PREMIER TRANSFORMING HEALTHCARE TOGETHER®

August 16, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–5540–NC

Submitted electronically to: http://www.regulations.gov

Re: Request for Information; Episode-Based Payment Model [Docket Number: CMS–5540–NC]

Dear Administrator Brooks-LaSure:

Premier Inc. appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) in response to its request for information (RFI) on the design of a potential new episode-based payment model that is centered around improving beneficiary care, lowering Medicare expenditures, reducing fragmentation, and increasing care coordination across healthcare settings.

In our detailed comments below, Premier urges CMS to:

- Focus episodic models on acute conditions or procedures that have defined and well-established care practices or medical protocols.
- Design episodes that are tailored to the specific condition or procedure and needs of the patient, including varying the length of the episode, defining the initial episode trigger and refining what items or services are included in the episode based on clinical protocols.
- Ensure a mandatory episodic model provides meaningful opportunities for participants to take on two-sided risk, including opportunities for upside financial gain and gradual risk options. CMS must also ensure to establish appropriate provider exclusion criteria and provide sufficient information in advance of the model start.
- Grant precedence to providers participating in existing alternative payment models (APMs) when addressing overlap with a new mandatory episodic model. CMS should also provide opportunities for voluntary participation under the new mandatory model.
- Maintain flexibility and establish incentives to support accountable care organizations (ACOs) and episode initiators in developing partnerships that improve care coordination and patient outcomes.
- Adopt new incentives and modify existing policies to support integration of specialists into ACOs, including supporting ACOs in the development of “shadow bundles.”
- Modify existing episodic target price methodologies to adopt regional or national target pricing, provide greater transparency around trend factors, improve risk adjustments to account for high-cost patients and modify timing of financial reconciliations.
- Advance health equity by improving collection and standardization of social determinations of health (SDOH) data and by adjusting episodic payment methodologies to ensure target prices appropriately account for the needs of underserved patients.
- Ensure quality measures are relevant to the care furnished in the episode and minimize burden for participants.

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I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier operates a Bundled Payment Collaborative which has worked with more than 300 hospitals and physician group practices (PGPs) across CMS Innovation Center bundled payment models over the last decade.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. CLINICAL EPISODES

To date, CMS has included a broad array of episodes under its voluntary bundled payment models. For example, the Bundled Payments for Care Improvement (BPCI) Advanced model includes 34 separate medical and surgical episode categories. As CMS acknowledges in the RFI, its evaluations have had mixed results across BPCI Advanced episodes – with surgical episodes achieving more significant reductions in costs compared to medical episodes.[1] CMS anticipates pursuing a narrower set of clinical episodes under its next episodic payment model and seeks comment from stakeholders on the design of those episodes.

The goal of episodes should be centered around the management of acute medical events or procedures that present opportunities for improving quality of patient outcomes and addressing variations in cost. This stands in contrast to total cost of care models, which are centered around preventive care and are better suited to addressing chronic conditions over longer periods of time. To that end, ***Premier recommends that CMS differentiate episodes of care based on the condition and procedures, needs of the patient and which entity is best suited to manage care of the patient.*** To support those efforts, Premier recommends the following principles for the design of clinical episodes:

- ***Standalone episodes of care should focus on acute conditions or procedures that have defined and well-established care practices or medical protocols***, such as orthopedic procedures, certain cardiac procedures/care, spinal procedures and neurological conditions, such as stroke or seizures. These types of procedures or conditions typically will require care for a set-period of time, which will be managed by a specialist in coordination with other providers. The types of care furnished under these procedures or conditions are also typically well-defined, lending themself to be included in an episode of care.

  As discussed in greater detail below, chronic conditions generally require care to be managed longer term and are likely best managed through ACOs, with a focus on prevention and care management. As a result,

[1] https://innovation.cms.gov/data-and-reports/2022/bpci-adv-ar3-findings-aag

CMS should generally consider dropping any chronic condition episodes that are typically managed by primary care physicians or other specialists long-term and allow those to be managed through accountable care relationships.

- ***Episode design should be based on the clinical protocols for the acute condition or procedure*.** To date, CMS has typically designed episodes around an acute care hospitalization or outpatient procedure (or a "trigger" event) and includes nearly all care furnished during the hospitalization and for 90 days post-discharge with minimal exclusions. This can create challenges for participants who are oftentimes held accountable for additional care that is unrelated to the episode, such as hospitalizations for a new condition or drug costs for treatment of unrelated health issues.

  As a result, CMS notes that it is exploring a shorter episode of care, which would hold participants responsible for care furnished during the hospitalization and 30-days post-discharge. Premier is concerned that this approach may severely limit the ability of participants to improve both the quality and efficiency of care furnished during the episode. For example, under a surgical episode in the BPCI Advanced model, post-acute spending makes up approximately 38 percent of total episode costs, with approximately a third of those costs occurring between days 31-90 of the episode, according to a Premier analysis. Moving to a 30-day episode would mean that the anchor hospitalization accounts for 70 percent of the episode costs and that the post-acute spending makes up approximately 30 percent. Given hospitals are paid a MS-DRG payment – which is an episodic payment – participants would be left with minimal opportunities to improve care coordination and reduce Medicare spending post-discharge. The challenge is even more pronounced when looking at certain surgical episodes, such as cardiac procedures. Under a 30-day cardiac episode, nearly 85 percent of the target price would be accounted for in the MS-DRG payment, leaving bundled payment initiators with minimal opportunity to improve care coordination post-discharge and reduce Medicare spending. This will not only limit the success of model participants but will also reduce the opportunities for CMS to realize Medicare savings under the model. As a result, instead of limiting the episode to only 30 days, ***Premier strongly recommends that CMS identify an appropriate trigger and set the length of the episode based on what is clinically appropriate***.

  Some episodes of care are planned and start prior to a hospital admission or outpatient procedure. As a result, CMS should explore modifying the point at which an episode is triggered and broaden episodes to include pre-operative care or office visits related to the procedure, with a focus on improving care coordination prior to the procedure or hospital stay.

  Finally, many of the challenges associated with a longer episode could be addressed if CMS were to revisit how it identifies which costs are included in the episode of care. The current "exclusion lists," which are used to identify which items or services are not included in the episode, are limited in scope and often leave many unrelated items and services as part of the episode. For example, some BPCI Advanced participants are being held accountable for items and services unrelated to the initial episode of care, such as a joint replacement on Day 80 of an episode triggered by a urinary tract infection. CMS should revisit the development of its exclusion list for episodes to ensure participants are only held accountable for care that is truly relevant and clinically appropriate to the episode of care.

To that end, ***Premier strongly recommends that CMS reconsider a 30-day episode of care and instead work with stakeholders, including clinicians, to model and design episodes of care around defined acute conditions or procedures.*** In doing this, CMS should prioritize episodes of care that provide meaningful opportunities for participants to engage in care re-design efforts. To improve stability of episode pricing methodologies and ensure participants have meaningful opportunities to participate, CMS should select episodes that are high volume and have variability in costs.

Episode design should <u>not</u> be one-size-fits all but instead be tailored to the specific condition or procedure and the needs of the patient. As part of this, CMS should vary the length of episodes to match what is clinically appropriate for a specific condition or procedure and set the "triggering" event based on when care was first planned or furnished, such as a pre-operative office visit. Finally, CMS should refine how it defines what care is included in the episode to ensure participants are only held accountable for care that is relevant to a procedure or acute condition and any follow-up or post-acute care, including preventable readmissions.

III. MANDATORY MODEL DESIGN

CMS notes that it anticipates under its next episodic model that it will require participation from certain Medicare providers to "help overcome voluntary model challenges such as clinical episode selection bias and participant attrition." As we have noted before, Premier believes that voluntary models with the appropriate incentives are ideal as they allow providers to select participation based on their mission, abilities and market realities. ***However, as CMS evaluates the design and considers adoption of future mandatory episodic models, Premier strongly urges CMS to consider the following key design principles****:*

- ***Provide opportunities for upside financial gains, as well as gradual risk options***. CMS should design APMs that allow for meaningful opportunities to take on two-sided risk. For example, when designing a mandatory model, CMS must ensure that there are opportunities to reward participants for their performance under the model and that the model is not simply a payment cut. A few years ago, CMS proposed a mandatory model centered around radiation oncology. Premier had raised several concerns with the design of that model, one being that the model was simply testing a payment cut to providers and offered no opportunity for providers to take on meaningful risk under the model.[2] The goal of APMs should be to fundamentally change care delivery and improve population health, rather than seeking opportunities to leverage market dynamics to reduce costs. To that end, CMS should incorporate opportunities for both upside and downside risk in models. For example, CMS should allow participants to "earn back" or reduce the discount applied under the model based on their quality performance.

  Mandatory models should also offer opportunities for providers to gradually assume financial risk to ensure all providers have an opportunity to succeed. For example, if CMS pursues a mandatory model, it should create a graduated glide path to risk, similar to the approach used in the Medicare Shared Savings Program (MSSP). This would allow providers who may have limited experience in APMs to gain experience in the model before incurring significant financial risk. Providers who are prepared for significant risk could accelerate to a track with higher risk (and higher reward) if they so choose.

  Additionally, to support practice transformation and ensure all providers can participate in the mandatory model, CMS should include a performance year 0 (PY0) to give providers an opportunity to evaluate their historical performance and operationalize the model. This approach would allow participants to change workflows to align with the model, utilize performance data from CMS to identify areas for transformation and receive additional education from CMS on model parameters and meeting objectives. Additionally, it would allow CMS to work through any operational challenges to help minimize any changes to the model prior to model launch.

- ***Address overlap with other models by granting precedence to providers in existing models*****.** Premier urges CMS to provide exceptions for providers already in APMs when existing models overlap with the new mandatory model. Precedence should be given to the previously established models that are already in testing, as these providers have voluntarily taken on the work and invested in value transformation.

[2] https://www.premierinc.com/newsroom/policy/premier-submits-comments-on-cy-2022-medicare-outpatient-proposed-rule

Additionally, as discussed in greater detail below, CMS should create a process for providers to request an exemption from the mandatory episodic model if they are participating in an ACO that is actively managing the procedure or condition through a shadow bundle or other type of care intervention.

Finally, CMS should explore targeting regions for mandatory participation that do not already have a high penetration of APM participants. For example, CMS could consider stratifying regions based on share of beneficiaries that are aligned with the MSSP or Innovation Center models. When selecting regions, CMS should give greater weight to regions that have a lower share of beneficiaries already aligned with models. This will not only help to better target the model to regions where APM participation has been historically low but will also help reduce potential overlap with existing efforts or initiatives. Furthermore, this approach may assist with creating better diversity in the patients participating in APMs as well as geographical diversity. This policy should be paired with appropriate provider exclusions and grant providers not selected for participation with an opportunity to voluntarily participate, as discussed in greater detail below.

- ***Establish appropriate provider exclusion criteria that recognize the challenges that rural and low-volume providers face with mandatory participation***. Many rural and low-volume providers cannot absorb the additional costs and potential payment cuts that may result from mandatory payment models. Additionally, providers who have low volume of procedures can face significant variability in performance and large losses due to only a handful of patients. For example, under the Comprehensive Care for Joint Replacement (CJR) model, the low-volume threshold is set at fewer than 20 procedures across a three-year historical period. This threshold is exceptionally low and has resulted in CJR participants being included in the model who may not see more than 10 to 15 joint replacement procedures each year. Not only will this limit the participant's ability to fully engage and invest in the model, but the low volume can create significant variability in their performance. For example, one CJR participant that Premier works with never exceeded 15 episodes per performance period. The low volume combined with social determinants of the population they served resulted in significant financial losses due to the inability to create a normalized population distribution. Premier urges CMS to design appropriate exclusion criteria that protect rural and low volume providers and help protect access in these communities.

- ***Provide sufficient information and data in advance of model test starts***, including provision of actionable claims data to allow sufficient time for data analysis and subsequent information sharing with participant stakeholders. It is essential that CMS provides participants with sufficient time from when policies are finalized until the launch of the model. Ideally, ***CMS should provide participants with a minimum of one year from when the final rule/model is published to the launch of the model to ensure all participants have sufficient time to prepare.***

  Additionally, evaluating claims data is an important component of successful participation in any value-based model. Prior to the model start, it is important for participants to understand historical performance, identify opportunities for improvement and monitor the effects of implemented change over time. There are multiple challenges with analyzing claims data, ranging from varying time periods, timeliness of data availability, accuracy of data and inability to replicate methodologies or validate outcomes. Providing enough data to allow participants to evaluate a patient's care is of critical importance as we look to create efficient care across the continuum.

  In addition to the claims that make up an episode, supplemental data is also beneficial to participants in understanding other opportunities for improvement. For example, providing additional data such as SDOH data, integrating with hospital electronic health records (EHRs) to collect real-time information and providing information relate to other providers in the region associated with episode-specific care could serve to identify high-quality partners and high-risk beneficiaries. For example, Premier strongly encourages CMS to work with the stakeholder community to identify additional ways to get participants real-time or more timely

access to data, which would allow for them to identify transitions of care earlier and opportunities to further improve care coordination across the continuum.

As noted above, CMS should also consider a PY0 to allow participants enough time to perform internal analyses, identify improvement opportunities and prepare appropriate supportive infrastructure. In addition to finalizing the parameters of the model, it is also essential that CMS provide any relevant sub-regulatory guidance or data in a harmonious manner at least a year in advance of the model launch. This includes any information on waivers and other key policies for implementation, such as the financial methodology, any applicable target prices, benchmarks, reporting responsibilities or performance measures. Without this information providers do not have sufficient time to prepare for the model start.

- ***Provide options for participation***. Premier recognizes that CMS is interested in pursuing a mandatory model to ensure broad participation and to minimize selection bias. However, Premier strongly encourages CMS to provide flexibilities and options for those participants who are mandated to participate. For example, CMS should allow participants to select from a menu of available episodes, as this will allow participants to select those episodes of care that best meet the needs of their patient population and align with their facilities' experiences and clinical focus. CMS could also consider phasing in additional episodes over time.

- ***Provide opportunity for voluntary participation***. Finally, CMS should create an opportunity for providers to opt-in to the mandatory model to maintain momentum in value-based care and continue a patient-centric focus. Many providers have invested heavily in participation in episodic payments over the last decade and should be given an opportunity to continue those efforts. With the concentrated focus on health equity, allowing voluntary participants in a new mandatory model has the potential to extend beneficiary reach and access to high-quality care, as well as provide additional opportunities for CMS and providers to work together to improve cost, utilization and patient care broadly.

- ***Engage with stakeholders early on the design of mandatory models.*** Premier appreciates that CMS is soliciting input on the future direction of a mandatory episodic payment model through this RFI. We encourage CMS to continue to engage with the provider community on the specific design of the model, such as through roundtables or listening sessions, over the next several months prior to the release of the anticipated proposed rule. This will ensure that CMS puts forward a model that is both operational and grants providers meaningful opportunities to advance delivery system transformation.

IV. MODEL OVERLAP

In the RFI, CMS acknowledges the benefits of beneficiaries being aligned to both episode-based payment models and ACOs, while noting that overlap can create challenges for collaboration and may result in duplicative savings. Premier appreciates that CMS notes it wants to avoid precedence or exclusionary rules under a mandatory episode-based payment model and that it believes overlap between episodes and ACOs should be supported through complementary policies.

As noted above, ***Premier recommends that CMS allow providers already participating in voluntary APMs, such as ACOs, an opportunity to opt out of a mandatory episodic model if they are actively managing the procedure or condition through a shadow bundle or other type of care intervention.*** This would ensure that the new model does not duplicate the efforts that ACOs already have underway with hospital partners. CMS should work with stakeholders to identify a process for participants to identify these interventions – including the criteria for the types of interventions that would qualify – and to request an exclusion from the mandatory model.

CMS also seeks comment on how to handle overlap between beneficiaries who are aligned to both an ACO and episodic model. Premier understands that CMS is concerned around the need to account for how savings are accrued across model participants. However, Premier believes that existing overlap is relatively limited and the benefits to overlap likely outweigh the potential challenges that might be created through complex precedence rules that limit the ability of ACOs to partner with episodic initiators under the model. As CMS acknowledges in the RFI, research has also found significant benefit to beneficiaries being affiliated to both ACOs and bundled payment initiatives, including being associated with better outcomes and lower readmissions and post-acute spending.[3]

Instead of developing beneficiary exclusions, ***Premier encourages CMS to maintain flexibility and instead create incentives and policies that support ACOs and episode initiators in developing partnerships that improve care coordination and patient outcomes*.** When the model incentives align, participating in multiple programs can provide more opportunities to coordinate care for beneficiaries. Below we highlight several opportunities for how CMS could better support ACOs in the integration of specialists.

However, if CMS is to move forward with developing precedence rules under the new mandatory episode model, Premier recommends that they consider establishing the following hierarchy under circumstances when a beneficiary is aligned to both a mandatory model and total cost of care arrangement, such as an ACO:

1. **Beneficiaries aligned under both an episode and to a high-risk ACO (i.e., MSSP Track E, Enhanced Track, and ACO-REACH):** The ACO would retain beneficiary attribution, and the responsibility for the cost of care would be reconciled under the ACO benchmark. 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. CMS would either (1) make payments directly to the ACO, which would distribute funds to providers under the episodic arrangement; or (2) make direct payments to providers under the bundled payment model. As part of this, CMS should explore including providers associated with the episode, such as specialists, as temporary ACO participants, ensuring they have access to all accompanying waivers to support care transformation efforts and care coordination.
    - *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 through a shadow bundle or other arrangement, as discussed in greater detail below.

2. **Beneficiaries aligned under both an episode and to a low or moderate risk ACO (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 or program, CMS should advance APM alignment by establishing a model overlap policy that grants precedence 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. For example, CMS should give preference to models based on number of beneficiaries served, length of episode, percentage of cost of care included in the model, level of risk and consideration for specialized complex conditions.

<u>High-Low Revenue ACOs</u>

CMS also seeks comment on whether it should vary its overlap policy based on whether an ACO is considered high- or low-revenue. ***Premier strongly urges CMS to avoid distinguishing participants in episodes based on their partnership with high- or low-revenue ACOs*.** As discussed in greater detail below, Premier continues

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8796940/

to urge CMS to eliminate the high-low revenue distinction in MSSP, which is flawed and creates market distortions by advantaging one provider type over another.

Under Pathways to Success, CMS began distinguishing between high- and low-revenue ACOs as a means of differentiating ACOs by type of provider (e.g., hospital-led vs. physician-led ACOs). This policy is built on the false premise that: 1) physician-owned ACOs (low-revenue) perform better than hospital-led (high-revenue) ones; and 2) that low-revenue ACOs have less ability to control expenditures for beneficiaries. CMS has continued to state its belief that low-revenue ACOs outperform high-revenue ACOs, noting in the proposed rule that low-revenue ACOs have historically had better financial performance than high-revenue ACOs. However, a recent Premier analysis found that differences between high-revenue and low-revenue ACOs may be driven by other factors beyond ACO composition.[4] Findings include:

- Low-revenue ACOs have more flexibility in selecting providers in certain locations, meaning they may be better able to reduce spending and achieve savings targets;
- High-revenue ACOs serve higher cost beneficiaries attributed through specialists; and
- No significant differences in performance could be found once adjustments accounted for differences in attribution and geography.

These findings demonstrate that other factors outside of an ACO's control, such as geographic location or attribution, are more significant factors that explain differences in ACO financial performance. Continuing to distinguish ACO participants as high- versus low-revenue creates an unlevel playing field that disadvantages hospital-led ACOs relative to their physician-led counterparts. The best way to drive high-quality care for patients is to create incentives that drive all providers to collaborate and innovate to deliver high-quality, cost-effective healthcare. Unfortunately, the high-low revenue distinction has discouraged partnership with certain types of providers, such as hospitals and specialists. Eliminating the high-low revenue distinction will ensure that high performers are encouraged to participate in models regardless of provider type and will allow providers to more effectively collaborate in ways that best meet the needs of their population.

V. CARE DELIVERY AND INCENTIVES STRUCTURE ALIGNMENT

To date, episodic payment and total cost of care models have been developed independent of one another and with minimal opportunities for collaboration between specialists and ACOs. Last November, CMS released its Innovation Center strategy for supporting access to high-quality integrated specialty care. At the core of that strategy was an acknowledgement of the need to develop episodic payments in coordination with total cost of care models and to ensure ACOs have the necessary flexibilities and policies in place to support partnership and integration with specialists.

As noted above, chronic conditions generally require care to be delivered over a longer period of time and management of these conditions is best achieved under a total cost of care arrangement. As a result, Premier encourages CMS to not focus on episodes of care around chronic care management. However, there are instances where a chronic condition may be either managed by a specialist or a patient may have an acute event related to the chronic condition that may lend itself for the design of an episode. Under these circumstances, there are several ways that CMS can better support integration of specialists into ACOs:

- ***Allow entities to define capitation or bundled payment approaches within a total cost of care arrangement – either through "shadow" bundles established by the ACO or through CMS-established bundled payment programs*.** CMS can support ACOs in developing shadow bundles by

[4] https://premierinc.com/newsroom/blog/pinc-ai-analysis-hospital-led-acos-perform-as-well-as-physician-led-models

providing additional data on specialist performance and by developing best practices or standards for defining episodic care, as discussed in greater detail below. CMS should also explore developing a capitated payment option for ACOs who wish to engage with specialists on select chronic conditions.

- **Testing new types of beneficiary attribution.** Existing ACO attribution methodologies focus on plurality of primary care services, which can result in a low volume of patients being aligned to the ACO through the specialists. As a result, many specialists may not find it worthwhile to engage with the ACO. CMS should test other forms of attribution or alignment, such as voluntary alignment through specialists or other providers.

- ***Modify risk adjustment and benchmarking methodologies to better account for complex and high-needs populations*.** Currently, the financial methodologies under ACOs do not appropriately account for patient clinical risk, especially for complex populations. The current benchmarking and risk adjustment methodologies favor patients who are attributed based on primary care services. As a result, benchmarks are often artificially lower for certain high-cost patient populations, which can disincentivize inclusion of specialists in ACOs. CMS should explore ways to further stratify benchmarking based on patient risk factors. For example, in recent years we have seen a rapid increase in Part B drug costs for oncology patients. These increased costs are not sufficiently accounted for in existing benchmarking or risk adjustment methodologies, resulting in losses for ACOs who may serve a large oncology population. To better account for these high-cost patients, CMS should further stratify its current benchmarking approach to set separate benchmarks for patients with certain high-cost chronic conditions or treatments. Finally, CMS should explore use of the concurrent HCC risk adjustment model under MSSP for high-needs patients or patients with complex medical needs.

- ***Evaluate the impact of policy changes on inclusion of specialists*.** When developing policies, CMS must consider the unintended consequences that may result in ACOs narrowing the network of providers they work with. For example, the high-low revenue distinction in MSSP has discouraged ACOs from partnering with certain types of providers, such as hospitals or specialists. Additionally, CMS recently finalized significant changes to the MSSP quality reporting requirements and will soon require ACOs to report quality measures from the total population of patients seen by all providers affiliated with the ACO, including specialists. All-payer measurement could significantly impact ACO performance on certain measures where historically certain clinicians (e.g., orthopedist) may have not performed these assessments or measurements (e.g., depression screening) because they are not relevant to or reflective of the clinical care the clinician is furnishing. Given the challenges associated with these new requirements, some ACOs are considering removing specialists from their ACOs.

Shadow Bundles

Allowing for "shadow bundles" and setting capitated payments for subpopulations of beneficiaries may allow ACOs to better engage with specialists in managing the care of certain high-cost patients who may have complex medical needs. Shadow bundles can create opportunities for ACOs to evaluate key drivers of spending for high-cost patients and identify the greatest opportunities to partner with specialists to improve care delivery. It can also assist the ACO in developing clear targets and metrics for the specialists they work with.

However, there can be several notable challenges to ACOs in operationalizing shadow bundles. While CMS generally provides ACOs with robust data relevant to their aligned patients, many ACOs may not be able to utilize this data to assess specialist performance due to resource constraints. Moreover, ACOs only receive data on the populations aligned to them, which can make it difficult to evaluate performance against others in their region. Defining episodes or specialty care metrics can also be difficult without additional guidance.

To help support ACOs in engaging specialists through "shadow bundles," CMS should:

- ***Develop initial dashboards for common or high-volume chronic conditions or episodes to assist ACOs that may lack the resources to develop their own dashboards*.** Chronic conditions typically offer the greatest opportunity for ACOs to identify practices for improving care than for emergent procedures (e.g., CABG, PCI), which are generally triggered by an unavoidable admission and the only opportunity to achieve savings is through changes in post-acute care. The dashboard should focus on metrics (both cost and quality) that can help inform ACOs on their engagement with specialist around the management of chronic conditions. While the metrics will depend on the selected conditions, CMS should look to existing episodic models and the Quality Payment Program (QPP) for identifying metrics. Some metrics to consider include admissions/readmissions, emergency department visits, post-acute care utilization, hospice utilization, chemotherapy in last 14 days of life, excess days in acute care for acute myocardial infarction (AMI), Patient Safety and Adverse Events Composite (PSI-90), treatment metrics (e.g. Beta-blocker therapy/ACE Inhibitor), complication rates, testing & screening metrics (e.g. cardiac stress imaging outcomes, pain assessment), and closing referral loops.

- ***Provide ACOs with additional data and information on specialist performance, including the technical constructs or specifications for defining certain specialty care episodes and other metrics of specialist performance to help develop their own internal analytical capabilities*.** Even for those ACOs with the resources to develop their own internal dashboards and analyses, they can still face challenges in developing the metrics or episodes necessary to effectively evaluate specialist performance. CMS should assist ACOs by providing additional guidance and specifications, such as guidance on episode design and methods for attributing beneficiaries.

  CMS should also consider establishing national or regional benchmarks for certain metrics of specialist performance. ACOs generally only receive data on their aligned beneficiaries because of data privacy rules. Benchmarks can be useful for specialists in assessing their performance against peers in a region or nationwide. While the ACO may be able to assess performance across specialists they partner with, CMS provided benchmarks would give them a better sense of how their performance measures up against other specialists in each region that the ACO may not be partnering with already. Additionally, specialists may be more receptive to benchmarks set by CMS, rather than ones set by an ACO.

- ***Provide additional guidance on allowable relationships and gainsharing under Stark Law, Anti-Kickback Statute (AKS), or other applicable Fraud, Waste, and Abuse (FWA) statutes*.** Finally, ACOs are reluctant to enter agreements with providers that are not on their participant lists. In 2020, CMS and the HHS Office of Inspector General (OIG) finalized new exceptions and safe harbors that were centered around value-based care and established pathways to engage in arrangements with providers that are not on the participant list. While these new regulations have created new opportunities for partnership, they are complex and challenging to operationalize. Accordingly, many providers are not using these new flexibilities. CMS should provide more education, examples and guidance on how these regulations could be used to create payment arrangements within an ACO.

VI. PAYMENT METHODOLOGY AND STRUCTURE

For both the BPCI Classic and BPCI Advanced models, CMS based the target prices primarily on an episode initiator's historical performance with a discount applied to account for Medicare savings. As bundles have matured this is no longer a sustainable method of deriving targets. This methodology does not recognize efficiencies gained under prior models and may limit a participant's ability to succeed overtime, creating a "race to the bottom."

Another challenge with the current pricing methodology has been the significant fluctuations between initial target price and the final target price at reconciliation. This can create notable uncertainty and makes it difficult for participants to plan accordingly. Additionally, there is often a lack of transparency around why trend factors or target prices may vary from the start of the performance period to reconciliation.

Finally, risk adjustment in episodic models to date has been largely indirect and imprecise. For example, under the CJR model the presence of hip fracture is used as a proxy to collectively represent all of the procedural and beneficiary variables that result in higher costs and poorer clinical outcomes. This can create notable challenges for participants where certain high-cost patients or scenarios can negatively impact a participant's performance under the models. For example, a fracture patient in CJR with advanced dementia will lead to costlier bundles; however, cognitive status is not currently accounted for.

Premier strongly recommends that CMS adopt the following improvements to its episodic payment methodologies:

- ***Adopt regional and/or national target pricing*.** Regional pricing, as seen in the CJR model alleviates some concern, while accounting for regional differences in care referral patterns. Furthermore, a regional pricing methodology encourages even the most efficient providers to continue to refine care coordination across the continuum to remain efficient as compared to peers in the region. A second step may be a blend of region and the peer groups, similar to what is included under the BPCI Advanced model. This could further refine pricing to align similar organizations (e.g., large hospitals and/or Academic Medical Centers).

- ***Provide greater transparency around trend factors and limit updates as much as possible*.** Participants need predictable, achievable target prices that allow them to identify the desired goal under an episodic arrangement. There have been several challenges to establishing prospective trends. As a result, Premier understands that it is likely that CMS will need to continue to make retrospective updates to the target prices. However, Premier encourages CMS to provide greater transparency around its update of these factors and the calculation of target prices, including providing current trends at the start of each performance year and by updating trends on a quarterly basis. Additionally, Premier encourages CMS to consider capping fluctuations on target prices (e.g., +/- 2 percent) to avoid dramatic changes between the start of the performance period and reconciliation. Any targets, trends and caps that are in place must have the option to be reevaluated and adjusted as needed. This is especially true for extreme and uncontrollable circumstances, such as pandemics or natural disasters. Finally, Premier recommends that CMS review the target price in its acute versus post-acute components to ensure adequate dollars for patient care as Premier has observed instances where some target prices for episodes were set so low that it left less than $2,000 for participants to manage post-acute care during the 90 days following discharge, which is unrealistic and does not recognize the needs of patients.

- ***Improve risk stratification or adjustments to account for high-cost patients*.** As noted above, past methodologies to account for high-cost patients, such as through winsorization or risk adjustment based on hip fractures, have not been effective at adjusting target prices for high-cost patients. Premier strongly encourages CMS to work with specialty societies to ensure risk adjustment models reflect clinical criteria and effectively account for cost of care during an episode. Some risk factors that CMS should consider include age, HCC count, dual status and access to care other than an emergency room. Additionally, CMS should take into consideration the clinical and social risk factors. Finally, CMS should consider refinishing use of its concurrent risk adjustment model which is used in other models and apply those lessons learned to episodic models.

- ***Provide participants with a preliminary reconciliation*.** CMS seeks feedback on the timing of financial reconciliations, recognizing the tradeoff between providing participants with results soon after the end of a performance period and the need to allow for sufficient claims runout. Premier recommends that CMS perform a preliminary reconciliation no later than 6 months after the end of the performance period and either exchange no funds or provide only partial payment. This would help balance the need to provide participants with feedback on their performance earlier and CMS' concern about potentially needing to claw-back reconciliation payments once there has been sufficient claims run out. Delayed results and reconciliations have a negative impact on participants as they may not have clarity on which of their cost reduction initiatives are driving the most value and if they will receive positive reconciliation to continue to enhance and reinvest in bundled payment programs. CMS should perform final reconciliations no later than nine to 12 months after the end of the performance period. If CMS determines it needs to "claw-back" reconciliation payments from participants, it should do so through future reconciliations.

VII. HEALTH EQUITY

Reducing disparities in care and achieving health equity across communities requires a holistic approach to care, shifting the incentives in our health system from sickness-based to wellness-based. When providers are responsible the cost and quality of care for their patients, such as through APMs, and have flexibility to address SDOH, providers will be proactive in addressing inequity and disparities. However, addressing the underlying social and economic inequities as well as systemic barriers and biases that drive disparities in care requires (1) data collection and monitoring of key outcomes and health equity measures; and (2) shifting the payment system to account for a more comprehensive set of services that address disparities.

Premier applauds CMS' ongoing recognition that current APM financial methodologies may undervalue the healthcare needs of underserved beneficiaries given historically low healthcare utilization by these populations. However, one of the major challenges to adjusting payments and benchmarks to address disparities in care is the lack of standardized sociodemographic data at the patient-level. As a result, some models are relying on proxies for identifying undeserved beneficiaries, such as duals status or area deprivation index (ADI), which may not fully identify undeserved beneficiaries. Below we provide recommendations on how CMS can better standardize SDOH data collection and how payment methodologies should be adjusted to address the needs of underserved populations.

Standardization of SDOH Data

Health systems are currently capturing SDOH data, but the information is not easily translatable for CMS purposes. For example, despite an available framework for mapping the more than 900 race ethnicity codes provided by the Centers for Disease Control and Prevention (CDC) to the Office of Management and Budget (OMB), race and ethnicity codes captured in the EHR cannot be consistently mapped. This is a result of lack of use of standard taxonomies - in part by the EHRs and in part by the providers to allow the category selections to align with how their populations would like to report information. Similarly, there are an abundance of tools to screen for SDOH with underlying definitions for certain social risk factors (e.g., food insecurity) varying significantly even when the same tool is used by different providers.

Premier continues to urge CMS to focus on improving data collection and standardization, which is vital to providers' success in driving towards health equity as it will foster the development and sharing of best practices within and among clinical settings, health systems and delivery system designs. The Agency for Healthcare Research and Quality (AHRQ) has found that one of the biggest barriers most health systems face in improving quality and reducing disparities within their own walls is systematically identifying the populations they serve,

addressing the needs of these populations and monitoring improvements over time.[5] AHRQ further found that the principal challenges in obtaining race, ethnicity and language data for use in quality improvement assessments include a lack of standardization and understanding of why the data are being collected.

To help foster better data collection and standardization, CMS should:

- ***Invest in educating both patients and providers about the importance of collecting SDOH information, the evidence for how it affects care and existing privacy requirements under HIPAA that safeguard information patients share with their providers.***

- ***Adopt incentives, such as quality program bonuses, to help incentivize standardized data collection*.** For example, CMS should consider developing a health equity adjustment to its quality program under the new episodic model. The bonus points should be based on the percentage of SDOH and/or demographic data that model participants report on their aligned beneficiaries. Over time, CMS could evolve this adjustment to address other challenges with SDOH data collection, with the goal of eventually setting the adjustment based on patient-level SDOH data. For example, CMS took a similar approach under the OCM model for metastatic status reporting, which was eventually incorporated into the target price.

- ***Consider advancing standards that clearly indicate the dates and times associated with data collection***, as certain sociodemographic factors (e.g., homelessness) are subject to change. In particular, Premier encourages CMS to use existing tools such as the United States Core Data for Interoperability (USCDI), Z-codes, HL7 and Fast Healthcare Interoperability Resources (FHIR) standards. This coordinated approach requires significant input from providers across the continuum, vendors, payers, and suppliers.

- ***Explore collecting demographics data in all future APMs***, as well as the use of a standardized set of evaluation metrics (based on outcome measures that are applicable to both primary care providers and specialists participating in a model) that can be stratified by these factors to compare different population segments and identify any existing health disparities.

- ***Evaluate the standards that hospitals and other entities already have in place to advance health equity.*** This creates opportunities for CMS to build on and create synergies where possible on existing efforts as CMS and other federal partners work towards a national standard.

Recognizing it will be difficult for CMS to assess health equity outcomes until race, ethnicity and SDOH information is standardized, Premier encourages CMS to consider incorporating structural measures that address health equity, such as collection of SDOH information and engagement with community-based organizations.

<u>Adjustments to Financial Methodologies to Address Health Equity</u>

As noted above, Premier appreciates CMS' recognition that current APM financial methodologies may need to be modified to ensure target prices and benchmarks are appropriately set to account for the needs of undeserved patients. ***Premier recommends that CMS consider the following financial methodologies to advance health equity*:**

[5] https://www.ahrq.gov/research/findings/final-reports/iomracereport/index.html

- ***Explore ways to incorporate SDOH into risk adjustment*.** As noted above, CMS should explore ways to improve its risk adjustment methodologies to ensure benchmarks and target prices appropriately capture the costs of patients with high-cost or chronic conditions. It is essential that episode initiators are not disadvantaged for serving medically and socially complex beneficiaries. Use of proxies such as dual status, area deprivation index at the beneficiary level, rural geographies or percentage of charitable care at the participant level is a good start until data collection is standardized. However, CMS should continue to advance standardization of SDOH data to further improve these methodologies.

- ***Adopt additional adjustments to ensure payments are adequate to address needs of underserved patients.*** CMS should ensure that models have the appropriate flexibilities and payments to allow APM participants to strengthen their focus on addressing health equity, such as paying for services that address social determinants of health. This includes:

    - ***Modifying target prices to account for historical underutilization of services*.** CMS has modified payments under Innovation Center models, such as ACO REACH, to better account for historical underutilization of services by underserved patients. However, under ACO REACH CMS offsets those increases by reducing benchmarks for lower risk patients. Premier strongly urges CMS to ensure any modifications it makes to target prices to account for underutilization is done as additional payments and not offset through reductions elsewhere in the model. Reducing target prices for other beneficiaries introduces new inaccuracies into the payment methodology and potential introduces new inequities.

    - ***Adopt episode related payments per beneficiary to support enhanced services****.* Under the Oncology Care Model (OCM), participants received a monthly fee for delivering enhanced services. This allowed participants to create triage clinics, hydration stations and hire financial counselors. Premier encourages CMS to consider adopting a similar enhanced payment for participants which would allow them to provide innovative wrap-around services aimed at addressing SDOH and advancing health equity. In designing that payment, Premier encourages CMS to establish an automatic payment to participants based on attributed beneficiaries, rather than doing a claims-based payment. Under OCM, CMS had included a claims-based payment which had created several operational challenges for OCM practices.

VIII. QUALITY MEASURES AND MULTI-PAYER ALIGNMENT

Quality Measures

In the RFI, CMS notes that it has used a combination of claims data, participant-reported or registry-based quality and patient-reported outcomes measures when evaluating quality of care across its various bundled payment models. It also notes, that in effort to reduce provider burden, the Innovation Center is interested in including multi-payer alignment where possible.

Based on our experience with quality measurement across past and current bundled payment initiatives, ***Premier recommends the following principles for selection of quality measures under the next episodic payment model****:*

- ***Selected measures should be relevant to the care that is furnished in the episode.*** For measures to be meaningful, those selected must be focused on what the model is trying to accomplish and limited to the model's patient population to ensure participants have meaningful opportunities to improve quality and are held accountable under the model for care that is relevant to their care improvement efforts. For

example, under the CJR model, CMS utilizes the hospital-wide HACHPS measure. Unfortunately, this measure includes all patients' perceptions of their entire hospital experience, including Medicare and non-Medicare beneficiaries admitted to medical, surgical and maternity service lines. Those results account for 40 percent of the CJR participant's quality score, which factors into determining the discount rate that CMS applies to the target price. This approach has greatly frustrated CJR participants who feel like that given the breadth of the HCAHPS measure they have limited opportunities to drive improvement under the model, but yet such a large share of their discount is impacted by their performance on the measure.

Another challenge that has occurred in the CJR model is the lack of relevant measures for outpatient procedures. CMS modified the CJR model a few years back to address changes to the Inpatient Only List which now allow for joint replacements to be furnished in an outpatient setting. Over the last couple of years, we have seen a significant shift in the volume of joint replacement procedures performed in outpatient settings. While CMS modified the model to allow for outpatient procedures to trigger episodes, it did not update the quality measures included in the model. As a result, CJR participants are held accountable for complication rates for elective joint replacements that are conducted in the inpatient setting, but not outpatient. Patients who continue to receive elective joint replacements in the inpatient tend to be higher risk, which has negatively impacted performance on the complications quality measure. Additionally, the shift to outpatient has also resulted in significantly lower inpatient volume, which can create volatility in quality measurement. Given the complications quality measure accounts for 50 percent of the participants' quality scores (and therefore impacts the discount that participants receive), this has had a negative impact on participation in the model.

To minimize the burden on providers and ensure quality measures reflect quality performance and quality care, measures should reflect the care furnished in the episode and be limited to those beneficiaries aligned under the model. In those instances where the measure cannot be tailored to the model or cannot be limited to aligned beneficiaries, then less weight should be given to that metric, or the measure should not be selected. Ultimately, it is best to have fewer meaningful measures than more measures of moderate impact.

Finally, CMS has expressed interest in creating quality alignment across all programs, including the Innovation Center, by utilizing a core set of measures as part of its recently announced Universal Foundation initiative. Measures most often included in the core set are primary care centric and may not be appropriate for episodic or specialty care models. As a result, Premier cautions CMS in its evaluation of measures for inclusion under an episodic model to ensure whatever measures are selected are appropriate and relevant to the model.

- ***Consider claims-based measures when feasible*.** Reporting quality metrics requires resources and time that participants must absorb in addition to the discounts applied under the model. Use of claims-based measures can significantly reduce burden and resource costs for participants. CMS simplified quality reporting under the BPCI Advanced model by introducing the option of reporting the Administrative Quality Data Set, which is extracted from claims data. The majority of BPCI Advanced participants have selected this option. Premier urges CMS to explore available claims-based measure as much as possible under the new episodic model.

- ***Improve timing of when quality metrics are used and communicated to participants*.** In addition to meaningful measurement selection, the timing of the measurement relative to reconciliation is also essential. For example, in the BPCI Advanced model, reconciliation occurs in the spring and fall. During the spring reconciliation, CMS applies a 10 percent quality withhold to reconciliation payments. Just before the fall reconciliation, CMS releases the Participants' Quality Report, which accounts for actual Quality Performance for the prior performance year. Given the reports' arrival time, the quality

performance data may be anywhere from 10 to 20 months old once received. This makes it virtually impossible for participants to utilize the data to drive quality improvement efforts. Premier encourages CMS to evaluate when it reports quality performance to participants and explore ways to provide participants with more timely data on performance.

- ***Work with stakeholders on the design of Patient-Reported Outcome Measures (PROMs).*** Hospitals participating in the CJR payment model have had the option of reporting a PROM related to care furnished during an elective joint replacement since the model began in 2016 in exchange for bonus points under the model's quality reporting program. Many model participants have found that the burden of data collection for this measure outweighed any potential for bonus points for successful measure reporting and thus took a pass on reporting this voluntary measure.

  While Premier is supportive of PROMs and acknowledges that PROMs can be the impetus for initiating conversations between patients and providers and improving shared-decision making, a number of challenges exist to the current construct. ***As a result, Premier encourages CMS to consider the following principles when designing PROMs for future episodic payment models:***

  - ***Ensure timing of survey and who administers the survey aligns with the practice of care and does not create undue burden on episodic participants***. For example, under the CJR model, the point at which the post-operative survey is currently conducted is well after the procedure (anywhere from 275 to 425 day after the procedure.) At this point, the patient has long left the hospital and is likely being followed by an orthopedic practice. The longer the beneficiary waits to complete the post-operative survey, the more opportunity exists for bias to be introduced into the patient's response. Events that may have happened outside the program's control may also now influence the patients' responses. Additionally, once the patient leaves the hospital, any ongoing follow-up is likely to occur through the specialists' practice. As a result, it may be more appropriate for the specialists to field the survey. CMS should explore modifying data collection to be done through a specialist practice rather than assigning the responsibility to the hospital.

  - ***Partner with patient advocacy groups to test patient and family-centered care and patient experience questions*****.** CMS should be more specific in asking patients about whether they were involved in the development of their treatment plan and post- discharge plan, whether their discharge instructions were clearly understood and whether their family and caregivers were involved in decision making processes around their care. CMS should consider allowing larger sample sizes of patients to respond to the survey, rather than restricting based on the number of clinicians in a practice, to combat declining response rates.

Multi-payer Alignment

Aligning bundled payment approaches across payers can help create larger populations and provide more incentives for specialists to participate. A current challenge with engaging with specialists, either through shadow bundles or other arrangements, is ensuring that the specialist participating in the bundle has a sufficient patient volume. Without sufficient volume, specialists may not find it worthwhile to invest the time and resources necessary to participate under the model. Additionally, low-patient volume can contribute to volatility in target prices or benchmarks.

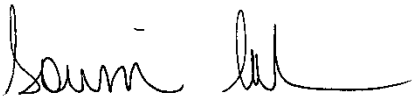
As a result, ***Premier encourages CMS to work with states and the private sector to accelerate the movement to value-based care.*** For example, CMS should work with payers to standardize how bundled episodes are defined and data is formatted to create consistency around measure specification. Additionally, CMS should consider other incentives for payers who adopt risk-based arrangements with providers, such as

offering Medicare Advantage (MA) star-rating bonuses or working with states to offer incentives to managed care organizations (MCOs) through procurement points or reductions in payment cuts.

IX. CONCLUSION

In closing, Premier appreciates the opportunity to submit these comments in response to the Episode-based Payment Model RFI. If you have any questions regarding our comments or need more information, please contact Melissa Medeiros, Senior Director of Policy, at melissa_medeiros@premierinc.com or 202-879-4107.

Sincerely,



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