Chapter 6: Operational Considerations

In this section, the CEP Work Group does not offer specific recommendations. Instead, the Work Group has developed a set of questions that all adopters of clinical episode payment should consider and discuss when they begin planning and designing episode payment models.

While the design of an episode of care is critical to its success, some aspects of the way episode payments are conducted affect the likelihood that payers and providers will be able to adopt a given model. These operational considerations include: remaining mindful of the perspectives of stakeholders; building and maintaining an appropriate infrastructure for data collection, analysis, and payment; staying abreast of regulatory statutes and regulations that could affect the design and operation of episode payments; and, finally, considering how episode payments interact with population-based payments (Figure 12).

1. Role and Perspectives of Stakeholders

How do the perspectives of stakeholders impact the design and operation of clinical episode payment?

It is important to understand the varied perspectives of those who will be impacted by the clinical episode payment. Each stakeholder, whether payer, provider, consumer, or purchaser, has unique expectations, goals, and limitations during the design of an episode payment. Because of the multiplicity of these diverse perspectives, it is important to consider all stakeholder voices in the design and operation of episode payments.
Many stakeholders have multiple and sometimes conflicting viewpoints. For example, commercial health plans and large payers (including states and the federal government), may be interested in creating incentives for providers to develop the capacity to invest in data infrastructure to support that goal. Meanwhile, providers may be equally interested in the potential of episode payments and can be valuable innovators. But they may have reservations about leadership and accountability when it comes to care coordination across multiple medical settings. Involving patients and families in myriad ways throughout the episode as partners in their own care and in the design, implementation and evaluation of episode payment models is an essential strategy for advancing value-based care and improving outcomes. They can also provide valuable feedback on how the methodology impacts the patient.

Finally, because of their purchasing power, employers and other entities that purchase health care can align incentives between themselves and providers through episode payment. Purchasers’ interests coincide with those of consumers and patients, because both groups share a vested interest in ensuring that episode payment models tie reimbursement to performance.

Well-designed payment models consider all of the perspectives above, as well as support reliable delivery of care that is provided at the right time in the right setting. Another consideration that impacts the roles and relationships among the various stakeholders is whether the initiative is voluntary or mandatory. For example, if a given market is characterized by having significant alignment of multiple payers or has one dominant payer, there is greater opportunity for a payer to make participation mandatory. Whether it is voluntary or mandatory, the negotiations among providers, purchasers, and payers will need to ensure that participation is feasible for those to whom it applies.
2. Data Infrastructure Issues

What data systems do payers, providers, and consumers need to successfully operationalize episode payment?

One of the biggest challenges to implementing a clinical episode payment model is the process of managing and sharing the vast amounts of data necessary to assess, manage, and mitigate risk and to use it to improve quality and outcomes for patients. Effective data infrastructure systems must be able to achieve two things:

- Group claims into episodes for analysis and payment; and
- Meet providers’ need for critical patient information to be accessible across providers and to patients to coordinate care and engage patients in their care.

At present, the field lacks scalable infrastructure for widespread, effective, efficient adoption of episode-based payment. Payer systems are set up for FFS payment, or, in some cases, full capitation. The intermediate steps of bundled payment require pulling claims from multiple data files, applying exclusionary rules, calculating and updating benchmarks and target episode prices, and doing so within the context of multiple provider contracts and enrollee benefit designs. Simply put, some payers are struggling to develop the business case and justify the return on investment for building these systems.

For episode payment to achieve its potential requires a data infrastructure that supports and facilitates analysis for the following purposes:

- Determining which clinical episodes/conditions to target and what services and costs are considered part of the episode;
- Establishing the episode price;
- Bundling claims to determine historical/actual expenditures; and
- Communicating clinical, patient-generated, and care coordination data across providers, including primary and specialty physicians, hospitals, post-acute care settings, and others who are part of the patients’ care teams.

This data infrastructure must also support the ability of clinicians to understand patient preferences and expectations, and for patients and family caregivers to communicate preferences and goals. For these purposes, an episode payment data system by itself may not be sufficient. Other clinical data and patient decision aid information will also be important. However, the payment systems that analyze FFS claims data can also provide important information on the types of clinical decisions and the impact of those decisions on patients experiencing similar conditions.

In addition, whether clinical episode payment is prospective or utilizes retrospective reconciliation with upfront FFS payment, it is critical to build and implement software and systems to group these claims to estimate and establish the episode price, to calculate actual costs, and to make the correct payment adjustments. Currently, the data analysis and systems being used are too manual, and the expense of either replacing or building this type of process on top of legacy systems will limit broader
implementation of episode payment. Depending on the volume of payment that is done in this manner and the monetary impact, revising legacy systems to be able to handle this level of complexity may not be a high priority for a payer. Payers are faced with a “buy or build scenario” whereby they can either buy the complex infrastructure, albeit with little knowledge about the quality of the product, or try to build it themselves, with the understanding that it will be a long-term investment in this type of payment reform. Although the needs are complex, some companies have developed the capacity to assist payers and providers in these functions. Further movement toward the use of clinical episode payments will create an even greater market for such services whether they are developed by a third party or whether the payer creates their own solution.

Moreover, these systems must be able to support data sharing with providers and payers in a transparent manner to ensure that all involved understand where the opportunities for efficiencies and improvements in care occur across the episode, including potentially individual patient management. However, it is often very difficult to obtain useful data in a sufficiently timely manner to allow for the most effective care management of the patient. Another issue is the capacity for provider entities, and in some cases, payers, to analyze the data. Even if the underlying claims are available and the logic for running the data was shared, provider entities often find it challenging to run the necessary reports.

Finally, for the care to be as effective as possible, digital systems that provide information to patients and enable them to communicate with their providers and take an active role in their care are also key and must be tied to the provider data analytics. The grouping of claims is primarily a payer function; however, the clinical infrastructure is something that a provider may want/need to develop on its own, or it is possible that a payer can assist. This is a critical decision point when implementing CEP.

The Work Group recommends the following two concepts for operationalizing the data infrastructure needed to implement episode payment.

A Service or “Utility” Model: In this model, a group of payers pay a third party to develop a core set of logic that could be used to group claims; provide feedback and benchmarking to providers; and support data sharing for patient management, instead of each payer having to develop the capacity individually. Several examples were provided by Work Group members including vendors that are performing this capacity; large payers, such as Medicaid in one state; and regional initiatives whereby purchasers or payers support a third party to perform these tasks in a uniform manner. State-sponsored All-Payer Claims Databases (APCDs) are an example of a data warehouse that could pull together data across payers for these purposes. In any implementation scenario, neutral sources of such data and analysis will help to facilitate multi-payer analysis. This ensures that providers involved in this form of payment are not subject to multiple definitions of episodes and benchmarking formulas. Another concept that was important to the Work Group to ensure high-quality products was to potentially create a “certification” process for this type of function.

A Core Set of Logic: A core set of logic will assist the health care industry in developing the capacity for grouping claims into bundles by standardizing the core logic, but allowing each payer to customize a portion of the more granular rules. This could be applied individually by payers or within the context of a third party described above.
3. Regulatory Environment

How can the current and evolving federal and state legal landscape in the health care industry affect episode payment implementation?

Any organization pursuing an episode payment initiative needs to remain cognizant of the statutory and regulatory framework that may impact the manner in which it creates relationships with providers and the way incentive and risk structures are established.

The manner in which clinical episode payment is designed and implemented will be affected by existing and emerging laws and regulations at both the federal and state levels. Certain arrangements and relationships between providers and suppliers, as well as between patients and providers and suppliers, may implicate federal laws and regulations designed to prevent inappropriate incentives and to protect beneficiaries. Further, many states have created, or are considering creating, regulations designed to ensure that providers do not take on a level of risk that they might not be able to support without harming the patient or other consumers (regardless of whether it is characterized as insurance or service risk).

Three federal laws of significant importance to health care systems are the physician self-referral law, the anti-kickback statute, and the civil monetary penalty (CMP) laws. It will be important for provider organizations to discuss with legal counsel the potential implications of these and other laws on proposed arrangements for clinical episode payment. HHS issued limited waivers of these laws for specific types of models, including the Bundled Payment for Care Improvement (BPCI) initiative and the CJR. More discussion can be found on the CMS Fraud and Abuse Waivers web page (Centers for Medicare & Medicaid Services, 2016c).

Several other legal issues also impact the implementation of clinical episode payment. For example, EMTALA is an important consideration when pricing the three episodes of care discussed in this paper. Patients being seen for the first time in the emergency room will be given whatever care the hospital and clinician on call determine feasible without regard or awareness of the clinical episode payment context. This may be particularly important for maternity episodes if the bundled payment is developed using the cost of a birth-center birth.

Regarding medical liability, it may be the case that clinicians and facilities need to consider concerns related to liability with their preferred treatment. There may also be concerns with liability when multiple providers are sharing accountability in a team-based approach. Payers need to be aware of and acknowledge these concerns. With maternity care, liability laws for the clinicians (including OB/GYN, midwives, and birth centers) vary across states regarding birth; those establishing a maternity care initiative should have an understanding of their state laws.

Many states have created, or are considering creating, regulations designed to ensure that providers do not take on a level of risk that they might not be able to support without harming the patient or other consumers (regardless of whether it is characterized as insurance or service risk).

In addition, we note that, given limits on reassignment of claims, if a state pays FFS for EJR, Maternity or Cardiac care under Medicaid it may not be feasible to prospectively pay for a clinical episode of care to
one accountable entity that would then remunerate other providers. We highlight this issue for maternity because of the importance of Medicaid as a payer, but it is relevant to the episode types as well.

In the maternity context, we found evidence that it may be helpful for the various participants to know that a series of evaluations of rigorous quality improvement programs has documented rapidly plummeting liability claims, payments, and premiums (Sakala, Yang, & Corry, 2013). It will be important to include these dimensions of care in evaluations of episode payment models because of this relationship.

### Regulatory Areas That May Additionally Impact Maternity Payment Strategy

**States** define the types of providers, including practitioners, and settings of care that support birth. They define licensure and certification of providers and the scope of practice under which the providers operate. At a minimum, these regulations will impact decisions related to participating providers, services covered, and episode price determination. For example, laws that require written agreements for transfers between birth centers and hospitals or that require OB/GYN supervision of births in a birth center can limit the availability of that birthing option if no hospital or OB/GYN is willing to engage in such an agreement. Other state laws create a different minimum length of stay for a birth than the federal minimum and may also need to be considered.

The **Medicaid context** is important to consider, given a large number of births are paid for by Medicaid. A high percentage of those births are paid through MCOs; therefore, it will be important to consider the manner in which a state contracts with MCOs. These contracts must determine whether states could encourage such payment arrangements or whether the Medicaid MCOs may be interested in paying for maternity care in that manner without state encouragement. There are examples whereby a state encourages these types of payment arrangements through their contracted MCOs; whereas, other states have MCOs build bundled payments for maternity care into their contracts with providers without state encouragement. We note that, given limits on reassignment of claims, if a state pays FFS for births under Medicaid it may not be feasible to prospectively pay for a clinical episode of care to one accountable entity that would then remunerate other providers.

Many states have created, or are considering creating, regulations designed to ensure that providers do not take on a level of risk that they might not be able to support without harming the patient or other consumers (regardless of whether it is characterized as insurance or service risk).

---

16 See Section 1903(a) (32) of the Social Security Act and the regulations at 42 CFR 447.10.)
4. Interaction between CEP and Population-Based Payment

How do clinical episode payment and population-based payment interact to move payment reform forward?

As the LAN develops recommendations specific to implementing either clinical episode payment or population-based payment, questions arise from those in the field who see opportunities, or at some point in the future, mandates, related to implementing both of these alternative payment models within one organization. There are many questions that payers, purchasers, and providers will need to think about and address when determining whether and how to implement multiple payment models. The discussion here centers on integrating both CEP and PBP, but may apply to other APMs as well.

It is critical that the decision to implement both of these payment reforms (either separate or together) will be taken within the context of a broader strategic goal. As the health system moves towards APMs of all types, a clear vision is needed to avoid confusion and unnecessary complexity. In some instances, it may be the case that using CEP will incentivize the necessary delivery system changes to ensure person-centered care. In other initiatives, payers may implement PBP and find that clinical episodes within the continuum of care become person-centered without CEP. Establishing a goal for adopting one or multiple APMs and measuring movement towards it is critical.

Implementing one APM, either CEP or PBP, has its own challenges; these challenges are compounded when an organization considers implementing both types of APMs. Questions that arise when implementing both CEP and PBP may include:

• Can initially implementing the model that focuses on the risk limited to an episode of care (clinical episode payment) serve as a transition to implementing the broader model of population-based payment? If so, how?

• What are some potential operational practices for implementing CEP and PBP in an integrated way?

Can Clinical Episode Payment Serve as a Transition to Implementing Population-Based Payment?

As policymakers and payers consider various APMs, the movement towards PBP is often described as a progression from “less disruptive” forms of APMs to “more disruptive” forms. For example, accountability for value in the HCPLAN Framework Category 2 (FFS link to payment/quality) is only related to the services provided by individual providers. In Category 3, accountability for value is across several settings and providers, but not all. Category 4 holds one entity accountable across all care for the enrollee. Thus one question is whether CEP can (or should) serve as an appropriate “stepping stone” toward a potential goal of broad population-based payment.

While it may be the case, as noted below, that implementing CEP before a PBP reform may help build a foundation for PBP, it is also the case that CEP is a goal on its own. CEP can be quite complex to implement as it requires defining hard-to-define beginnings and endings of episodes within the continuum of patient care and also separating out the costs of the episode from other costs of care. These distinctions are not always clear. Thus, implementation of CEP should not be considered only as a stepping stone to PBP. It may also be the case that a payer or provider finds CEP on its own to be
effective at focusing on the types of care of most interest to its population and thus, see no need to implement PBP.

While CEP can be implemented on its own, below are some ways in which CEP could encourage the development of infrastructure and relationships among providers that would be useful for moving towards PBP:

- Encouraging providers to create mechanisms for coordinating across settings within a clinical episode and, potentially, with primary care before and after the episode. The mechanisms and infrastructure needed to facilitate this kind of coordination would create a foundation for coordinating care in a PBP environment.
- Creating expectations for accountability beyond a provider’s own setting and for the patient over time. Accountability across settings, clinicians, and phases of the care continuum is critical for PBP and CEP. A culture of shared accountability and team-based care is particularly important given the need to measure patient-reported outcomes and key quality metrics across settings in both models.
- Incentivizing new structures, including care management protocols, information sharing systems, and ongoing quality improvement programs that make it more feasible to take on additional risk.
- Providing experience for providers to learn how to take on financial risk and distribute payment across providers.

Clinicians participating in a CEP model will likely need to share accountability across members of a patient’s care team, and will require the infrastructure to support that. Building this infrastructure for CEP may make it easier for them to become an entity capable of the risk involved in a PBP arrangement. From the payer or purchaser perspective, it may be easier to begin with CEP, as it requires less change in organization billing systems and will be applied to a smaller subset of claims. As billing systems become more facile at grouping claims to define the episodes, that capacity could be used to assist the provider organization in targeting their interventions on episodes and conditions with the greatest opportunity for improvement and cost savings under a PBP model.

**Operationalizing Integrated CEP and PBP Models**

In an integrated model, it is possible that the clinical episode payment will “nest” within the population-based payment. This is because a PBP model holds the accountable entity responsible for the costs and quality of care for all services an aligned enrollee uses across a continuum of care, while the CEP model will focus on the episodic portion of that care. From a clinical perspective, having an accountable entity under a CEP program within a PBP model could complement the primary care focus of the PBP model. The PBP accountable entity will have a need to prevent some high cost episodes, but also to effectively manage those that do occur. In this way, CEP could assist the PBP accountable entity reach its financial and quality benchmark goals by managing specific high-cost, high-volume episodes within the continuum of care. However, this complementary relationship is only feasible if the providers themselves coordinate the primary, specialty, and post-acute care for the patient both before and after the episode.

Before tackling these clinical questions, however, there are a number of operational issues that must be addressed when two entities have responsibility for costs that may arise for one patient, but could be attributed to both a clinical episode and a population-based care service. The primary issue when integrating CEP and PBP is that a patient may be attributed to two entities at the same time: the PBP entity for total cost of care, and the CEP entity if the patient needs care that aligns with a clinical
episode. Using a carve out mechanism—or some variety of carve out—can address this situation. In the three carve out examples provided below, we assume that each situation involves a single payer (Medicare, state Medicaid agency or Medicaid or Medicare MCO, or a commercial payer) implementing both CEP and PBP in the same region:

1. **Basic Carve Out**: The most straightforward way to address this is to carve out the dollars represented by those episodes from the total cost of care baseline calculation for which the PBP entity is accountable. The payer would keep track of the members and their costs assigned to these episodes, and subtract them out when payment is reconciled. The benchmarks would be based on these amounts.

2. **Carve Out with Metric-Based Provider Accountability**: A criticism of the basic carve out is that it provides no incentive for the PBP entity to coordinate with the CEP entity for things such as upfront shared decision making, or high quality, coordinated, follow-up care for the patient post discharge. One way to address this might be (when using the basic carve out methodology) to use quality metrics to hold providers accountable, and encourage PBP entity providers to work with the CEP entity to make sure the member or patient received seamless care around the episode.

3. **Carve Out with Savings Assigned to the PBP Entity**: Another criticism of a pure carve out is that carving out the costs of an episode removes part of the incentive for entities to enter into PBP arrangements as they are not able to obtain all of the savings from their efforts. One way to address this is to either establish the price less than the historic average episode price (essentially building in a guaranteed discount level). The PBP could absorb these upfront savings while the CEP entity would accept the risk beyond that amount.

For some providers, this discussion may still be in the realm of the theoretical. For providers participating in various ACO models and wishing to participate in a new episode-based demonstration initiative, these questions and challenges are important. As APM implementation evolves, the hope is that promising practices will emerge to support providers and payers in successful design, implementation, and sustainability of such integrated models.
Chapter 7: Conclusion

Overall, the recommendations developed by the CEP Work Group include design elements and operational considerations that together are designed to support APM alignment. The Work Group recognized that implementation must be tailored to market conduciveness, organizational readiness, and the characteristics of particular initiatives. For that reason, compromises will sometimes be necessary to achieve the goal of alignment. When compromises are made, there should be justifiable reasons for divergence from the Work Group’s recommendations.

The CEP Work Group also recognizes that there are many additional elements that can be helpful in deploying episode-based payment programs. These include technical assistance, detailed specification of care delivery models, and aligned benefit designs. While important, these elements are out-of-scope for the Work Group due to the charge from the LAN Guiding Committee and the designated focus of the LAN.

Finally, the recommendations and implementation options described in the body of the White Paper are directed toward all stakeholders. It is the intention of the CEP Work Group that payers, providers, consumers, patients and their family caregivers, purchasers, and states will all consider these recommendations and options as starting points for critical conversations about how to work together to promote aligned adoption of episode payment models. Specific priorities for moving this work forward are described below.

Moving Forward: Priorities for Supporting Episode Payment

The Work Group’s recommendations include actions that are feasible for stakeholders to implement in the current environment; in fact, many are based on existing initiatives. At the same time, there are a number of other areas in which evolution is still necessary in order to fully optimize the impact that APMs, in general, and episode payment, in particular, may have on patients and the health care system. While the following list is not exhaustive, the following issues stand out as being necessary in the short-term for moving the field of episode payment forward:

Creating an Infrastructure that Supports Person-Centered Care: The design and implementation of person-centered episode payment models requires the ability of providers and patients to engage in shared decision-making, shared care planning, sharing of critical information on cost and quality, and systematic care coordination that puts the patient first. Addressing the need for an overarching infrastructure that allows all of these interactions to occur is central to supporting episode payment.

Transparency of Cost Data: All stakeholders need transparent, detailed data on episode-based care prices that payers negotiate with providers. Having this data available via a trusted source will allow purchasers, payers, patients, and consumers to make informed decisions in the episode payment process. In addition, information on regional-cost variation and on how variation relates to different circumstances is particularly valuable. Ideally, participants will be able to compare episode to FFS costs, and understand cost implications for their situation.

Provider and System Readiness: Individual providers may have interest in participating in an episode payment initiative; however, in order for episode payment to be effective, it requires coordination among a collaborative care team that includes both clinical providers and payers. Most markets lack the systems and infrastructure to support this type of collaboration, and are still hallmarked by siloed-care environments that do not share common data or payment systems. Addressing the readiness of both
providers and the systems in which they deliver care will be critical to easing the path toward greater episode payment implementation.

**Quality Measurement:** While there are measures of process standards, patient outcomes, patient engagement tools, and functional status assessment tools available today, there are concerns about how well these tools support providers’ and payers’ abilities to assess whether a procedure truly improved the outcome for an individual patient. Continued development of key measures capable of measuring quality across settings of care will be critical for the effectiveness of episode payment models.

**High-Value, Underused Services:** As noted in the body of this White Paper, a wide variety of high-value services (both those currently covered and others non-covered) are underused today. Especially within maternity care, research suggests their use can increase vaginal birth rates, lower pre-term birth rates, and provide necessary support for childbearing women and newborns throughout the episode. There are a number of episode payment design elements that point to ensuring payment models incentivize the use of these high-value, underused services across all episode payment models.

**Low-Value, Overused Services:** Also noted in this paper is the fact that the current health care system is overusing services that do not provide value to the patient. These services may come in the form of unnecessary diagnostics or procedures. The goal of the episodes described herein is to reduce the incentives to providers for including these types of services in their care process, and replace them with services that are high value, and are appropriate for a given patient, based on clinical assessment and the patient’s preferences and values.