the care they provided for patients and a new system was needed to keep all practitioners apprised of the care a patient was receiving.

While the communication protocol does not address payment through Medicare or other payers, it is indicative of the type of collaboration between clinicians APMs should be fostering. For models focused on chronic conditions—diabetes in particular—the absence of specialists that treat all co-morbidities and sequelae of the disease means that beneficiaries are losing out on potentially better outcomes and more efficient, less disjointed care.

FOCUSING ON EARLY INTERVENTION

With the goals of improving value and incentivizing care coordination, ASRS recommends that PTAC center its efforts to bring specialists into value-based models by examining how earlier intervention by specialists could improve outcomes and help control costs.

Continuing with the example of diabetic care, integrating retina specialists into models and involving them in diabetics' care early on could help identify eye disease sooner, prevent more serious complications such as diabetic macular edema (DME), and over time mean the patient does not need as intensive or costly care. An integrated approach between primary care physicians and retina specialists could ensure that these patients get regular, dilated eye exams. Retina specialists have intensive, relevant training that allows them to diagnose these conditions more accurately than other eye care professionals, and before a patient experiences any symptoms or vision loss. With that knowledge, they can customize the most cost-effective treatment that will have benefits to the patient's overall health.

ADDRESSING INEQUITABLE ACCESS

ASRS also recommends PTAC explore how current models, and the entities in them, are exacerbating existing limitations some populations experience in accessing specialty care. It is well-documented that patients with limited transportation access, or who live in rural areas, may have poor access to healthcare of any kind, including specialists. ACOs and other models that are incentivized to keep their provider networks lean, and to keep beneficiaries within that network, may inadvertently prevent the most vulnerable patients, who would benefit the most, from receiving care from specialists more familiar with their individual disease or needs.

Again, this is demonstrated with the need to expand care and early intervention for diabetic eye disease. For example, the higher rate of diabetes in the nation's Black, Hispanic and Indigenous populations compared to white patients is well-established. Correspondingly, racial minorities also suffer from

diabetic retinopathy at a higher rate than white patients.¹ Making matters worse, this population also is hindered by a lack of screening and less accessible and reliable transportation causing them to be less likely to see a retina specialist before the disease has progressed to a more severe state.²

A model focused on early screening could help identify those patients early on and get them the care they need. The flexibilities provided to APMs, and not available under original Medicare, could be useful in developing creative strategies for serving these patients. For example, transportation programs similar to ones used by some state Medicaid programs could help patients travel to see a retina specialist or other provider, and potentially eliminate the need to have an escort accompany them.

CONSIDERING HEALTH IT CHALLENGES

Ensuring all providers involved in a patient's care receive information in an easily accessible format is a major stumbling block toward not only reaching goals for value-based care, but in the existing clinical framework. ASRS applauds and supports the efforts CMS has undertaken in recent years to improve the interoperability of electronic healthcare information, but significant work is left to be done. For eye care specifically, there are no widely-used standards for the exchange of ocular health information.

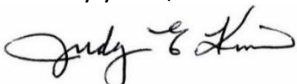
The flow of information between ophthalmologists, such as a cataract surgeon and a retina specialist caring for the same patient, is not seamless and often still involves faxing, downloading PDFs or relying on the patient to transfer the information. While ophthalmologists of two different sub-specialties are generally able to decipher each other's notes, as referenced above related to the diabetic eye disease protocol, that information is likely not well-understood by other non-ophthalmic specialists or providers. In addition, except for those in academic practices, most retina specialists are in small, private practices and use ophthalmic-specific EHR software, rather than hospital-based systems, such as Epic or Cerner.

ASRS recognizes that addressing these health IT issues is out of the purview of PTAC. However, we believe it is worth mentioning to demonstrate that the barriers to working toward value-based care can be as prosaic as these technical issues, as well as the overall mis-alignment of incentives across the healthcare system. However, models that are cognizant of these challenges and work toward overcoming them could contribute to better patient outcomes.

++++++

Thank you for this opportunity to provide feedback. Please contact Allison Madson, vice president of health policy, at allison.madson@asrs.org for assistance or if you have questions.

Sincerely yours,



Judy E. Kim, MD, FASRS
President

¹ Kaelber, DC. "A Descriptive Study of Diabetic Retinopathy Disparities among Millions of Patients." Association of Research in Vision and Ophthalmology Annual Meeting. May 2022.

² Barsegian, A. Boleoslav, K. Lee, J. Salifu, M. McFarlane, S. Diabetic Retinopathy: Focus on Minority Populations. Int J Clin Endocrinol Metab. 2017; 3(1): 034-045.

From: Emily Graham <egraham@hhs.com>

Sent: Friday, April 7, 2023 11:20 AM

To: PTAC (OS/ASPE) <PTAC@hhs.gov>

Subject: Comments from the Alliance of Specialty Medicine on PTACs Specialty Integration RFI

Good morning,

Please find attached comments from the Alliance of Specialty Medicine on PTAC's Improving Care Delivery and Integrating Specialty Care in Population-Based Models Request for Input. Thank you for considering this feedback as you prepare feedback for the Secretary of HHS. Should you have any questions, please let us know.

Best,

Emily

Emily L. Graham, MSHIM, RHIA, CCS-P

VP, Regulatory Affairs

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Sound Policy. Quality Care.

April 7, 2023

Miranda Lynch-Smith
Deputy Assistance Secretary, Office of Human Services Policy (HSP)
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201
Submitted electronically via: PTAC@HHS.gov

**RE: Improving Care Delivery and Integrating Specialty Care in Population-Based Models
Request for Input (RFI)**

Dear Ms. Lynch-Smith,

The Alliance of Specialty Medicine (the "Alliance"), representing more than 100,000 specialty physicians from sixteen specialty and subspecialty societies, is deeply committed to improving access to specialty medical care by advancing sound health policy. On behalf of the undersigned members, we write to provide feedback on the aforementioned request for input.

Background

Members of the Alliance have a long history of engaging the Physician-Focused Payment Model Technical Advisory Committee (PTAC) on the establishment of specialty-specific alternative payment models (APMs) that address recognized challenges in the delivery and cost of care for certain conditions and procedures. Unfortunately, none of the PTAC-recommended models from Alliance members have been approved by the Centers for Medicare and Medicaid Innovation (CMMI) as Advanced APMs for purposes of the Quality Payment Program (QPP).

In addition, Alliance members have also recommended that the Centers for Medicare and Medicaid Services (CMS) revise its regulations for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), and other ACO and population-based payment models, to enable more robust and meaningful participation by a broader range of specialists and subspecialists. Part of our recommendations included a request that CMS make data and information on specialty participation in ACOs publicly available. To date, the Agency has declined to adopt our recommendations (or consider them as part of annual rulemaking) to make specialty participation data and information available in the public domain. As a result, specialty societies do not have a full or clear understanding of the manner in which specialists currently engage in these models and the challenges they face.

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American Academy of Facial Plastic and Reconstructive Surgery • American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons • American College of Mohs Surgery • American College of Osteopathic Surgeons
American Gastroenterological Association • American Society for Dermatologic Surgery Association
American Society of Cataract & Refractive Surgery • American Society of Echocardiography • American Society of Plastic Surgeons
American Society of Retina Specialists • American Urological Association • Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons • National Association of Spine Specialists • Society of Interventional Radiology

Given the context in which the PTAC is making this request and the questions it poses, the Alliance urges this Committee to include our recommendations and our request for publicly available data on specialty engagement in APMs, as part of its report to the Secretary of Health and Human Services (HHS).

Value of Specialists

Specialty medical care is an essential and needed component of the health care system, and increasingly so as chronic, complex diseases become more prevalent. Unlike primary care physicians (PCPs), specialty physicians have advanced expertise, knowledge and skills that allow them to provide more thorough examinations, render more precise diagnoses, offer more targeted and clinically appropriate treatment options, and provide comprehensive and effective management of acute and chronic health conditions. For example:

- Rheumatologists are best positioned to render an accurate diagnosis, establish a plan of care, and manage life-long rheumatologic conditions such as rheumatoid arthritis, systemic lupus erythematosus, and other debilitating inflammatory diseases. Because these conditions are systemic and side effects from the necessary medications can affect various organ systems, such as renal or hematologic there is overlap with many primary care issues. Weight, blood pressure, blood sugar, bone density, kidney and bone marrow function are just a few of the areas that are monitored on a regular basis by rheumatologists in the care of their patients.
- Patients with diabetes often suffer from ocular comorbidities, such as diabetic retinopathy or diabetic macular edema. Primary care practices are not equipped to offer treatment for these diseases, which includes advanced imaging and often regular intravitreal injections. Retina specialists are an integral part of managing diabetic patients.
- Interventional radiologists (IRs) utilize cutting-edge, targeted, minimally invasive image-guided procedures to diagnose and treat diseases in nearly every organ system, particularly in difficult or challenging situations where a collaborative approach may provide the best outcome. IRs treat patients who suffer from a wide variety of conditions including arterial conditions (aneurysm and dissection, arteriovenous malformations (AVM), hereditary hemorrhagic telangiectasia (HHT), peripheral arterial disease), venous conditions (deep vein thrombosis (DVT), pulmonary embolism (PE), venous and lymphatic malformations), liver and biliary conditions (ascites, encephalopathy, liver cancer-hepatocellular carcinoma, liver cancer - metastatic, portal hypertension, variceal bleeding, biliary obstruction, biliary leak) gastrointestinal conditions (malnutrition, obstruction, gastrointestinal bleeding, gastrointestinal ischemia) male conditions (benign prostatic hyperplasia (BPH), varicocele), female conditions (uterine fibroids, pelvic congestion syndrome), osteoarthritis of the knee and vertebral fractures.

Physicians across our member organizations have found that primary care physicians routinely refer patients for specialty intervention very late in disease progression. Worse, some primary care physicians misdiagnose complex conditions or rely on outdated treatments or therapies given their limited experience in managing these diseases. Once these patients finally reach a specialist – often on their own volition – their disease state is heightened and more difficult to control, leading to diminished outcomes and increased costs. CMS' primary care-led APMs, such as ACOs, exacerbate this problem with misaligned financial incentives that fail to account for the role of the specialist, few quality measures reflecting specialized conditions, and a lack of requirements for the ACO to ensure specialists are included in the model, which can lead to situations similar to health plan narrow networks and resulting patient access issues.

Specialists' Role in Alternative Payment Models

Alliance organizations continue to hear from their specialty physician members that active engagement in APMs is extremely challenging. Specialty-focused APMs do exist, but they only consider a limited number of conditions or procedures, leaving the vast majority of specialists without a dedicated model. Others, such as the Bundled Payments for Care Improvement (BPCI) program, suffer from challenges related to holding providers accountable for specific clinical episodes (versus broader clinical service lines and fail to provide high performing practices with an incentive to stay in the program since they are held to exceedingly challenging cost targets that simply do not support high quality, appropriate care. Additionally, specialists that are “participants” in ACOs are usually part of large hospitals or health systems, but their role is passive; they do not meaningfully engage in quality improvement or cost containment activities specific to the ACO, as the accountability measures do not consider the conditions they treat or services provided. Other specialists attempt to join ACOs, but are blocked from entry by the primary care physicians who lead them.

These findings are not just speculative. As highlighted in the Medicare Payment Advisory Commission (MedPAC) July 2022 Data Book, [*Health Care Spending and the Medicare Program*](#),

Many specialties account for a larger share of clinicians in larger ACOs. This finding may reflect smaller ACOs being more often composed of independent physician practices with relatively fewer specialists, while larger ACOs are often affiliated with hospitals or health systems that have a broader range of specialists.

MedPAC also explains that,

Specialists' participation in ACOs relative to their share of all clinicians varies by specialty. For example, cardiologists comprise about 2 percent of all clinicians participating in FFS Medicare, but a larger share of clinicians participating in ACOs. By contrast, specialties such as anesthesiology and ophthalmology are underrepresented in ACOs relative to their share of all FFS clinicians.

At the outset of the Quality Payment Program (QPP), the Alliance and its member organizations – independently and collectively – proactively connected with the ACO member organization to discuss opportunities for improving specialists' participation in ACOs. One approach discussed, which is contemplated in this RFI, was the development of “shadow bundles,” or as described in this RFI, “nesting of episode-based or condition-specific models in PB-TCOC models”. Further attempts to coalesce around this concept were stalled. Ultimately, we were told that specialty medical care and treatment was expensive and hurt ACOs financial performance, and – in the case of primary care-led ACOs – there was no appetite for sharing “savings” with specialists.

We recognize that one-size-does-not-fit-all and there will be obstacles to establishing alternative payment and delivery models for specialists – whether stand-alone or “nested” in population-based total cost of care models. Each specialty, and subspecialty, is unique in how care is diagnosed, treated, and managed. Some methodologies will work for a broader range of conditions and services, while others will be exclusive to a single condition or procedure.

Recommendations

Members of the Alliance are beyond frustrated, especially those who have invested significant resources in the development of impactful specialty-focused models and provided their expertise on ways that APMs, including ACOs, could integrate specialists to address high-impact conditions while improving quality of care. This not only discourages the development of more innovative models but significantly limits the movement of specialists into value-based models. As you will recall, the first PTAC recommended payment model was Project Sonar, which focused on a high-impact condition in gastroenterology – inflammatory bowel disease (IBD). Despite the fact that HHS did not proceed with this model, it has been a success in the commercial space. Several thousands of patients have been managed under this accountable care model. It has consistently [demonstrated](#) the ability to lower emergency department visits and inpatient admissions and has returned savings of 7.5% to 15% on total cost of care.

In addition, the cataract surgeons developed a bundled payment model that would enable appropriate patients to receive same-day, bilateral cataract surgery at a lower cost, while maintaining and improving outcomes for patients. This model, which would reduce spending and improve the quality of care for a large population of patients, would be appropriate for “nesting” into an ACO or other PB-TCOC model. Despite extensive review and positive discussions about the proposed model by senior staff and leadership of the Center for Medicare (CM) and CMMI, agency officials have taken no action, nor communicated further with the model developers.

Moreover, although outside the purview of the PTAC, the burden of participating in the Merit-based Incentive Payment System (MIPS) – where incentives have evaporated and penalties are steep – continues to increase as many specialists find it increasingly challenging to participate in a meaningful manner. This is the result of CMS’ removal of meaningful, specialty-focused measures, constantly shifting goal-posts, and unnecessarily burdensome requirements for qualified clinical data registries (QCDR).

As a result, the vast majority of specialists are at a gross disadvantage in the QPP compared to their primary care counterparts, a disparity that has persisted for far too long and must be addressed swiftly.

We urge PTAC to include the below recommendations in its report to the Secretary:

- Adopt PTAC’s previously recommended APMs for specialists and continue to prioritize the development of specialty-focused models;
- Leverage CMS’ administrative data and analytics capabilities to:
 - Identify opportunities for specialists to engage in existing APMs, including ACOs and other population-based total cost of care models.
 - Establish episode-based and condition-specific models that appropriately reward specialists for care they can control within existing APMs, including ACOs and other PB-TCOC models.
- In considering embedded ACO or other PB-TOCC models, it is important that CMS:
 - Not simply carry over the methodologies of existing episode-based models, some of which are flawed and pose challenges to specialists in terms of long-term participation.
 - Keep in mind that one size will not fit all when it comes to specialty integration into population-based models.
 - Ensure that specialists can achieve QP status if participating in a nested model and be exempt from MIPS.

- Ensure that more specialty-specific quality and cost measures in any new nested model are aligned with MIPS so that even if a specialist does not achieve QP status, they can still receive credit simultaneously under both initiatives.
- Closely examine the referral patterns of existing APMs, including ACOs, and establish benchmarks that will foster an appropriate level of access to and care coordination with specialists, in addition to collecting feedback from beneficiaries on access to specialty care;
- Examine how the calculation of qualifying APM participant (QPs) thresholds creates incentives or barriers to specialty engagement, and adjust as necessary to ensure that APM entities are not penalized for engaging specialists and that specialists can qualify as QPs;
- Require APMs and ACOs to maintain and publicly-post a list of specialty physician participants on their websites, including their specialty and subspecialty designation;
- Adopt specialty designations for non-physician practitioners to ensure specialty practices are not limited to participation in a single ACO; and
- Release granular data on specialty participation in existing APMs, including ACOs.

We appreciate the opportunity to provide feedback on the proposals in this rule that aim to improve access to specialty and subspecialty care. Should you have any questions or would like to meet with the Alliance to discuss these recommendations further, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
 American Academy of Otolaryngology-Head and Neck Surgery
 American Association of Neurological Surgeons
 American College of Mohs Surgery
 American College of Osteopathic Surgeons
 American Gastroenterological Association
 American Society for Dermatologic Surgery Association
 American Society of Cataract and Refractive Surgery
 American Society of Echocardiography
 American Society of Plastic Surgeons
 American Society of Retina Specialists
 American Urological Association
 Coalition of State Rheumatology Organizations
 Congress of Neurological Surgeons
 North American Spine Society
 Society of Interventional Radiology



April 7, 2023

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

RE: Specialist integration within total cost of care models

Dear Members of the Physician-Focused Payment Model Technical Advisory Committee:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments in response to the request for input on how to better integrate specialty care into total cost of care models. NAACOS represents more than 400 accountable care organizations (ACOs) in Medicare, Medicaid, and commercial insurance working on behalf of health systems and physician provider organizations across the nation to improve quality of care for patients and reduce health care cost. NAACOS members serve over 8 million beneficiaries in Medicare value-based payment models, including the Medicare Shared Savings Program (MSSP) and the ACO Realizing Equity, Access, and Community Health (REACH) Model, among other alternative payment models (APMs). NAACOS appreciates PTAC's focus on this issue and its coordination with the Innovation Center's work on specialty engagement in value-based models.

NAACOS and our ACO members share the commitment to the administration's goal of having all Medicare patients and most Medicaid patients in an accountable care relationship responsible for total cost of care and quality by 2030. To achieve this goal, there must be a focus on allowing providers to coordinate care across the continuum of care, working together to achieve optimal patient outcomes. This includes engaging specialists in total cost of care models, like ACOs. After more than ten years of payment model design innovation, we have learned that concurrent episode models and total cost of care models results in a complex set of overlap rules, leading to provider and patient confusion and increased burden. Designing specialty payment approaches within a total cost of care arrangement can create the proper incentives to encourage coordinated care across the care continuum. CMS must first address ACO needs to further this work:

- Share data on cost and quality performance for specialists with ACOs.
- Support total cost of care ACOs with shadow or nested bundled payments for those who elect these arrangements.
- Address policy and program design elements that currently are prohibitive to this work.

Share data on cost and quality performance for specialists with ACOs. ACOs' range in their ability to engage specialists, with some ACOs currently engaging in gainsharing arrangements or sub-contracting

such as shadow bundles, while other ACOs may be in early phases of this work. Regardless of their approach, ACOs need more data on specialist cost and quality performance to identify variations in care, partner with specialists to implement evidence-based protocols to help reduce variation, inform referrals to high-value specialists, and create financial incentives that encourage coordination across the care continuum. Data that would be helpful to provide ACOs to further support this work include episode cost data and quality data along with regional and national benchmarks. While ACOs can develop cost data for specialists, this information is limited to the ACO population and lacks sufficient data to be actionable. Additionally, ACOs do not have access to data on the quality of care provided by specialists. ACOs are eager to obtain quality data on specialty performance, whether it be Merit-Based Incentive Payment System (MIPS) quality data or other sources to support specialist engagement.

While CMS has noted the agency plans to provide data specific to the ACO, it would be more helpful to provide specialist performance data across a broader population. At a minimum, CMS should provide specialist performance data across Medicare. CMS should work to include specialist data across other payers, such as Medicare Advantage, to provide ACOs with a more holistic and accurate picture of performance in the marketplace. Benchmarks will then allow ACOs to understand how a specialist data compares to the region and nation.

While there is broad interest in gaining access to specialty data across the spectrum, should CMS need to focus on certain specialties to start with, the most logical could include cardiology, gastroenterology, oncology, orthopedics, neurology, endocrinology, retina specialists, dermatology, physical therapy and behavioral health. Data should be timely and actionable so it can be used at the point of care. CMS should also consider:

- Intended use of data. Whether the information is being shared to gain a better understanding of quality and performance information to support referral patterns is different than a use case of designing payment approaches within a total cost of care arrangement. Further, if the data sharing is to help inform patients, there will be very different needs (such as to share performance information with beneficiaries to allow them to make better decisions about their care).
- Ensuring sufficient sample size. ACOs engaging specialists in shadow or nested bundles are often faced with challenges regarding small numbers. Performance data must be based on a sufficient volume of cases so that spending estimates are statistically reliable.

ACOs are very interested and actively engaged in finding ways to further engage specialists in total cost of care models. Providing more data, specifically episode cost data as well as quality data and patient reported outcomes data, will help support this work. Sharing this information with ACOs will allow for enhanced referral management that is based on quality, cost and outcome data for some ACOs, while more sophisticated ACOs may be prepared to engage in sub-contracting within the ACO through financial arrangements such as gainsharing with the ACO.

Support ACOs ready to implement shadow or nested bundled by standardizing definitions. As a secondary priority, CMS could also support ACOs who are more advanced in their work on specialty engagement by creating and sharing target prices as well as quality performance data for episodes and appropriate risk adjustment for ACOs to use in designing their own nested bundles or specialist payment approaches. These increased data transparency efforts will be critical in helping ACOs to facilitate better communication among primary care clinicians and specialists. Efforts to engage specialists should allow for options from a menu set of more standardized approaches while still allowing for flexibility. For example, the Innovation Center should develop industry standard definitions for episodes to be used by

ACOs and others in the way that best suits their particular organization and regional market. Importantly, because ACOs are engaged in arrangements with other Medicare Advantage and other payers, CMS's role to develop standardize definitions should include other payer efforts.

In creating industry standard definitions consideration must also be given to the type of episode. Procedural episodes have been successful in programs like the Bundled Payments for Care Improvement- Advanced (BPCI-A) and the Comprehensive Care for Joint Replacement (CJR) models because the episode can be accurately attributed to a facility and provider. Accordingly, there may be more readiness to implement episodic bundles within ACOs. There has been less success in defining chronic condition episodes because attribution is less clear. It is difficult to assign accountability and more testing and work needs to be done in this area. CMS should work with ACOs to understand opportunities to shift payment for specialists providing chronic care.

It is critical that these types of arrangements remain voluntary, as not all ACOs and markets would be appropriate for such arrangements. There must also be flexibility to allow ACOs, plans and other entities to design approaches that are best for their population. Efforts to engage specialists should allow for options from a menu set of more standardized approaches while still allowing for flexibility. For example, an ACO in a rural area may have very few if any specialist referral options so a program built around enhancing referrals would not meet its patients' needs in that particular market or region.

Address policy and program design elements that currently are prohibitive to the inclusion of specialists. Currently there are several policies that discourage specialist participation in ACOs.

- The MSSP quality requirement to move to electronic clinical quality measures (eCQMs)/MIPS clinical quality measures by 2025 inadvertently penalizes ACOs with specialist participants by requiring reporting and assessment of all-payer and all-patient data rather than focusing on ACO assigned patients. As a result, specialists in the ACO are held accountable for primary care measures that are not clinically appropriate. For example, dermatologists in the ACO would be required to assess and do follow-up on depression screenings, which would not be clinically appropriate. Ultimately this would lead to artificially lowering the ACOs quality score and assessing ACOs based on the case-mix of their population.
- The Qualifying Advanced APM Participant (QP) thresholds, which determine who is eligible for the 5 percent Advanced APMs incentive payment, penalizes ACOs who have a higher proportion of specialists. CMS should consider approaches for reducing the impact of this disincentive.
- The high/low revenue distinction in MSSP discourages ACOs from including specialists. ACOs with more participating specialists are likely to have a larger percent of the ACO's revenue for all expenditures of the assigned beneficiaries. Removing the high/low revenue distinction would remove the disincentive to include specialists in the ACO.
- Participation in MSSP ACOs is predominantly primary care focused because attribution is focused solely on primary care services. To encourage more specialist participation CMS should allow National Provider Identifier (NPI) level participation in the MSSP, which would allow for certain specialists to participate in the model. Currently, specialists who employ advanced practice providers (APPs) may align beneficiaries to the ACO; however, these beneficiaries typically align to the ACO for only one year during a high-cost episode. This discourages ACOs including specialists because they cannot truly manage the cost and care for patients who align for such a brief period. Additionally, specialists who join total cost of care models have only a small proportion of their patient panel in the ACO. CMS should consider attribution approaches that would allow a greater portion of a specialists' patient panel to align to an ACO.

These policies must be addressed to ensure there are strong incentives for collaboration among primary care clinicians and specialists. Importantly there should be no mandatory bundles participation for ACOs or beneficiaries aligned to ACOs. This will create the proper incentives for bundles done within a total cost of care model to ensure there is no incentive for overutilization.

CONCLUSION

NAACOS looks forward to continuing to work with the Innovation Center, CMS and ACOs on this issue to find ways to meaningfully engage specialists in total cost of care models. We thank PTAC for its attention to this issue. If you have any questions, please contact Aisha Pittman, senior vice president, government affairs at aisha_pittman@naacos.com.

Sincerely,

Clif Gaus, Sc.D.
President and CEO
NAACOS



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April 18, 2023

Lauran Hardin, MSN, FAAN

Angelo Sinopoli, MD

Co-Chairs, 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: Improving Care Delivery and Integrating Specialty Care in
Population-Based Models Request for Input (RFI)

Dear Ms. Hardin and Dr. Sinopoli,

The American Society for Radiation Oncology¹ (ASTRO) appreciates the opportunity to provide written comments in response to the “Improving Care Delivery and Integrating Specialty Care in Population-Based Models Request for Information” (RFI).

ASTRO appreciates PTAC’s thoughtful approach to specialty care integration within broader population-based models, particularly the focus on establishing roles and responsibilities for specialty care providers that are “clearly delineated throughout the care journey for a given condition or episode of care.” This recognizes the value of services, like radiation therapy, in multimodality treatment.

Below are ASTRO’s responses to the RFI questions:

1. Variation of primary and specialty care providers’ roles in managing patients’ care

The role of the primary care physician may be to continue providing primary care to the patient with referral to a specialist for cancer related issues. The role of the specialist may be to provide

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.

continuing follow-up for cancer-related issues, or to be the sole provider of follow-up care. If a patient is without evidence of disease for a long period of time, then the primary care provider may become the sole care provider.

Variation in primary care provider engagement associated with cancer care is usually due to limited initial exposure to oncology care as part of medical education, as well as a lack of resources and time necessary to stay abreast of a rapidly changing and complex field of medicine. Additionally, once established collaborative partnerships vary based on each patient's unique care needs underscoring the importance of guideline-based care and appropriate referrals.

Unfortunately, many efforts to pursue collaborative care are stymied by a lack of resources and incentives to support collaborative team-based approaches. These challenges can be met with the establishment of reimbursed quality metrics that encourage collaboration between primary care physicians and oncologists. However, even quality-based incentives won't address some of the overarching challenges that exist, such as Electronic Health Records systems that don't allow for seamless transfer of clinical information, time-consuming prior authorization requirements, and other related administrative burdens. Until each of these pressure points are addressed, it will be difficult to achieve the goal of patient-centered care through improved provider collaboration.

2. Defining primary and specialty care with regard to chronic care management

In the future, as more cancer related conditions become manageable over longer periods of time, it will be critical for primary care physicians to become more familiar with the different types of cancer treatment provided to patients. They also will need to collaborate with specialists to manage treatment related symptoms and identify situations in which the patient may require additional interventions. Chronic disease management is a key area in which primary care and specialty care integration can lead to efficient use of services, as well as better patient outcomes.

3. Common approaches to coordination between primary and specialty care

Lack of exposure to specialty care in medical education leads to fragmentation in patient care and results in missed opportunities to improve patient outcomes. In 2019, ASTRO engaged a research firm to learn more about the perceptions that primary care physicians have about oncology care. The findings demonstrated that many primary care physicians have limited exposure to oncology care through their education and training, which impacts referral patterns and ultimately patient care.

Once in practice, primary care physicians indicated that a majority of their patients present with chronic conditions, such as diabetes, asthma or heart disease, and that for more complex issues such as cancer, they refer the patient to specialists. The primary care physicians don't have the bandwidth nor see the need to learn more about the different types of oncology care. Their patient engagement time is extremely limited, and they must make a cost-benefit analysis based on a handful of their patients that are diagnosed with cancer each year. This limited exposure

during training is a missed opportunity and can negatively impact patients who need multidisciplinary cancer care.

4. Common approaches to coordination between primary and specialty care within ACOs

Accountable Care Organizations (ACOs) tend to focus on increasing access to primary care, while also reducing unnecessary ED visits and inpatient admissions, rather than attempt to establish broader integration programs with specialty providers². However, it can be expected that over time focus will shift towards specialty care as ACOs achieve improved primary care integration and patient care management.

One of the best practices for integrating and improving coordination of care between primary care and oncology care providers is to establish consultation with a broad range of providers representing surgical oncology, medical oncology and radiation oncology. If it is not possible to consult a broad range of oncology providers, then primary care physicians can reference clinical guidelines, such as those issued by the National Comprehensive Cancer Network, to make an appropriate referral. Too often, referring physicians solely rely on previous experience or limited medical education, as referenced above, 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, they should be referred to a coordinated group of oncology specialists to ensure the patient has a variety of treatment options to select from, and, 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.

5. Approaches to improving coordination between primary care and behavioral health

Coordination with behavioral health should not be limited to primary care. The Radiation Oncology Model (RO Model) included a quality measure that required screening for depression, which is a common condition that many patients with cancer experience. This requirement did not actually help patients experiencing depression because it did not include the resources to ensure coordination with a behavioral health specialist, who could provide the patient with counseling and other services. While well intentioned, the quality measure would have done little to improve behavioral health outcomes for cancer patients. Coordination with other specialties must include the resources required to successfully ensure integration and support related patient care management, which in this case would have been the counseling provided by a behavioral health specialist.

6. Examples of organizations that have successfully implemented specialty care within the context of value-based care

While there have been numerous value-based specialty care initiatives, none thus far have been particularly successful in the cancer care space. The RO Model, which was indefinitely delayed,

² Lewis VA, Schoenherr K, Frazee T, Cunningham A. Clinical coordination in accountable care organizations: A qualitative study. *Health Care Manage Rev.* 2019 Apr/Jun;44(2):127-136. doi: 10.1097/HMR.000000000000141. PMID: 27926614; PMCID: PMC5461217.

was foundationally correct in that it established a discrete radiation oncology episode of care; however, rather than achieve the goal of value-based payment for radiation therapy services, the Model was used to implement a significant rate cut on an already high-value form of treatment. The Oncology Care Model (OCM) improved patient care coordination but did not save CMS any money. Rather than build on better patient outcomes demonstrated as part of OCM, CMMI decided to reduce the Monthly Enhanced Oncology Services (MEOS) payment when it introduced the Enhancing Oncology Model, forcing many OCM participants to reconsider continued involvement under the new model. Overemphasis on savings over quality improvement have become common themes in CMMI models, despite recognition that encouraging lasting transformation and broader investments in quality improvements are of equal, if not greater, value.³

7. The role of primary care providers in specialist selection

As previously stated, primary care physicians have limited clinical education regarding advances in oncology care, which may impact referral patterns. While ASTRO's study was specific to oncology care, it may be an indication of limitations in other specialty areas that should be taken into consideration. This needs to be further explored so that appropriate referrals are made by primary care physicians to specialists that will ensure optimal patient care outcomes.

Additionally, as previously stated, reimbursed quality metrics should be considered that provide primary care physicians with the incentives and resources necessary to invest in collaboration with specialists. Currently, the barriers of bandwidth and burnout outweigh the incentives to collaborate with specialty care physicians.

8. Best practices for improving equity related to specialty integration

Research has shown that minority populations are less likely to complete their course of radiation therapy than whites, due to lack of access to transportation⁴. Improving equity related to specialty integration will require consideration of the barriers to care that disadvantaged populations may experience. True integration takes place when specialty specific barriers are identified and addressed across the continuum of care. This includes identifying and securing the resources necessary to reduce those barriers, so that patients can successfully access care.

9. The role of telehealth

The role of telehealth has expanded as a result of the COVID-19 public health emergency. For radiation oncology, the use of real-time audio-video technology that satisfied patient supervision requirements was initially critical to ensuring that patients with cancer could continue receiving

³ Brooks-LaSure, Chiquita, Elizabeth Fowler, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." *HealthAffairs*. August 12, 2021. <https://www.healthaffairs.org/doi/10.1377/hblog20210812.211558/full/>

⁴ Mantz CA, Thaker NG, Deville C Jr, Hubbard A, Pendyala P, Mohideen N, Kavadi V, Winkfield KM. A Medicare Claims Analysis of Racial and Ethnic Disparities in the Access to Radiation Therapy Services. *J Racial Ethn Health Disparities*. 2022 Jan 21. doi: 10.1007/s40615-022-01239-0. Epub ahead of print. PMID: 35064522.

radiation treatments, while also limiting COVID exposure. However, as radiation oncology clinics established protocols for limiting COVID exposure and were able to secure adequate PPE, the need for real-time audio-video supervision of care diminished significantly.

While expanded use of telehealth may be appropriate for some aspects of primary care and some specialty services, it is of limited use for radiation oncology due to the nature of the regular treatments that require physician supervision to ensure compliance with patient safety requirements.

10. Financial incentives for supporting specialty integration

Financial incentives for supporting specialty integration within broader value-based payment initiatives begin with adequate and stable payment for the services being delivered. ASTRO has long advocated for episode-based payment for radiation oncology services, which are already high-value in comparison to other forms of cancer treatment.

Additional resources are necessary for the cost associated with care integration and wrap around services required to ensure access for those patient populations that experience healthcare inequities. Interoperable EHR systems that allow for seamless transfer of patient clinical information, staff navigation services, physician generated patient care summaries, and other hallmarks of care coordination require resources that are currently unavailable. Until these services are valued and resources are made available, it will be difficult to achieve meaningful integration.

11. Best approaches for defining chronic outpatient episodes of care

During the March 2-3rd PTAC meeting, several guest presenters acknowledged provider concerns regarding the establishment of episode-based care models, including:

- If specialists are going to successfully participate in TCOC there need to be appropriate incentives for compliance with guideline concordant care, while also recognizing concerns regarding cookbook medicine.
- Specialists should be responsible for their specific role in the patient's care, which creates accountability across broader systems and establishes more accurate benchmarking that can be used by PCPs for making referrals.
- Recognition that specialists are mistrustful of payers, worried about losing clinical autonomy, frustrated by administrative burden, and have yet to see how value-based payment initiatives amount to anything more than a pay cut.

These are key issues that must be addressed as part of establishing chronic outpatient episodes of care. ASTRO urges PTAC to push for broad stakeholder input as a key component in the development of episodes of care.

12. Design features that facilitate nesting of episodes

One of the tenets of value-based care is the development of alternative payment models that allow physicians to manage the care and related costs that they control. Episode-based models are appropriate for distinct segments of care that are delivered within a specific period as part of a broader continuum of care. Radiation therapy is appropriate for episode-based payment and thus can be nested within a 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.

Establishing nested episodes of care allows for better alignment of incentives that take into consideration the providers and costs involved in all related services. In many existing models, the initiating provider gets all the risk and reward for participation, whereas there is no risk or reward for the other care providers. 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 episode⁵. 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.

According to the recently issued Bundled Payments for Care Improvement (BPCI) Advanced Model Fourth Evaluation report, this misalignment is playing out to the detriment of patients⁶. According to the report, patient reported change in functional status between BPCI Advanced and comparison respondents indicated unfavorable or declining functional status and ability to perform activities of daily living for several Clinical Episode Service Line Groups (CESLG). Of note, the orthopedics CESLGs were less likely than comparison respondents to report high levels of satisfaction with recovery. These findings support the concern that multi-service bundles may disincentivize adequate post-acute care. This misalignment can be addressed when distinct episodes are established recognizing the role and the cost associated with all related services.

13. Performance measures that encourage specialty integration

During the March PTAC meeting, it was reassuring to hear several speakers point to the need for incentives and payment constructs that recognize the cost of entering into and participating in integrated care delivery. Efforts should be made to identify those aspects of integrated care delivery that require appropriate valuation and reimbursement before establishing performance measures to encourage integration. Performance measures are of little use without appropriate support and upfront investment in care integration. Once that is established, measures can be

⁵ Westhead, Monica. "Influence Downstream Provider Behavior: Key strategies to achieve success in an era of risk." Advisory Board. Post Acute Collaborative. 2017.

⁶ CMS BPCI Advanced Evaluation – Fourth Evaluation Report. Prepared for CMS by The Lewin Group Inc. with Abt Associates, GDIT, and Telligen. March 2023. <https://innovation.cms.gov/data-and-reports/2023/bpci-adv-ar4>

American Society for Radiation Oncology

April 18, 2023

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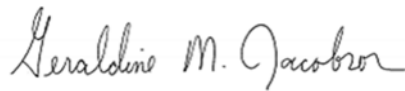
developed to monitor the success of the supports and investments on improving patient outcomes.

ASTRO appreciates the opportunity to comment on the RFI and looks forward to future opportunities to engage with PTAC on value-based payment initiatives. If you have 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



Geraldine Jacobson, MD, MBA, MPH, FASTRO
Chair of the Board

May 4, 2023

Lauran Hardin, MSN, FAAN
Angelo Sinopoli, MD
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Physician-Focused Payment Model Technical Advisory Committee
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U.S. Department of Health and Human Services
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RE: Improving Care Delivery and Integrating Specialty Care in Population-Based Models Request for Input (RFI)

Dear Ms. Hardin and Dr. Sinopoli:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on a request for information (RFI) released by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) related to how specialty care can be integrated into population-based payment models. We would like to provide input on a few of the questions that the PTAC includes in the RFI.

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Question: What model design features can help to facilitate the nesting of episodes of care within PB-TCOC models?

ACEP strongly believes that emergency physicians can and should be integrated in population-based models as key participants. Emergency physicians are a gatekeeper to hospitals, as they decide whether a patient should be admitted to the hospital, placed in observation, or safely discharged. Roughly 60 percent of all Medicare hospital admissions come through the emergency department (ED).¹ There are also great financial implications from these decisions. An average Medicare admit costs \$14,900 more than a discharge.² Health care systems truly cannot get a handle on health care costs without engaging the ED.

Unfortunately, despite this critical role that emergency physicians play in the health care system, there are no alternative payment models (APMs) in which emergency physicians can directly participate.

¹ Gonzalez Morganti, Kristy, Sebastian Bauhoff, Janice C. Blanchard, Mahshid Abir, Neema Iyer, Alexandria Smith, Joseph Vesely, Edward N. Okeke, and Arthur L. Kellermann, The Evolving Role of Emergency Departments in the United States. Santa Monica, CA: RAND Corporation, 2013. https://www.rand.org/pubs/research_reports/RR280.html. Also available in print form.

² Moore BJ (IBM Watson Health), Liang L (AHRQ). Medicare Advantage Versus the Traditional Medicare Program: Costs of Inpatient Stays, 2009–2017. HCUP Statistical Brief #262. August 2020. Agency for Healthcare Research and Quality, Rockville, MD. www.hcup-us.ahrq.gov/reports/statbriefs/sb262-Medicare-Advantage-Costs-2009-2017.pdf.

To fill this gap in available APMs, ACEP developed a physician-focused payment model (PFPM) called the [Acute Unscheduled Care Model \(AUCM\)](#). ACEP presented the AUCM to the PTAC in 2018, and the PTAC [fully recommended](#) to the Secretary of Health of Human Services (HHS) for implementation. In 2019, the former HHS Secretary, Alex Azar, [recommended](#) that the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare & Medicaid Services (CMS) “assess how key mechanisms of action in this model could operate as a component in a larger model dedicated to improving population health.”

The AUCM specifically fosters care coordination by holding emergency physician groups accountable for the cost and quality of care Medicare beneficiaries receive over a 30-day period for specific episodes of acute unscheduled care. The model includes payment waivers for ED acute care transition services, telehealth services, and post discharge home visits. The waivers provide emergency physicians with the necessary tools to better coordinate care and promote improved patient outcomes. Concurrent to clinical care provided during the patients’ ED visit, an emergency medicine health care professional will administer a safe discharge assessment (SDA) to identify socio-economic factors and potential barriers to safe discharge, needs related to care coordination, and additional assistance that may be necessary. Information captured in the SDA informs unique patient care instructions provided at the time of discharge. The emergency physician participates in shared decision-making by coordinating with the primary care physician or specialist assuming care of the patient after ED discharge. Finally, the ED group arranges follow-up services by telephone, in-person visits, or telehealth outreach.

ACEP is eager to work with CMS on integrating concepts of the AUCM into population-based models, such as accountable care organization (ACO) initiatives. For more information about the AUCM, please visit www.acep.org/apm.

Question: What approaches are most commonly being used to facilitate coordination between primary and specialty care providers in ACOs? Why are these approaches being used?

Currently, ACOs have not effectively engaged specialists to help meet their cost targets and quality metrics. ACOs can perform even better on these benchmarks if they get specialists more involved in the care of their assigned patients. In fact, in CMMI’s [strategic plan](#), the Center states that *specialists must be engaged* in ACO initiatives to help achieve an overarching goal getting all Medicare beneficiaries and the vast majority of Medicaid beneficiaries in “a care relationship with accountability for quality and total cost of care” by 2030 (emphasis added). CMMI has stated that it wants to “test incentives to drive coordination between providers responsible for accountable care relationships and specialty providers accountable for delivering high-cost episodic and/or complex care.”

To help achieve this goal of ACO and specialty care integration, we have recently been working with the American Medical Association (AMA) on a concept called “Payments for Accountable Specialty Care (PASC).” Developed by the AMA, the PASC model would serve as an additional component to ACO initiatives. Under the PASC concept, ACOs could enter into performance-based agreements (called PASC agreements) with different specialty groups. Specialists would then agree to take accountability for delivering specific types of services to patients assigned to the ACO in a way designed to improve outcomes and/or reduce avoidable spending, thereby helping the ACO to meet its cost and quality goals. In return, the specialists would receive enhanced condition services (ECS) payments that would compensate them for the additional work it takes to manage patients and improve care coordination. The ECS payments to the specialists would be counted in the total spending for the ACO when shared savings or losses for the ACO are calculated. Consequently, if the specialists’ services do not result in sufficient reductions in spending or improvements in quality to meet the ACO’s goals, the ACO’s shared savings would be lower, or its shared losses would be higher than they would have been otherwise.

There would be three different kinds of ECS payments available.

1. **(Standard) ECS Payments.** The standard *Enhanced Condition Services Payment* would be a one-time payment for up to one month of services related to diagnosis, treatment planning, treatment of an acute condition, or initial treatment of a chronic condition. For example, the payment could allow the specialist to engage in a shared decision-making process with the patient about the type of treatment needed or to provide education and training for the patient and family about how to successfully manage their condition.
2. **Continued ECS Payments.** For patients who need to continue receiving services from the specialist for longer than a month, the PASC Agreement could include a provision enabling the specialist to receive a *Continued Enhanced Condition Services Payment* for one or more additional months. For example, the specialty practice could provide condition-specific symptom monitoring and care management services designed to avoid exacerbations of a complex chronic condition or to avoid complications from surgery or cancer treatment.
3. **Special ECS Payments.** If a patient has characteristics that will make care of their health problem significantly more challenging (e.g., language barriers, food insecurity, lack of housing or transportation, etc.), and if the patient's primary care physician and specialist agree that the specialty practice should provide additional services to the patient to address these issues, the PASC Agreement could specify that the specialist would be paid a *Special Enhanced Condition Services Payment* for that patient in addition to either the ECS Payment or Continued ECS Payment.

The agreements between ACOs and specialists and the ECS payments themselves would be designed and used differently depending on the specialty type. With respect to emergency physicians, the ECS payments would be used similar to how the additional payments under the AUCM would be: to help with ED discharge planning, coordination with primary care physicians and other specialists and transitional care management after discharge. For example, emergency physicians could receive an initial ECS payment when an individual assigned to the ACO comes to the ED. The payment could be used to help set up the infrastructure and staffing necessary to enable the emergency physician to coordinate with the patient's primary care physician to determine whether the patient should be admitted or could be safely discharged to the patient's home. As with the AUCM, the emergency physician could help reduce overall costs by reducing admissions to the hospital.

Emergency physicians could also be eligible to receive special ECS payments in cases where patients need additional assistance in order to be safely discharged from the ED. For example, for patients with social risk factors, the payments could be used by the emergency physician group to help hire a community health worker that would assist patients in obtaining medications and food after discharge and ensure that patients see their primary care physician for follow-up care.

All in all, ACEP strongly believes that elements of the AUCM and/or the PASC model could and should be incorporated into ACO initiatives.

Question: What approaches are most commonly being used to facilitate coordination between primary and specialty care providers in advanced primary care models? Why are these approaches being used?

One innovative approach that EDs used during the COVID-19 public health emergency to enhance care coordination has been to increase the use of follow-up telehealth services. Emergency physician groups have set up systems and protocols to follow up with patients once they are discharged from the ED, ensuring that patients are taking their medications appropriately or are seeing their primary care physician or specialist if needed. These follow-up services have helped enhance care coordination efforts and avoid trips back to the ED or inpatient admissions.

Emergency physicians have learned an important lesson during the pandemic when discharging acutely ill patients in situations where there is a lack of hospital capacity. They have been able to improve the safety of that discharge and follow-up care using three tools (all of which are available in the AUCM): transitional care management services, telehealth services, and post discharge home visits.

Another extremely promising approach revolves around focusing on a specific population, such as geriatric patients. Geriatric emergency departments (GEDs), for example, incorporate specially trained staff, assess older patients in a more comprehensive way, and take steps to make sure the patient experience is more comfortable and less intimidating for older adults. All of this allows for a better care experience for older adults while in the ED and safer transitions to a community setting for those who do not need medical admission. A GED has four key areas of differentiation from a traditional ED. First, physicians and nurses receive additional education in geriatric emergency medicine that provides added expertise in the emergency care of older adults. Additional education focuses on:

- Geriatric specific syndromes and concepts (e.g., atypical presentation of disease, changes with age, transitions of care) relevant to emergency medicine,
- Clinical issues nearly exclusive to geriatric patients (e.g., end of life care, dementia, delirium, systems of care for older adults), and
- Issues common to all ED patients but focused on the unique factors found in older adults (e.g., trauma in older adults, cardiac arrest care for the geriatric patient).

Second, GEDs have enhanced screening processes. Patients receive additional screenings that can quickly uncover physical or mental health risks that are more common in older adults. For example, screening tools uncover geriatric syndromes (like falls, polypharmacy, delirium, dementia) as well as social vulnerabilities (like food scarcity or elder mistreatment).

Third, GEDs are often supported by interdisciplinary team members that help provide enhanced community connections for the most vulnerable older adults, as well as focus on transitions of care. Team members can reach out to the local agency on aging, services like Meals on Wheels, physical therapy providers and home health agencies, or help facilitate direct to skilled nursing facility (SNF) transfers when an in-patient admission is not required.

Finally, a GED is usually not a separate space or standalone ED, but rather has structural enhancements to the physical environment that make the experience more conducive to older adults. Oftentimes this includes a designated, quieter, cordoned-off space within an ED, light dimmers, non-stick flooring to minimize falls, comfortable space for caregivers in the ED, or the inclusion of handrails.

In summary, the goals of GEDs are to improve transitions of care, avoid unhelpful hospital admissions or readmissions, identify unmet needs, and improve care quality and the patient experience. GEDs do this through the use of transitional care nurses or social workers by:

- Identifying underlying geriatric syndromes and social vulnerabilities through enhanced screenings
- Intervening upon findings
- Connecting to social services
- If appropriate and feasible, transitioning to home or community-based settings (hospital at home, primary care provider, etc.)

Though research in improving emergency care for older adults has been underway for decades, wide-scale adoption of geriatric emergency medicine care processes is relatively new. In 2013, [the Geriatric ED Guidelines](#) were created. In 2018, ACEP launched the [Geriatric Emergency Department Accreditation program](#), which established criteria for three levels of GED accreditation. There are now over 300 GEDs in the US, along with a growing presence internationally.

There is a growing body of literature that supports the outcomes of GEDs to lower cost, improve quality, and improve the patient experience:

- Up to 16.5 percent reduced risk of hospital admission³ and 17.3 percent of readmission⁴
- Up to \$3,202 savings per Medicare beneficiary after 60 days⁵
- Decreased odds of 30- and 60-day fall-related ED revisit with PT services⁶
- 3 percent satisfaction with the clarity of discharge information and perceived wellbeing⁷
- Multiple studies showcasing improved experience across a variety of interventions⁸

GEDs are a proven example of emergency medicine facilitating higher value care for complex patients. They decrease the risk of unnecessary hospital admissions, improve patient experience in the ED and care transitions to the community, and decrease the need for repeat ED visits and re-hospitalizations by addressing the underlying risk factors (such as falls risks, polypharmacy, elder abuse, care giver fatigue, etc.) that may have precipitated the ED visit in the first place. EDs need to lead the charge to value-based care (and be supported for doing so), and GEDs demonstrate how this is possible.

Which financial incentives are most appropriate for supporting specialty integration? How should specialty integration be structured to support accountability for quality and TCOC in advanced primary care models and ACOs?

Aligning financial incentives to support integration of specialty care into total cost of care models is critical. Under the current fee-for-service model, there are no rewards for the hospital or the physicians to take the time to adopt a strong care coordination model and to engage specialists.

³ Hwang, U., Dresden, S.M., Rosenberg, M.S., Garrido, M.M., Loo, G., Sze, J., Gravenor, S., Courtney, D.M., Kang, R., Zhu, C.W., Vargas-Torres, C., Grudzen, C.R., Richardson, L.D. and (2018), Geriatric Emergency Department Innovations: Transitional Care Nurses and Hospital Use. *J Am Geriatr Soc*, 66: 459-466. <https://doi.org/10.1111/jgs.15235>

⁴ Dresden SM, Hwang U, Garrido MM, Sze J, Kang R, Vargas-Torres C, Courtney DM, Loo G, Rosenberg M, Richardson L. Geriatric Emergency Department Innovations: The Impact of Transitional Care Nurses on 30-day Readmissions for Older Adults. *Acad Emerg Med*. 2020 Jan;27(1):43-53. doi: 10.1111/acem.13880. Epub 2019 Dec 1. PMID: 31663245.

⁵ Hwang U, Dresden SM, Vargas-Torres C, et al. Association of a Geriatric Emergency Department Innovation Program With Cost Outcomes Among Medicare Beneficiaries. *JAMA Netw Open*. 2021;4(3):e2037334. doi:10.1001/jamanetworkopen.2020.37334

⁶ Lesser A, Israni J, Kent T, Ko KJ. Association Between Physical Therapy in the Emergency Department and Emergency Department Revisits for Older Adult Fallers: A Nationally Representative Analysis. *J Am Geriatr Soc*. 2018 Nov;66(11):2205-2212. doi: 10.1111/jgs.15469. Epub 2018 Aug 21. PMID: 30132800.

⁷ Guttman A, Afilalo M, Guttman R, Colacone A, Robitaille C, Lang E, Rosenthal S. An emergency department-based nurse discharge coordinator for elder patients: does it make a difference? *Acad Emerg Med*. 2004 Dec;11(12):1318-27. doi: 10.1197/j.aem.2004.07.006. Erratum in: *Acad Emerg Med*. 2005 Jan;12(1):12. PMID: 15576523.

⁸ Berning MJ, Oliveira J E Silva L, Suarez NE, Walker LE, Erwin P, Carpenter CR, Bellolio F. Interventions to improve older adults' Emergency Department patient experience: A systematic review. *Am J Emerg Med*. 2020 Jun;38(6):1257-1269. doi: 10.1016/j.ajem.2020.03.012. Epub 2020 Mar 12. PMID: 3222314.

One possible way to align financial incentives is through a global budget model. Since 2014, Maryland's global budget model has paid hospitals a fixed amount to manage all ED and in-hospital care for a population of patients, through its Global Budget Revenue (GBR) model which is administered by the Health Services Cost Review Commission (HSCRC). ACEP members in Maryland have come up with a concept to expand the global budget model to cover physician services, thus improving the alignment of incentives for Maryland hospitals and physicians.

This model, if effective, would be anticipated to:

1. Reduce the uncertainty in payments to Maryland ED physicians allowing them to more consistently and effectively staff EDs.
2. Improve access to care for Maryland residents and visitors.
3. Improve the experience and quality of care of people who come to use Maryland EDs.
4. Reduce avoidable Maryland ED utilization.
5. Ensure that Maryland ED patients have safe transitions in care post-discharge.
6. Address the social determinants of health that lead to frequent ED use and improve health equity.
7. Reduce total cost of care in Maryland.

The conceptual design of the emergency physician global budget is below. The target would be to launch in the year 2025 utilizing 2022-2024 data, or a subset thereof. This would occur as a pilot program with groups of ED physicians partnering with hospitals to align on interventions in a small group of hospitals aimed at improving access and reducing total of care. Global budgets would be piloted after the existing ED Episode Quality Improvement Program (EQIP) that is currently being implemented by Maryland's Health Service Cost Review Commission (HSCRC) has been in place for two years. We anticipate that ED EQIP would remain in place for EDs that want to utilize the program, however, we anticipate the ED-physician global budget program could eventually replace that program, particularly for sites that had already effectively reduced 14-day total cost of care. While EQIP does an essential job by infusing the current fee-for-service chassis of emergency physician reimbursement with incentives for value-based care, transitioning to non-fee-for-service based global budget for emergency physicians can further align their incentives with the goals of the Maryland GBR.

A 2025 ED physician global budget could be calculated based upon the following components:

1. Average ED-specific historical health care consumer price index (CPI)-adjusted revenues for fee-for-service billings for the years 2022-2023. Data would include clinical revenue only (e.g., from fee-for-service billings), specifically from fee-for-service care delivery by ED physicians within the hospital. Any non-clinical revenue would not be included within the model.
2. An upward adjustment factor based on the medical CPI index, relative to the base period.
3. An upward adjustment factor for hospitals with EDs that average > 40 patients per day to allow time for investment in improving post-discharge care, by moving from their current staffing (measured as patients per physician per hour) to a maximum of 1.8 patients per hour, based on extrapolated 2022-2023 volumes.
4. An upward adjustment factor for hospitals with less than 50 patients per day that would allow them to maintain 24/7/365 emergency physician staffing, with a maximum of 1.8 patients per hour during peak periods.
5. *Expansion of telehealth services, intended to reduce ED use, where patients are served better elsewhere, and those resources are available.* An upward adjustment factor for providing pre-ED emergency physician-led tele-triage / telehealth services for the local population, including advice on when an ED visit is warranted, versus an urgent care

visit, a primary care visit, or watchful waiting for less-serious, non-urgent conditions such as infectious disease. This could be combined across multiple EDs within a health system for economies of scale.

6. *Expansion to include telehealth follow-up for high-needs patients.* An adjustment factor for providing post-ED follow-up telehealth services for high-needs or high-risk patients, who have a higher risk of repeat ED visits or for unanticipated clinical problems after discharge. This could be combined across multiple EDs within a health system for economies of scale.
7. *ED physician engagement in hospital-based programs intended to reduce high-cost users.* An adjustment factor for executing a program within the ED that focuses on high-cost, frequent ED users. This would consist of identifying patients who are frequent ED users, and the creation and deployment of specific care plans for the ED or offline services to address the social determinants of health (e.g., social work services).
8. A bonus pool, that would be distributed to EDs and hospitals for meeting / exceeding specific quality metrics:
 - Admission rate for ED intensity measure (i.e., the proportion of visits admitted to the hospital with 535 ICD-10 codes [same measure as is used in ED EQIP])
 - Left without being seen rate (i.e., the proportion of patients who present to the ED who leave without being seen or leave against medical advice)
 - Average length of stay for ED discharged patients (i.e., the median length of visit for ED patients who are treated and released from the ED)
 - CT imaging rate for discharged patients < 60 years of age (i.e., the proportion of visits < 60 years who receive one or more CT imaging studies), and ≥60 years for imaging excluding head, spine, and abdominal CT imaging.
 - Opioid prescribing rate at discharge (i.e., the proportion of ED discharges with one or more opioid prescriptions)
 - Repeat ED visit with hospital admission within defined periods (e.g., 72-hours, 30 days) with admission to the hospital or transfer to another facility)

The model could be administered through the state's GBR 2.0 infrastructure through HSCRC, or through another mechanism if that became available. Within GBR 2.0, EDs would need to partner with hospitals implementing the program and partner on quality metrics.

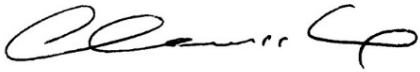
Success for this program would be measured by:

1. Monitoring utilization of the triage telemedicine services and tele-follow-up services.
2. Monitoring quality in Maryland EDs. The goal would be to decrease left without being seen, reduce length of stay to a target level, judged to be clinically reasonable, lower ED intensity of care metric (hospital admission rate), lower opioid prescribing, and lower rates of repeat ED visits with admission to the hospital or transfer to another facility.
3. Population-level utilization of avoidable, low-acuity ED use would be monitored in each ED. Lower rates of low-acuity use would be a marker of success.
4. Reduce total cost of care in Maryland, specifically includes ED and hospital costs, as well as total population-level costs within a hospital's catchment area.

We are happy to meet with the PTAC to discuss this model concept in more detail.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory and External Affairs, at jdavis@acep.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Kang". The signature is fluid and cursive, with a large initial "C" and a stylized "K".

Christopher S. Kang, MD, FACEP

ACEP President

May 5, 2023

Lauran Hardin, MSN, FAAN
Angelo Sinopoli, MD
Co-Chairs
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Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
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RE: Request for Input on Improving Care Delivery and Integrating Specialty Care in Population-Based Models

Dear Co-Chairs Hardin and Sinopoli:

On behalf of the physician and medical student members of the American Medical Association (AMA), thank you for the opportunity to provide our input on how to improve care delivery and integrate specialty care in population-based payment models. The AMA commends the Physician-Focused Payment Model Technical Advisory Committee (PTAC) for recognizing that “population-based” payments do not automatically result in higher-quality, more integrated care, and that current approaches to population-based payment have not been successful in engaging specialists in care improvement initiatives or supporting better coordination between primary care physicians and specialists. We urge you to recommend that the Centers for Medicare & Medicaid Services (CMS) implement a payment approach that we have developed, Payments for Accountable Specialty Care (PASC), to address these problems. PASC would also support partial implementation of many of the physician-focused payment model proposals that the PTAC recommended between 2017 and 2020.

Barriers to Improving Specialty Care in Population-Based Models

Many patients have health problems that require diagnosis or treatment from one or more specialists. Unfortunately, these specialists often face challenges in delivering the highest-quality care to their patients at the most affordable cost due to barriers created by the current payment system. These barriers may include lack of support for the detailed assessment of diagnosis, symptom monitoring, and patient-physician shared decision-making in conjunction with primary care physicians that is needed to avoid unnecessary testing, as well as for patient self-management training and care management services that could prevent hospitalizations. Many specialists say they cannot afford to use an approach that could improve outcomes or reduce the total cost of care because there are no payments for the new services they would need to provide (or the payments are less than the cost of delivering the services), and the time they would be spending providing those services would reduce the revenues needed to sustain their practices. Although Congress authorized CMS to create alternative payment models (APMs) as a means of correcting these types of problems, there are no APMs available that enable most specialists to deliver care in significantly different ways. Between 2017 and 2020, the PTAC recommended more than a dozen

physician-focused payment models that would support better specialty care, but the PTAC-recommended APMs have not been implemented by CMS.

In theory, a capitated or population-based payment would give an accountable care organization (ACO) the flexibility to pay specialists in different and better ways. However, as a practical matter, most ACOs do not have systems for paying individual physicians for the services they deliver. Consequently, changes in the way Medicare and other payers pay specialists are needed even when population-based payments are used.

Solution: Payments for Accountable Specialty Care (PASC)

Over a year ago, the CMS Innovation Center asked the AMA to recommend ways of addressing these problems. Drawing upon over a decade of work with many physician specialty societies, including those representing primary care physicians, the AMA developed PASC to complement shared savings and population-based payment systems. Under PASC:

1. A specialist or a specialist group would sign a PASC Agreement with an ACO describing how the specialist would deliver care in different ways for specific types of patients.
2. Primary care physicians participating in the ACO would refer the types of patients described in the Agreement to the specialist.
3. The specialist would deliver additional or different services to ACO patients in the ways described in the Agreement.
4. The specialist would receive Enhanced Condition Services payments from Medicare to pay for the cost of delivering the enhanced services to the patients.
5. In a shared savings payment model, CMS and the ACO would share the savings resulting from the delivery of higher-value care by the specialists, whereas in a population-based payment model, all of the savings would accrue to the ACO. In both cases, the ACO could share the savings with its participating primary care physicians.

Details of the PASC Agreement would differ for different types of health conditions:

- Chronic Conditions. For patients with chronic conditions (e.g., heart failure or rheumatoid arthritis), the PASC Agreement could focus on avoiding the use of unnecessary and unnecessarily expensive medications and/or reducing exacerbations that can result in emergency visits and hospital admissions.
- Acute Symptoms. For patients with acute symptoms (e.g., chest pain or fever), the PASC Agreement could focus on achieving prompt, accurate diagnoses without unnecessary testing, and on improving coordination of treatment and follow-up with the patient's primary care physician.
- Acute Conditions. For patients with acute conditions (e.g., an infection or injury), the PASC Agreement could focus on choosing the most appropriate treatment for patients and delivering treatment safely and cost-effectively.

Rather than expecting every ACO to develop the capability of directly paying specialists for individual services in new ways, PASC is based on having CMS agree to make three new types of payments to specialists when they deliver services authorized by a PASC Agreement:

- When a specialist delivers one-time services described in the PASC Agreement to an ACO patient, the specialist would be able to bill Medicare for an Enhanced Condition Services (ECS) payment for the patient. The ECS Payment would be in addition to any other payments the specialist would ordinarily be eligible to receive (unless the Agreement specified otherwise).
- If the PASC Agreement authorizes the use of Special ECS payments for a subset of patients with specific characteristics requiring additional time or assistance, and if the patient who is being treated by the specialist has those characteristics, the specialist could also bill Medicare for a Special ECS payment. This would be a direct way of addressing inequities in care delivery for patients with health-related social needs.
- If the primary care physician and specialist agree that the patient would benefit from continued services from the specialist and if the PASC Agreement authorized the use of Continued ECS payments, the specialist could bill Medicare for a Continued ECS Payment each month as long as the patient continued to need and receive the additional services supported by the payment.

How PASC Would Benefit Patients and Payers

PASC would enable specialists to implement better approaches to care for patients with specific types of health conditions. There are many types of conditions where specialists have already developed such care models, but current payment systems do not support the different types of services that need to be delivered. The ECS payments in PASC would fill that gap and enable the improved care models to be quickly implemented in many ACOs. Some of these care models have already been tested in demonstration projects, but there has been no way to continue them because the necessary payment changes have not been made by Medicare and other payers. For example:

- Reducing Hospital Admissions for Chronic Disease Exacerbations. One PTAC member developed a specialty medical home model for patients with Crohn's disease and ulcerative colitis using data and financial support from Illinois Blue Cross Blue Shield. Under the model, gastroenterologists receive payments that enable them to hire nurse care managers to proactively monitor patients' symptoms and identify when medication adjustments are needed. This approach cut the rate of hospitalizations in half for the participating patients. It was the first payment model recommended for testing in Medicare by PTAC in 2017, but it has never been implemented by CMS. The ECS and Continued ECS payments under PASC would enable gastroenterologists and other specialists to deliver these services to Medicare patients who have inflammatory bowel disease.

Similar approaches have been developed by other specialists and specialty societies for other chronic conditions that have a significant risk for hospitalization, such as asthma, COPD, headache, and heart failure. ECS and Continued ECS payments could allow allergists, cardiologists, neurologists, pulmonologists, and other specialists who manage these types of conditions to provide the proactive services needed to reduce ED visits, hospitalizations, and post-acute care.

- Reducing Repeat Emergency Visits and Hospital Admissions. A team of emergency physicians in Colorado led by another PTAC member used grant funds from the CMS Innovation Center to improve care delivery for patients who utilize the emergency department multiple times per year. The award supported home visits by an interdisciplinary team following an emergency department (ED) visit. As described in a [paper published in Health Affairs](#), the model was able to substantially reduce the rate of ED visits and hospitalizations for these patients, and it doubled their number of visits to primary care physicians. Enabling this approach to continue and be replicated was one of the reasons the American College of Emergency Physicians (ACEP) developed the Acute Unscheduled Care Model (AUCM). This payment model was recommended by PTAC in 2018, but it has never been implemented by CMS. The ECS payments under PASC would allow emergency physicians to deliver these kinds of services for patients assigned to an ACO, and the Special ECS payments would allow more extensive services to be delivered to dual eligible patients and other patients with more complex needs, similar to what was done in the CMS-funded project.
- Reducing Complications and Post-Acute Care for Higher-Risk Joint Surgery Candidates. An orthopedic surgeon in New Jersey, Dr. Stephen Zabinski, developed a program of [intensive pre-operative care](#) designed to reduce modifiable risks such as weight, anemia, diabetes control, and smoking for patients who needed joint replacement. These services are not supported by standard fee-for-service payment systems, but thanks to a payment arrangement with [Horizon Blue Cross and Blue Shield](#), physicians were able to significantly reduce inpatient complication rates, more than double the percentage of patients discharged to their home instead of a rehabilitation or skilled nursing facility, reduce total costs, and achieve high patient satisfaction rates. ECS payments under PASC would enable surgeons to deliver similar kinds of services to Medicare patients even if they are not participating in CMS bundled payment models.

We are confident that more specialists would develop innovative care models for additional conditions and for specific subsets of patients who need different approaches to care when the physicians know there is a way to be paid for those care delivery approaches through the PASC program.

Responses to PTAC Questions

- **PASC would assist primary care physicians in making referrals to high-value specialists.** The PASC Agreements would define when and how specialists would deliver services in response to a referral from a primary care physician. This will make it much easier for primary care physicians to know which specialist to refer to in what circumstances and what to expect when a referral is made. Rather than primary care physicians choosing specialists based on limited data about what the specialists have done in the past under the current payment system, the PASC Agreement would specify what the specialist would do prospectively for the referring physician's current patients with support from the ECS payments, and the performance standards they would meet.
- **PASC would enable primary care physicians and other specialists to divide their roles and coordinate their services appropriately for patients with chronic conditions.** The PASC Agreements would provide a formal mechanism to define when a primary care physician should manage care of a chronic condition with assistance from the specialist, when the specialist should manage ongoing care of the patient, or when primary care and specialist physicians should share ongoing management responsibilities. The one-time ECS payment would support the ability of specialists to provide the short-term assistance that primary care physicians often need during the

diagnosis, care planning, and initial treatment phase of chronic condition care. For the subset of patients who require ongoing management by a specialist, the Continuing ECS payments would provide needed support for the specialist to do that while also ensuring that the specialist continues to coordinate services with the primary care physician, as specified in the PASC Agreement.

- **PASC Agreements would provide a mechanism for primary care and specialist physicians to define the methods they would use to communicate about and coordinate patient care.** For example, PASC Agreements could incorporate the principles and processes for care coordination described in [*Beyond the Referral: Principles of Effective, Ongoing Primary and Specialty Care Collaboration*](#) developed by the American College of Physicians.
- **PASC would support greater equity in services and outcomes for underserved populations and patients with health-related social needs.** The Special ECS payments would be specifically designed to support improved services for patients with health-related social needs or other more complex needs. For example, Special ECS payments could be used to support having community health workers assist patients in obtaining medications and food after discharge from an ED or hospital and ensuring that they see their primary care physician for follow-up care.
- **PASC would improve timely access for patients to specialists.** Most specialists want to be more accessible to patients, but their schedules are often filled with visits from many patients who do not really need to see them or who have not been referred to the right specialist. The PASC Agreement could define which patients should be referred to the specialist and how the ACO primary care physicians can get assistance from the specialist to determine whether a referral is needed. The PASC Agreement could also include standards regarding timeliness of the specialist's response when contacted by the primary care physician for information or a referral. By providing support for the enhanced services that specialists would provide, the ECS payments would enable specialists to hold more appointment slots open for the types of referrals covered by the PASC Agreements.
- **PASC would provide incentives for specialists to deliver high-value care without requiring them to take on unmanageable financial risk.** A specialist could only receive an ECS payment for a patient if the specialist has a PASC Agreement with the ACO, and they could only continue to receive payments for patients if they meet the performance standards specified in the PASC Agreement. This means the ECS payments are inherently "performance-based" payments, but the performance standards and the penalties for failure to perform would depend on the specific agreement. For example, falling short of the performance standards could potentially lead to the ACO not renewing the agreement with the specialist.
- **PASC would enable the use of performance measures that match the specific types of care being delivered and the outcomes expected.** There are no quality measures used in the Medicare program for many aspects of the care delivered by specialists. PASC Agreements would define appropriate performance measures for specific types of patients: (a) that would support the ACO's overall goals for delivering quality care and controlling costs, and (b) that the specialist would be able to meet with the additional resources available from the ECS payments. These could be measures of quality, utilization, or both. If a quality or cost measure used in the Merit-Based Incentive Payment System (MIPS) or an ACO quality measure is appropriate, it could be used, but PASC performance measures would not be limited to current MIPS or ACO measures. For example, if a specialist has agreed to follow a specific evidence-based clinical pathway for ordering a specific

Lauran Hardin, MSN, FAAN
Angelo Sinopoli, MD
May 5, 2023
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medication, test, or procedure, the specialist would document whether that pathway was followed for each patient who has the condition that is the focus of the PASC Agreement. The specialist would then provide documentation to the ACO on the percentage of patients who received services consistent with the pathway.

Paying for the Care Patients Need

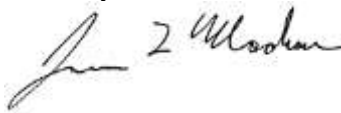
Eight years after the passage of MACRA, most physicians still do not have the opportunity to participate in an APM designed for the kinds of patients they treat or the level of risk they are equipped to take on. Many frontline physicians who have experienced barriers to value-based care in their practices have put in years of work to develop more patient-centered approaches to care delivery for patients, but they cannot implement these approaches without appropriate changes in the Medicare payment system. PASC would enable them to do so.

The use of telemedicine during the pandemic illustrates the critical role of payment policy as both a barrier and potential catalyst for the uptake of care delivery reforms with known potential to improve value. The 2020 expansion in access was made possible only because Medicare and other health plans started paying adequately for these services for the first time.

To achieve higher-quality, more affordable care while addressing our nation's chronic disease epidemics and unacceptable health inequities, we need to accelerate efforts to remove the barriers created by our current payment systems. Population-based payments will not remove these barriers unless Medicare and other payers make specific changes in the way individual physicians are paid for services. Implementing PASC would be a win-win-win – it would enable better care for patients, reduce spending for Medicare and other payers, and help to attract and retain high-quality physicians in medical practice.

Thank you for your work on this important issue and for considering our input. If you need any additional information, please contact Sandy Marks at sandy.marks@ama-assn.org or by phone at 202-789-4585.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with the first name "James" being the most prominent.

James L. Madara, MD



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May 5, 2023

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Request for Public Input to inform PTAC's review of specialty integration in population-based total cost of care (TCOC) models and PFPMs

Dear PTAC members and Staff:

The American Vein & Lymphatic Society is a professional medical association of approximately 1,800 members with a 30-plus year history of advancing patient care and scientific research in venous and lymphatic disorders. We are the largest US professional medical association devoted to venous disorders, and are committed to evidence-based patient care, research, and public education in venous and lymphatic health. Members of our Society come from multiple specialties including vascular surgery, radiology, general surgery, cardiology, dermatology, family practice, and others. Nearly all of our physician members have made venous and lymphatic care their exclusive professional clinical focus.

We appreciate the opportunity to comment, and in general, our comments on this topic are likely mirrored by other medical specialties. We support and encourage the work of the PTAC, but highlight that all models must include careful consideration of specialty care and how pathways for referral for specialty care must be part of any model and the care pathways be transparent.

As a medical condition, venous disease is more prevalent in the United States than coronary artery disease, peripheral artery disease, congestive heart failure, and stroke combined. (<https://www.sciencedirect.com/science/article/pii/S0749379718312030>. Some venous patients can be successfully managed with conservative care, but patients with more advanced chronic venous insufficiency require procedures to solve the underlying venous cause of progressive damage to the skin and soft tissues of the extremities. In our view, venous leg ulceration patients are the most underserved group of wound patients in the current US healthcare system and caring for these patients is known to be quite costly to the Medicare Trust Fund.

However, we would assert that for vein care, the patient return on investment is robust, resulting in improved quality of life, reduced disability, and reduced pain. Chronic venous insufficiency patients frequently will need treatment several years after their initial treatment, which is why following these

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patients longitudinally by a specialist is important. Typically, patients who have no follow-up have venous recurrence of approximately 20-25% at 10 years, caused by perforated collateralization. Venous leg ulcers are the leading cause of a non-healing leg wounds. Chronic venous disease impacts up to 40% of the population and up to 4% of patients 65 years and older will suffer from venous leg ulceration. Venous leg ulcers (VLU) alone consume nearly 2% of the total healthcare budget in developed countries. The average annual incidence of VLU is estimated at 2.2% in Medicare and 0.5% in private insurance populations.

VLU are a \$15 billion a year public and private payer burden in the United States. To put this in perspective, diabetic foot ulcers are only a \$9-13 billion a year burden because the prevalence of venous disease is much higher than diabetes. Venous leg ulcer patients make up most patients in wound care centers, however, the recurrence rate of venous leg ulcers without venous intervention is shown to approximate 30% per year even under the best medical management. Leg ulcer patients in wound care centers often are not properly screened for venous disease even though venous disease is well-known to be the leading cause of leg ulcers. We note the landmark 2018 *New England Journal of Medicine* study, “A Randomized Trial of Early Endovenous Ablation in Venous Ulceration”, showing how ulcer patients who do not receive diagnosis and treatment of their underlying venous disease have ulcers that heal more slowly and recur more often. We also enclose a recent *JAMA* study that highlights to cost-effectiveness of early intervention for venous ulceration patients.

We encourage the work of the PTAC on Total Cost of Care models to consider the following principle:

- Primary Care physicians (PCPs) are usually the first caregivers to see venous disease. No model should have disincentives for PCPs to make a referral
- For patients who have visible vein disease and attest to symptoms, a diagnostic venous ultrasound exam in the standing position is the standard of care for diagnosis
- Conservative care may be appropriate in some cases, but vein clinicians know there is subset of patients who will likely not benefit from conservative care and should be candidates for prompt intervention as needed

We appreciate the opportunity to offer comments to the PTAC, and the AVLS is at the service of the Committee for additional discussions or questions regarding chronic venous disease. Please direct questions to our Healthcare Policy Committee Chair, Dr. John Blebea, and to our Executive Director, Mr. Dean Bender. Dr. Blebea may be reached at blebe1j@cmich.edu, and Mr. Bender at dbender@myavls.org.

With Best Regards,

Kathleen Gibson, MD, FAVLS
President



Original Investigation | Surgery

Cost-effectiveness of Compression Therapy With Early Endovenous Ablation in Venous Ulceration for a Medicare Population

Hanke Zheng, MS; Gregory A. Magee, MD, MSc; Tze-Woei Tan, MBBS, MPH; David G. Armstrong, DPM, MD, PhD; William V. Padula, PhD

Abstract

IMPORTANCE Venous leg ulcers (VLU) are the most common cause of lower extremity ulceration that commonly occur among older individuals and are characterized by a slow healing trajectory and frequent recurrence; in the United States, VLUs affect more than 600 000 people per year with an estimated cost of \$3.5 billion. Clinical trial data show that early intervention with endovenous ablation substantially improves the healing rate and reduces recurrence among patients with VLUs, but there is a need to assess the cost-effectiveness of early endovenous ablation in the US context.

OBJECTIVES To evaluate the cost-effectiveness of early endovenous ablation of superficial venous reflux in patients with VLU from the US Medicare perspective.

DESIGN, SETTING, AND PARTICIPANTS This economic evaluation used a Markov model to simulate the disease progression of VLU for patients receiving compression therapy with early vs deferred ablation over 3 years. The simulated cohort included patients with VLU aged 65 years and older who had clinical characteristics similar to those in the randomized Early Venous Reflux Ablation trial in the United Kingdom. Data were analyzed from September 2021 to June 2022.

MAIN OUTCOMES AND MEASURES Direct medical costs, quality-adjusted life years (QALYs), and the incremental monetary benefits at a willingness-to-pay threshold of \$100 000/QALY. Univariate and probabilistic sensitivity analyses were performed to test uncertainty of model results.

RESULTS This model used a simulated cohort of patients with VLU aged 65 years and older enrolled in Medicare. Early ablation dominated, with a lower per-patient cost of \$12 527 and an increase of 2.011 QALYs, whereas compression therapy with deferred ablation yielded a per-patient cost of \$15 208 and 1.985 QALYs gained. At a \$100 000/QALY cost-effectiveness threshold, the incremental net monetary benefit was \$5226 per patient in favor of early ablation. Probability of healing, followed by the probability of recurrence, was the parameter with greatest impact on model uncertainty. The probabilistic sensitivity analysis showed that early ablation was cost-effective in 59.2% of simulations at the \$100 000/QALY threshold.

CONCLUSIONS AND RELEVANCE In this economic evaluation of compression therapy with early endovenous ablation, early intervention was dominant, as it was cost saving and generated greater QALYs over 3 years from the US Medicare perspective. Payers should prioritize coverage for early ablation to prevent VLU complications rather than treat a costly outcome that also reduces patient well-being.

JAMA Network Open. 2022;5(12):e2248152. doi:10.1001/jamanetworkopen.2022.48152

Key Points

Question What is the cost-effectiveness of early intervention of endovenous ablation for patients with venous leg ulcerations (VLUs) from the Medicare perspective?

Findings In this economic evaluation, early ablation dominated, with a lower per patient cost of \$12 527 and an increase of 2.011 quality-adjusted life years (QALYs), whereas compression therapy with deferred ablation yielded a per patient cost of \$15 208 and 1.985 QALYs gained from the Medicare perspective over a 3-year time horizon.

Meaning In this study, compression therapy with early endovenous ablation was the dominant strategy, as it was cost saving and generated more QALYs over a 3-year time horizon from the US Medicare perspective.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

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December 21, 2022 1/11

Introduction

Venous leg ulcers (VLU) are the most common cause of lower extremity ulceration and are characterized by slow healing trajectory and frequent recurrence. VLUs lead to significant disability, reduced quality of life, and tremendous economic burden.^{1,2} The United States prevalence of VLU ranges from 0.15% to 0.30%, equating to approximately 600 000 cases per year, and is higher among women and older patients.^{3,4} The estimated annual cost of VLU treatment exceeds \$3.5 billion.⁵

The traditional standard of care for VLU is compression therapy, which has been demonstrated as clinically beneficial.⁶ However, adherence to compression therapy is poor due to unacceptability.^{7,8} Alternative treatments including surgical interventions have been proposed. In addition to superficial venous surgery, minimally invasive endothermal treatments, including endovenous laser ablation, radiofrequency ablation, and mechanochemical ablation, have shown valid effectiveness in healing VLU.⁹ In a recent study, cyanoacrylate adhesive ablation was found to be cost-effective compared with surgical stripping for treating varicose veins from the societal perspective in Spain, considering the opportunity costs of medical leave.¹⁰

The Early Venous Reflux Ablation (EVRA) trial conducted in the UK suggests that early ablation with compression therapy substantially increases the healing rate and reduces the chance of recurrence of VLU.^{11,12} Early ablation has also shown to be cost-effective in the long term from the UK health care sector perspective.¹² Given the uniqueness and complexity of the US health care system, particularly in the Medicare and dual-eligible (ie, Medicare and Medicaid) populations, we aim to assess the cost-effectiveness of early endovenous ablation with compression therapy among older patients with VLU from the US Medicare perspective. These economic data can be used by payers that participate in Medicare programs to cover and rank early ablation for VLU with respect to other alternative forms of treatment.

Methods

Model Overview

Our study analyzed the cost-effectiveness of compression therapy with early vs deferred endovenous ablation among VLU patients aged 65 years and older from the US Medicare perspective, following methods prescribed by the US Panel on Cost-effectiveness in Health and Medicine and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) reporting guidelines.^{13,14} Per the Common Rule, this study was exempted from institutional review board approval and informed consent because no human participants were involved.

The treatment assignment and the clinical features of the patients included in the model were based on the UK EVRA trial.^{11,12} Specifically, the early intervention was defined as receiving compression therapy and undergoing early endovenous ablation, ie, performed within 2 weeks after VLU became clinically significant. Patients receiving deferred intervention would receive compression therapy alone and deferred the ablation until the ulcer had healed or after 6 months if the ulcer had not healed.

Patients entered the model with an open VLU for a period of between 6 weeks and 6 months, an ankle-brachial index of 0.8 or higher, and primary or recurrent superficial venous reflux that was deemed by the treating clinician to be clinically significant. We developed a Markov model with 3 mutually exclusive health states (ie, unhealed VLU, post-VLU [healed], and death) to simulate the disease progression of VLU (**Figure 1**). Patients began in the unhealed VLU state and could stay unhealed or transition to post-VLU (healed) or death states based on their assigned transition probabilities.

Monthly cycles were used to assess the costs and outcomes associated with the 3 health states. The time horizon used for the base case was 3 years. Both costs and health outcomes were discounted at an annual rate of 3%. All monetary terms were converted to 2021 US dollars using the

Medical Component of the Consumer Price Index.¹⁵ The primary outcomes of the model included the costs associated with VLU treatment and management and quality-adjusted life years (QALYs) gained per patient. These data were used to derive the incremental net monetary benefits (NMB) at a cost-effectiveness threshold of \$100 000/QALY.

Probabilities

Transition probabilities between unhealed VLU and post-VLU (healed) were calculated based on the healing rate and recurrence rate from the EVRA trial (Table 1).^{11,12,16} The EVRA trial reported the healing rate at 6 months and 12 months as well as the recurrence rate from 1 year up to 3 years after the treatment initiation. Most patients were healed within 6 months (85.6% in the early ablation group vs 76.3% in the deferred ablation group); more were healed within 12 months (93.7% in the early ablation group vs 85.8% in the deferred ablation group). The recurrence rates at 3 years were 24.5% for the early ablation group and 29.9% for the deferred group. Based on the EVRA trial data, we calculated the monthly between-state transition probabilities applying the declining exponential approximation of life expectancy methods.¹⁷ The probability of healing after 12 months was assumed to be half of that between 6 and 12 months to reflect the reality that some patients might have smaller chance to heal. Given the insufficient evidence for an increased risk of mortality associated with VLU, we used all-cause mortality for the general population age 65 years and older in the United States.¹⁶

Figure 1. Markov Model Simulation of Venous Leg Ulceration (VLU) Disease Progression

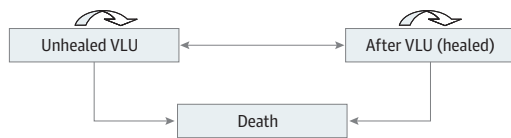


Table 1. Transition Probability Base Case Inputs and Range for Sensitivity Analyses

Parameter	Cycle transition probability (±20% range)	Source
Compression with early ablation		
Probability of healing		
Month 1 to <6	0.133 (0.106-0.160)	Gohel et al, ¹² 2020
Month 6 to <12	0.090 (0.072-0.108)	Gohel et al, ¹² 2020
Month ≥12	0.045 (0.036-0.054)	Gohel et al, ¹² 2020
Probability of recurrence		
Month 1 to <12	0.011 (0.009-0.013)	Gohel et al, ¹² 2020
Month 12 to <24	0.004 (0.003-0.004)	Gohel et al, ¹² 2020
Month 24 to <36	0.007 (0.006-0.009)	Gohel et al, ¹² 2020
Compression with deferred ablation		
Probability of healing		
Month 1 to <6	0.119 (0.096-0.143)	Gohel et al, ¹² 2020
Month 6 to <12	0.065 (0.052-0.078)	Gohel et al, ¹² 2020
Month ≥12	0.032 (0.026-0.039)	Gohel et al, ¹² 2020
Probability of recurrence		
Month 1 to <12	0.016 (0.013-0.019)	Gohel et al, ¹² 2020
Month 12 to <24	0.005 (0.004-0.006)	Gohel et al, ¹² 2020
Month 24 to <36	0.007 (0.005-0.008)	Gohel et al, ¹² 2020
All-cause mortality		
Month 1 to <12	0.001 (0.0008-0.0012)	CDC, ¹⁶ 2017
Month 12 to <24	0.001 (0.0008-0.0012)	CDC, ¹⁶ 2017
Month 24 to <36	0.001 (0.0008-0.0012)	CDC, ¹⁶ 2017

Abbreviation: CDC, Centers for Disease Control and Prevention.

Costs

Direct medical costs associated with VLU treatment were considered in the model (Table 2).¹⁸⁻²¹ Specific cost components included costs of endovenous ablation, compression therapy, pain medication, additional home health, and hospitalization due to infections and complications of VLU. The Medicare national average reimbursement rates in accordance with the *Current Procedural Terminology (CPT)* codes and diagnosis-related groups (DRGs) identified for the VLU-related medical procedures and services were sourced from the Centers for Medicare & Medicaid Services (CMS) data sets and published literature.¹⁸⁻²¹ We derived the total costs as the product of quantity used and the relevant unit costs. The CPT codes were identified to target costs for the endovenous ablation (mechanochemical ablation: 36473 and 36474; endovenous radiofrequency: 36475 and 36476; endovenous laser: 36478 and 36479).²² In the EVRA trial, the endovenous treatment decision was left to the discretion of the clinicians, and no granular data about the specific procedure utilization were reported. Thus, according to the expert opinion of Gregory A. Magee, MD, MSc (May 10, 2021; online meeting), we assumed 40% of patients to be treated with mechanochemical ablation, 40%

Table 2. Direct Costs of Venous Leg Ulceration Treatment

Cost parameter	CPT or DRG code	Medicare costs (±20% range), \$	Source
Intervention costs			
Endovenous radiofrequency	36475	1323 (1059-1588)	CMS, ¹⁸ 2021
Radiofrequency added on with multiple veins treatment	36476	314 (251-377)	CMS, ¹⁸ 2021
Endovenous laser	36478	1215 (972-1458)	CMS, ¹⁸ 2021
Laser added on with multiple veins treatment	36479	138 (111-166)	CMS, ¹⁸ 2021
Mechanochemical			
Ablation	36473	1448 (1158-1737)	CMS, ¹⁸ 2021
Ablation added on with multiple veins treatment	36474	296 (237-356)	CMS, ¹⁸ 2021
Physician payment, facility			
Physician initial visit			
Evaluation	99203	85 (68-102)	CMS, ¹⁸ 2021
Debridement	11042	63 (51-76)	CMS, ¹⁸ 2021
Physician, debridement, established visit	97597	36 (29-44)	CMS, ¹⁸ 2021
Physician, compression only	99212	36 (29-44)	CMS, ¹⁸ 2021
Facility reimbursement			
Initial visit	99213	86 (69-104)	Nherera et al, ¹⁹ 2016
Debridement, initial visit	11042	220 (176-264)	Nherera et al, ¹⁹ 2016
Debridement established visit	97597	114 (91-137)	Nherera et al, ¹⁹ 2016
Compression only	29581	83 (66-99)	Nherera et al, ¹⁹ 2016
Home health			
Home health (60-d episode)	C2F2S1	2808 (2246-3370)	Carter et al, ²⁰ 2014
Compression			
Compression stocking (per pair for 6 mo)	A6532	72 (58-86)	Carter et al, ²⁰ 2014
Hospitalization costs			
Skin debridement with complication	571	10 832 (8665-12 998)	CMS, ²¹ 2019
Skin ulcer with complication	593	8882 (7105-10 658)	CMS, ²¹ 2019
Cellulitis			
No major complication	603	5562 (4449-6674)	CMS, ²¹ 2019
Major complication	602	9872 (7898-11 847)	CMS, ²¹ 2019
Pain medications (prescription drugs), calculated monthly cost			
Amitriptyline	NA	43 (35-52)	Carter et al, ²⁰ 2014
Gabapentin	NA	124 (99-149)	Carter et al, ²⁰ 2014
Hydrocodone	NA	22 (17-26)	Carter et al, ²⁰ 2014

Abbreviations: CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; DRG, diagnosis-related group; NA, not applicable.

to receive endovenous radiofrequency, and 20% to receive endovenous laser. Among them, 10% were assumed to have more than 1 vein treated on a single extremity. Since the Medicare reimbursement rate for these 3 ablation procedures were nearly equivalent (Table 2), the assumption about specific procedure utilization was not expected to result in great variations in the calculated costs.

Costs of compression stocking and outpatient visits associated with debridement and compression therapy were also considered. For the outpatient visits, we assumed 1 visit per week to reflect a typical frequency of visits until the wound healed.²⁰ According to the CMS reimbursement policy, no compression billing is allowed if debridement occurs.²⁰ Taking the established data from the existing cost-effectiveness analyses, the estimated likelihood of debridement per week was 12.5%, and it was assumed to only occur within the first 3 months, representing a reasonable debridement frequency of the VLU treatment.^{20,23} After that, only CPT codes for an established clinic visit for compression were used to generate costs for outpatient visits. Additionally, 25% of patients would have 1 home health care visit per week to change dressing.²⁰ We used the code C2F2S1 from the Medicare home health prospective payment system to obtain the cost of home health within a 60-day episode for Medicare.

We incorporated the costs of hospitalization due to VLU and common infections, such as cellulitis, into the model.²⁴⁻²⁶ For patients with unhealed VLU, the annual rate of hospitalization for VLU visits and infections were referenced from a cost-effectiveness analysis assessing the management of chronic VLU, which translated to a monthly probability of 0.83% for hospitalization due to skin debridement with complications and/or due to skin ulcer with complications, 0.08% for cellulitis with major complications, and 0.33% for cellulitis without complications. The DRG codes for VLU were extracted to derive the hospitalization costs, including DRG 571 (skin debridement with complications and comorbidities) and 593 (skin ulcer with complications and comorbidities).^{19,20} DRGs 602 and 603 (cellulitis with and without major complications) were used to determine the hospitalization costs for infections.^{19,20} The national average Medicare hospitalization payment was referenced to calculate the costs to the payer.²¹ We omitted the costs associated with antibiotics for infection because it was low and negligible.²⁰

Given the fact that patients with VLU commonly exhibit pain caused by the disease, our study considered the costs of pain management directly associated with VLU, including amitriptyline (40%), gabapentin (10%), and hydrocodone (50%).^{20,27} For patients healed from VLU, we included the costs of compression stockings as it is considered as a standard care in the management after VLU.²⁸

Health Utilities

The utilities measuring patients' quality of life (QOL) were assigned by health state, based on data reported from the Euro-QOL 5-Domain index of US nationally representative QALYs reported by Sullivan and Ghushchyan.²⁹ We took the utility score of people affected by chronic ulcer of skin, based on *International Classification of Diseases, Ninth Revision (ICD-9)* codes 707.0 for the unhealed VLU state (0.69) (eTable in Supplement 1). The utility score for the healed VLU state (0.75) was derived from another study³⁰ that assessed the effect of VLU on QOL in the UK population (eTable in Supplement 1). To account for the impact of aging on people's preference of QOL, we adjusted these utility scores to estimate the perception of individuals aged between 65 and 74 years using the US population disutility for aging.³¹

Sensitivity Analyses

To understand the how changes in value of a specific parameter would affect the model results, univariate sensitivity analysis was performed by varying each parameter within its $\pm 20\%$ range. Probabilistic sensitivity analyses (PSAs) were carried out to test concurrent uncertainty of the base case results based on model structure, parameter sourcing, and sampling simultaneously. We generated 10 000 Monte Carlo simulations for the PSA by varying all model inputs according to their

given distributions. We then created a cost-effectiveness acceptability curve using the simulated cases, which allows for the visualization of the likelihood that early ablation is cost-effective at varying willingness-to-pay thresholds. The expected value of perfect information (EVPI) per person was calculated to inform the amount to invest for future research to eliminate the uncertainty for the recommended optimal strategy.

Budget Impact Analysis

To estimate the monetary impact of implementing early ablation for patients with VLU from the payer’s perspective, we conducted a budget impact analysis in a hypothetical population of 1 million members, assuming 1000 VLU cases among the members having clinical characteristics as presented in the model. We reported the total budget impact of early endovenous ablation and the per-member-per-month (PMPM) amount at 1 year, 3 years, and 5 years after the intervention.

Statistical Analysis

Descriptive statistics of costs and QALYs over 1 year and 3 years are presented. Excel 2016 (Microsoft Corp) was used for all statistical calculations, simulations, and figure production. Data were analyzed from September 2021 to June 2022.

Results

We created a simulated cohort of patients with VLU aged 65 years and older enrolled in Medicare. Compression therapy with early endovenous ablation was the dominant option by yielding more QALYs at a lower cost. The total cost of early intervention was \$12 527, and the total QALYs gained were 2.011 per person at a 3-year time horizon from the US Medicare perspective (Table 3). In contrast, compression therapy with deferred ablation yielded a total cost of \$15 208 and 1.985 QALYs per person. Thus, at the cost-effectiveness threshold of \$100 000/QALY, the incremental NMB of early ablation was \$5226 per person at 3 years. The base case results of early ablation were dominant at both 1 year and 3 years, with an increasing incremental NMB with longer time horizon.

Sensitivity Analyses

In the univariate sensitivity analysis, the parameter showing the greatest impact on the incremental NMB was the probability of healing, followed by the probability of recurrence. If varying the probability of healing for patients receiving early ablation in the first 6 months within its ±20% range, the incremental NMB would range from −\$17 192 to \$27 691 per patient.

Based on the 100 000 cases simulated in the PSA, the average incremental NMB generated by early intervention was \$5286 per person. The cost-effectiveness acceptability curve derived from the PSA illustrates a greater likelihood of early ablation being cost-effective regardless of the cost-effectiveness threshold (Figure 2). At \$100 000/QALY thresholds, compression with early endovenous ablation was cost-effective in 59.2% of the 100 000 simulated cases, and this probability decreased to 57.4% if applying a \$150 000/QALY threshold. At a \$100 000/QALY

Table 3. Base Case Results

Treatment	\$		QALYs	Incremental QALYs	ICER	INMB, \$
	Cost	Cost difference				
1 y						
Deferred ablation	8423	−636	0.699	0.004	Early ablation dominates	981
Early ablation	7787		0.703			
3 y						
Deferred ablation	15 208	−2681	1.985	0.026	Early ablation dominates	5226
Early ablation	12 527		2.011			

Abbreviations: ICER, incremental cost-effectiveness ratio; INMB, incremental net monetary benefits; QALYs, quality-adjusted life years.

threshold, the EVPI was \$6341 per person from the Medicare perspective, meaning that investing \$6341 in research on each person with VLU would increase our confidence in the recommendation of optimal strategy.

Budget Impact Analysis

Assuming 1000 patients with VLU in a hypothetical 1-million-member health plan, compression therapy with early endovenous ablation generated a total cost saving of \$636 238 at 1 year and \$2 680 246 at 3 years, which was equivalent to a PMPM difference of \$0.053 at 1 year and \$0.075 at 3 years. Therefore, early endovenous ablation for patients with VLU was cost-saving from a payer’s perspective,

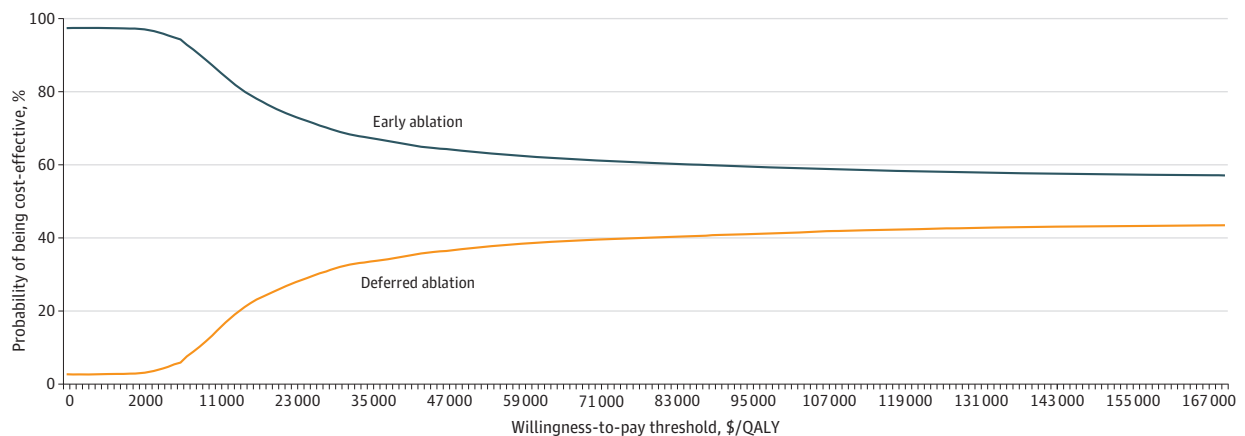
Discussion

Our study addressed the unmet need for an economic evaluation of early intervention of endovenous ablation for patients with VLU. According to our analysis, compression therapy with early endovenous ablation dominated deferred ablation since it provided care for VLU at a lower cost and improved patient QOL over a 3-year period from the Medicare perspective. This finding is robust, as supported by PSA results. These cost-effectiveness results apply specifically to a simulated cohort of individuals aged 65 years and older, among whom the highest concentration of VLUs occur in the United States.^{3,4} Payers wishing to deliver greater health benefits for their patients while saving costs should place early endovenous ablation at the top of their formulary for patients with VLU. While the calculated budget saving is insignificant, it increases the likelihood for payers to adopt early ablation without displacing resources for other patients in need.

Medicare programs stand to benefit from the findings of the EVRA trial combined with this economic evaluation. Medicare spends more than \$1.0 billion per year on the chronic management of VLUs.³² The findings of this study suggest that this spending could be conserved if more interventional procedures, such as early endovenous ablation, are undertaken decisively for patients with clinically significant VLU to mitigate downstream costs of chronic wound care, not to mention gains in clinical benefits for patients through intact skin.

Health systems that implement these types of early interventions need to be properly incentivized by Medicare payments and performance measures to be sustainable. Currently, health systems reap approximately \$100 billion per year in chronic wound management because conditions including VLU, pressure injury, diabetic foot ulcer, and others require chronic wound care in outpatient and long-term care settings.^{32,33} Health systems that transition to measures such as early

Figure 2. Cost-effectiveness Acceptability Curve of Early vs Deferred Ablation



Abbreviation: QALY, quality-adjusted life years.

endovenous ablation may lose money by providing procedures up front for a fraction of the cost to avert downstream chronic wound care costs. As a result, Medicare should work with health systems to increase the reimbursement rate for early endovenous ablation while maintaining its dominance as cost-effective to increase incentives for its use and to compensate for losses from less chronic wound care in the long run. Medicare could also develop a pay-for-performance incentive that would reward health systems that improve population health by effectively managing the prevention of escalated VLU cases in the chronic phase to leverage value of care, as has been piloted with other types of health outcomes, including cardiovascular disease, diabetes, and cancer.³⁴⁻³⁷

Limitations

This study has several limitations. First, data on the clinical efficacy of early endovenous ablation are based on a trial from the United Kingdom and do not necessarily represent outcomes that pertain to a US patient population. For example, in the EVRA trial, the average age of the participants randomized with early intervention was 67.0 years, and it was 68.9 years among those assigned to deferred intervention. The US Medicare population is likely to be older than the trial population, as most Medicare beneficiaries are aged 65 years and older.³⁸ Second, the EVRA trial examined the clinical benefits of early ablation compared with delayed ablation with compression therapy in a controlled setting. Since we know compression therapy has low adherence, the results of this economic evaluation represent a lower-bound given that patients in real-world settings gain fewer clinical benefits from delayed ablation with compression therapy when they lack adherence. Third, in the EVRA trial, the type of ablation technology to apply was left to the discretion of the clinical team. Due to the lack of data, an assumption was made about the share of different ablation procedures to account for the ablation-related costs in the US context based on expert opinion, but this assumption was not expected to result in great variation of the results because the costs of these ablation procedures borne by Medicare are close (Table 2). Furthermore, the healing rate after 12 months was assumed to be half of that between months 6 and 12 because it was not reported in the EVRA data. We captured the uncertainty of the assumption in our sensitivity analyses. In addition, the economic model did not control for variability in the population of patients with VLU, of which there are many sociodemographic causes. Patients in rural areas, or patients who are predisposed to health disparities that perpetuate challenges to accessing specialty care for VLU, may have less predictable outcomes.^{33,39} However, one could make that argument that a swift and effective treatment such as early ablation would be more efficient, particularly for individuals facing health disparities, than treatments that require consistent follow-up in the long run for chronic wound management.

Conclusions

In this economic evaluation of compression therapy with early endovenous ablation, we found early ablation to be a cost-effective alternative to delayed ablation with compression therapy for Medicare patients diagnosed with VLU. Medicare should consider innovative payment models that increase incentives for health systems to deploy early endovenous ablation to all eligible patients with VLU. Doing so will save on the excessive costs of chronic wound care and improve clinical benefits for patients that currently face long durations of follow-up and extreme pain caused by VLU.

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Author Contributions: Ms Zheng had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.

Acquisition, analysis, or interpretation of data: Zheng, Tan, Armstrong, Padula.

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Critical revision of the manuscript for important intellectual content: All authors.

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SUPPLEMENT 1.

eTable. Utility Values of Venous Leg Ulceration

eReferences.

SUPPLEMENT 2.

Data Sharing Statement