

Contracting for Bundled Payment



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Centers for Medicare & Medicaid Services

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Foreword

The Centers for Medicare & Medicaid Services (CMS) requested that The MITRE Corporation (MITRE) provide information that will support the development of a contract or contracts to help organizations partner to provide services in a Bundled Payment (BP) environment. Toward that end, MITRE worked with The Brookings Institution's Engelberg Center for Health Care Reform (Brookings) to conduct a comprehensive environmental scan of peer-reviewed journal articles, white papers, and publicly available evaluation reports from past BP pilots, and interviewed experts and thought leaders in the community. *Contracting for Bundled Payment* consolidates this information, and describes the means of establishing BP-specific components of contracts among organizations, preparing them to receive BP from CMS or potentially other payers.

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Executive Summary

A bundled payment (BP) is a single payment to multiple providers for an entire episode of care, that is, treatment for a specific medical condition during a set period. Unlike traditional fee-for-service payment, BP both incentivizes care redesign by holding provider teams accountable for clinical costs, quality, and outcomes, and rewards better care coordination. This document provides information to support the development of contracts between organizations intending to participate in BP programs with the Centers for Medicare & Medicaid Services (CMS) or potentially other payers.

An organization's initial steps toward ascertaining contractual features for BP may entail determining early leadership commitment and assessing whether the organizational structure will support optimal BP implementation. The initial steps should include the collection and analysis of financial and clinical data. Next, an organization may create a BP implementation plan focused on care redesign, data sharing, quality, and gain/risk sharing. Careful consideration and specification of these elements will inform the substance of the BP contract and drive successful BP implementation.

Care redesign is the primary objective of BP. The care redesign process may consist of several distinct parts: a readiness assessment, establishing the perspectives for redesign, creating a structure for the redesign process, gathering external and internal data, and selecting tools to enable redesign implementation. The substance of the redesign may entail better care coordination, clinical practice improvements, supply chain optimization, patient-focused interventions, or other mechanisms for improving quality and reducing cost.

Quality and other performance measures can confirm that providers achieve savings without diminishing care. These measures can enable continued improvements in care, and may be used to determine gainsharing and risk sharing allocations. Organizations should carefully select quality mea-

ures that align with their intended purposes. They should also clearly articulate the quality measures needed for continued BP participation, the quality benchmarks that will be used to allocate risk, and the manner in which the organization makes quality and performance achievements available to providers.

Data sharing arrangements can streamline care among healthcare providers. These arrangements may consist of contractual obligations to use certain systems, facilitating providers' access to patient data or their own performance data. Arrangements must comply with the legal and regulatory requirements for sharing clinical, financial, and proprietary information.

Gainsharing offers an incentive to engage providers in BP programs. Contracts among providers should specify the quality and performance metrics necessary to qualify for gainsharing, the formula used to apportion the gains, and the timing of the apportionments. Likewise, contracts should specify how providers will bear the risk of loss, which may vary from one party bearing 100 percent of the risk to allocating various amounts of risk among providers. Contracts may also specify the required activities for mitigating risks.

Leadership should vet and approve implementation plan details regarding care redesign; quality and performance measures; and arrangements for data sharing, gainsharing, and risk sharing. Once approved, one or more contracts can memorialize the plan details. Competent legal counsel should draft and assemble any contracts, which require close attention to federal and state legal and regulatory issues to enable successful BP participation with CMS or other potential payers. The resulting contract(s) should define key terms, set forth parties' rights and obligations, provide clarity with regard to the allocation of dollars, establish processes for decision making and dispute resolution, and address voluntary and involuntary termination.

Centers for Medicare & Medicaid Services

Table of Contents

Foreword	iv
1. Introduction.	9
1.1. Purpose	9
1.2. BP Contracting Process	10
2. Initial Steps	11
2.1. Establish Organizational and Physician Leadership Commitment	11
2.1.1. Identifying Leaders	11
2.1.2. Obtaining Commitment	11
2.2. Assess Organizational Structure and Governance	12
2.2.1. Organizational Structure.	12
2.2.2. Governance	13
2.3. Obtain and Analyze Price and Cost Data	13
2.3.1. Objectives of Price and Cost Data Collection and Analysis	13
2.3.2. Bundle Creation	14
3. Plan Creation (Informs Contract Formation)	14
3.1. Care Redesign.	15
3.1.1. Care Redesign Planning Process.	15
3.1.2. Care Redesign Options.	17
3.2. Quality and Other Performance Measures	17
3.2.1. Reporting to CMS.	18
3.2.2. Use Among Providers	18
3.2.3. Selecting Quality Measures	18
3.3. Data Sharing Arrangements.	19
3.3.1. Systems ⁵⁹	19
3.3.2. Data Transparency	20
3.3.3. HIPAA Privacy and Security Rules	20
3.3.4. Business Confidentiality	20
3.4. Gainsharing	20
3.4.1. Establish Gainsharing Systems and Data Requirements	21
3.4.2. Develop Gainsharing Performance and Quality Measures	21

Centers for Medicare & Medicaid Services

3.4.3. Creating Payment Structures22
3.4.4. Ensure Transparency for Gainsharing23
3.4.5. Risk Sharing23
3.4.6. Assessing the Risk Involved23
3.4.7. Mitigating Risk.24
3.4.8. Sharing Risk24
4. Contracting24
4.1. Engage Competent Counsel24
4.2. Assess the Legal and Regulatory Landscape25
4.2.1. Federal Laws.25
4.2.2. State Laws and Regulations26
4.3. Draft and Execute Contract26
4.3.1. Define Terms27
4.3.2. Set Forth Parties' Rights and Obligations27
4.3.3. Provide Clarity with Regard to the Allocation of Dollars27
4.3.4. Establish Processes for Decision Making and Dispute Resolution27
4.3.5. Address Voluntary and Involuntary Termination.27
5. Conclusion28
Acronyms29
Endnotes.30

1. Introduction

In the United States, concurrent pursuit of reduced health care costs and improved health care quality has sparked a number of activities. Some involve delivery system reorganization, such as accountable care organizations (ACO) or patient-centered medical homes (PCMH), to help coordinate health services or emphasize primary care services and prevention. These models as well as others involve care redesign and are grounded in evidence-based medicine or best practices. They all focus on some aspect of modifying payment systems to incentivize desired provider practices, such as Pay for Performance (P4P), or bundling health care services, which is our area of focus.

A bundled payment (BP) provides a single, predetermined amount of money for treatment by one or more providers during an entire episode of care.¹ An episode of care is the treatment of a specific medical condition during a set period of time. BP offers many advantages over the current fee-for-service (FFS) payment model, which compensates providers for individual services. Linked appropriately to outcome and other quality measures, a lump payment makes the entire treatment team more accountable for an episode's cost, quality, and outcome, and therefore aligns financial incentives for hospitals and physicians, who currently operate under different financial pressures. BP also provides incentives to reduce waste and care defects through better coordination and consideration of financial ramifications of individual care decisions. BP offers the opportunity for providers to share in the savings obtained from eliminating duplication of services and improving care coordination, and can drive care delivery changes and ensure that successful organizations are rewarded commensurately. BP is distinct from the ACO, which employs a shared savings strategy as well, but generally targets care for a specific population rather than a set of diagnosis groups.

The Centers for Medicare & Medicaid Services (CMS) has been exploring the use of BP through programs such as the Acute Care Episode (ACE) demonstration and the Bundled Payments for Care Improvement (BPCI).² Efforts like the BPCI and ACE encourage communication and collaboration among different providers to achieve better patient care, eliminate duplicative or unnecessary treatment, and achieve savings for the Medicare program, to the benefit of

all parties involved.³

Participation in BP will likely require new understandings between different types of health providers and certain non-providers, reflecting a shared commitment to care redesign and promoting the dual goals of improved quality and decreased cost. These new understandings may require fresh contractual arrangements that articulate parties' roles and responsibilities as they work toward shared goals. Depending on the focus of a particular bundle, contracts could involve a range of providers, e.g., acute care hospitals, health systems, post-acute care providers (such as skilled nursing facilities and home health agencies), physician hospital organizations, physician group practices, and other care providers.

1.1. Purpose

Contracting for Bundled Payment is one of a series of CMS-authorized documents on certain key topics essential to preparation for BP:

- Information Technology for Bundled Payment
- Implementing Bundled Payment: A Case Study of Crozer-Keystone Health System
- Moving Toward Bundled Payments – Physician Leadership as a Core Competency: A Case Study of Aurora Health Care
- Improvements in Care-Transitions: A Case Study of St. Luke's Hospital

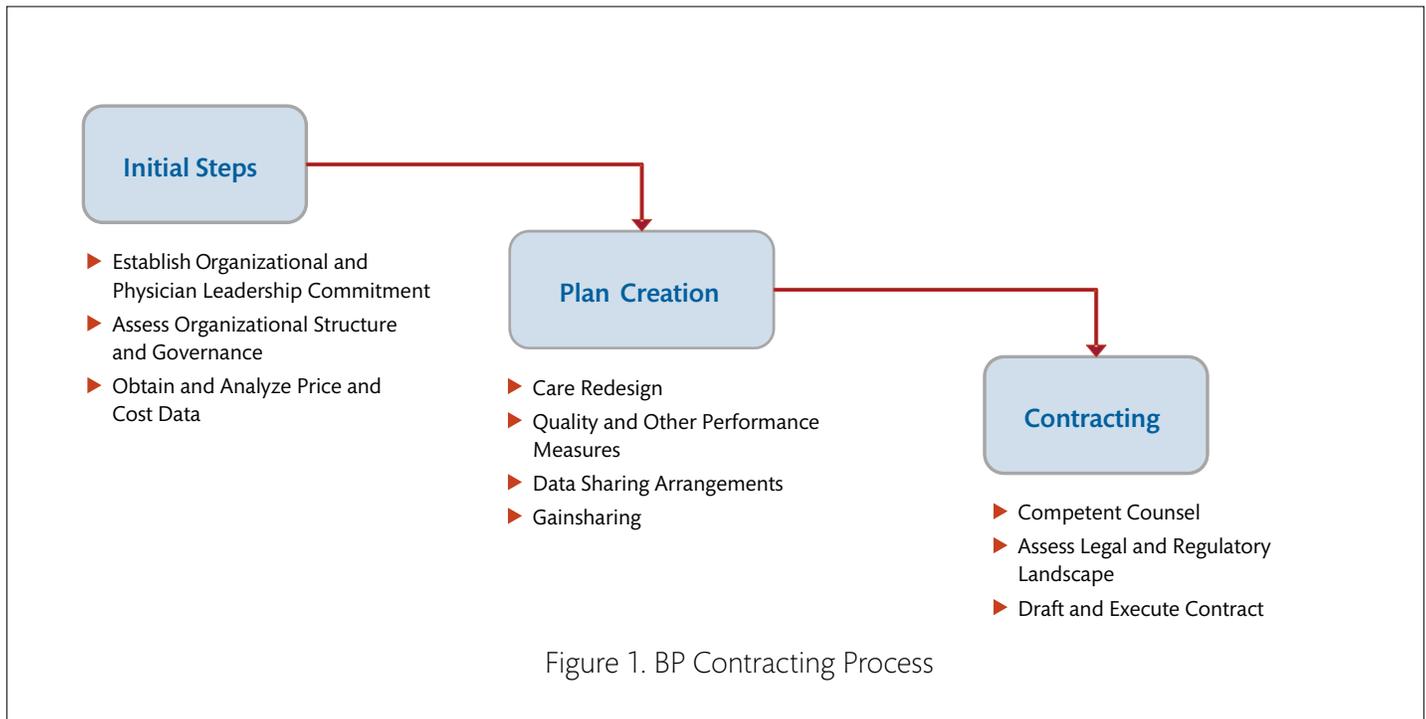
The purpose of Contracting for Bundled Payment is to help provider organizations to contract with one another in order to participate in BP programs with CMS or potentially other payers.⁴ The document focuses primarily on methods for defining contract contents that are unique to BP, such as those that flow from plans for care redesign, quality and performance measurement, data sharing requirements, and gainsharing agreements. Additional contract elements, such as dispute resolution or unwinding clauses, are essential, but not specific to BP. A competent contracting attorney may guide the construction of these clauses.

1.2. BP Contracting Process

The specifics of the BP contracting process may vary; however, organizations that have successfully implemented a BP program commonly describe a process that includes the elements portrayed in Figure 1. These elements include (a) several key initial steps, (b) the creation of a plan that informs the contract substance, and (c) the execution of a contract that establishes responsibilities and incentives for performing the critical BP plan details.

BP-specific topics that organizations may address during the contracting process. The figure also serves as a guide to the remainder of this document.

The BP contracting process is a subset of the larger BP process. There are critical activities that may take place prior to contracting, such as education of key decision makers, including Chief Executive Officers (CEO), Chief Financial Officers (CFO), and physician leaders, about the potential benefits of BP. Similarly, there are critical BP-related activi-



The specifics of each environment may necessitate a different ordering of the steps shown in Figure 1. For example, some organizations might engage counsel and survey the legal and regulatory landscape at the outset rather than at the end of the contracting process. The topic of care redesign could arise during the initial steps, at which time an organization could identify a care-redesign target area with wide variation in provider costs. If that occurred, the organization could create a detailed care redesign plan that attributes cost and quality to differences in specific provider practices much later in the process, even after the execution of the BP contract. Despite the potential for variation in process, we have set forth the steps above to illuminate the

ties that will take place after the BP contract is in place, including engagement strategies to gain physician buy-in, ongoing care redesign and improvement activities, and periodic evaluations, among others. All of these steps are important to BP; however, the contracting process itself is the subject of this document.

Section 2 explores the Initial Steps in the contracting process: establishing leadership commitment, assessing organizational structure and governance, and obtaining and analyzing price and cost data. Section 3 provides some detail about the Plan Creation process, which should generate key contractual features on care redesign, quality and

other performance measures, data sharing arrangements, gainsharing, and risk sharing. Section 4 focuses on the Contracting process, identifying some helpful questions for selecting qualified legal counsel, providing a survey of the laws and regulations that may have implications for BP implementation, and identifying the basic elements that should be included in the contract itself.

Although this document lays out the main BP-specific contractual features needed to successfully implement BP with CMS, it is neither intended nor should be construed as legal advice. It also does not represent an exhaustive analysis of all potential legal issues that organizations may encounter. Organizations should seek the advice of competent legal counsel in preparation for conducting BP.

2. Initial Steps

Experience demonstrates that certain initial steps can be useful when seeking to create one or more contracts to enable BP implementation. Obtaining organizational and physician leadership commitment can help drive and sustain the entire process. A focus on organizational structure and governance can help clarify and illuminate roles and responsibilities in BP planning and execution. Finally, obtaining and analyzing cost and price data is essential to creating a plan for care redesign and bundle creation.

2.1. Establish Organizational and Physician Leadership Commitment

Organizational and physician leaders will design, drive, and manage BP program planning and implementation.⁵ Leadership commitment is essential, because it engages the organization's decision makers—those ultimately responsible for organizational success or failure. Establishing this commitment also signals the importance of participation to all individuals and the prospects for reward. The process of establishing and mobilizing this commitment consists of identifying leaders, obtaining their commitment, and then establishing committees that carry out essential functions.

2.1.1. Identifying Leaders

Identifying the organizational and physician leaders with the authority to facilitate BP is a precursor to engaging

their participation. Organizational leaders might be members of the organization's senior leadership team: the CEO, CFO, and the like.⁶ Physician leaders, while not necessarily identified by their titles, are usually apparent to their peers. Physician leaders typically have the respect of their colleagues, demonstrate vision, and engage with hospital administration.

When the Aurora Health Care (AHC) organization was preparing for BP, it noted that as physicians were presented with data outlining the benefits of BP, “natural leaders who were highly engaged and eager to play a role in organizational change efforts emerged.”⁷ AHC's physician leaders began as volunteers, and now hold specially created positions in which they dedicate part of their time “to assist AHC in identifying and disseminating best practices.”⁸ AHC physician leaders demonstrate three characteristics: (1) clinical expertise; (2) operational effectiveness; and (3) good communication skills.⁹

2.1.2. Obtaining Commitment

The process for obtaining leadership commitment to BP is most effective when it is data driven. Both physician and organizational leaders respond well to case study examples that demonstrate how savings can be achieved with attention to clinical costs and quality measures. AHC's senior leadership, for example, held meetings at about 170 clinics sharing “clinical and cost data for the health system.”¹⁰ It was during these and subsequent presentations where the initial leaders emerged.

For the benefit of non-clinicians, special attention should be given to demonstrating how variations in clinical practice affect the actual cost of care. (See subsections 2.3.1 and 3.1.1.4 for additional discussion about data on the cost of care.) This information may be delivered by a qualified consultant, obtained at a BP seminar, and/or gleaned from literature and other sources and presented to leadership and motivated staff.

Successful early leadership discussions also typically focus on the parties' common or overlapping goals. These may include, for example, enhancing patient care and care coordination, achieving good patient outcomes, reducing cost,

engaging physicians and other providers in care redesign, ensuring sufficient resources, and recognizing a common commitment to treat all parties fairly. Resonance on each point is not required, but a shared understanding and a willingness to work together in a mutually respectful way is essential for success.

Once leadership's early buy-in has been established, it may be formalized through letters of commitment. From this point, leaders should participate in and direct or encourage others to become involved in the BP planning process, and ultimately in the implementation of the BP program. For example, in the Medicare ACE demonstration project, physician leaders participated in various committees (finance, quality measures, and provider incentive program), which enhanced physician commitment to these programs and protected against incentives that reduce care.¹¹ Trust among hospital and physician leaders, as well as joint participation, are markers of success in a BP program.

Organizational and physician leaders can help move an institution toward BP by developing committees to address key issues. These committees may conduct detailed work in such areas as gainsharing, information technology (IT), and quality. Emphasizing committee teamwork and integration has in many cases proved an essential first step in advancing past the difficulties created by silos of care.¹²

The structure and authority of committees can vary widely based on organizational structure, the maturity of the relationship between the participating care providers, the existing contractual relationships between the parties, and other considerations. For example, it may be necessary to contractually define the authority of a committee if it is comprised of representatives from multiple organizations, but not if it only involves the employees of one large health system. In addition, organizations can separately authorize different committees, as in the recent ACE Demonstration at Hillcrest, or can create them as components of the mission of a cross-functional bundle team. However structured, it is essential to integrate the work of various committees supporting BP to ensure a seamless design.

The composition of a given committee should depend on the competencies needed to accomplish its purpose. For example, a gainsharing committee would likely need to

identify gainsharing targets, determine risks, and define the mechanism for distributing gainsharing proceeds. It might also set minimum quality thresholds for gainsharing participation, identify areas for targeted savings, and develop the mechanisms for savings distributions.¹³ Therefore, a gainsharing committee should consist of physicians and representatives with expertise in quality measures, productivity, financial analysis, program administration, and communication.¹⁴

2.2. Assess Organizational Structure and Governance

Health care “silos,” or health care service organizations without connections to others relevant to patients, substantially contribute to the fragmentation in the U.S. health care system. One aim of BP is to break down these silos and better coordinate care. Patients transferred between siloed providers are more likely to experience duplicative or unnecessary care, which contributes to rising health care costs without necessarily contributing to improved quality of care.¹⁵

2.2.1. Organizational Structure

Organizations should consider what sort of structure is most appropriate for BP participation in light of applicable laws and regulations. Organizational structure may be determined in part by answering the question, “Who is going to act as the convener by contracting with the payer (CMS) to conduct BP?” The answer may help to determine how the providers involved in BP develop contractual arrangements among themselves.

One common organizational structure involves a convener that acts as a hub (typically a hospital or physician group), and executes a series of contracts with other organizations. Figure 2 illustrates a situation in which the hub is a hospital, which contracts with a physician group, a post-acute care facility, and a home health agency to conduct BP with CMS. Another common structure involves a convener that is a single entity with multiple stakeholder organizations. Figure 3 shows an example of a single entity comprised of a hospital, a physician group, a post-acute care facility, and a home health agency, constructed to conduct BP with CMS. Other structures, including hybrids of these two, are also possible.

Contracting for Bundled Payment

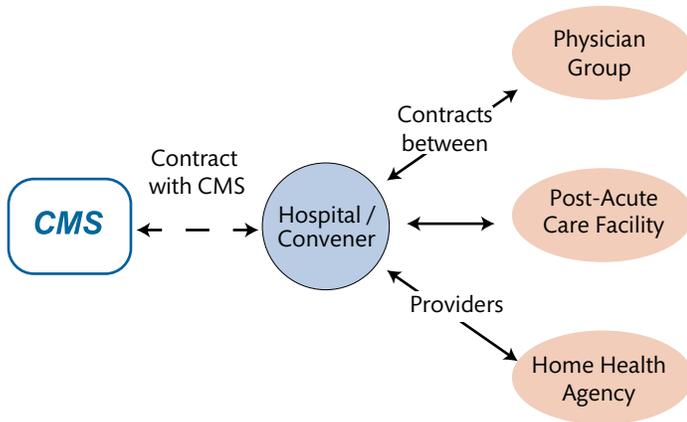


Figure 2. Example of Hub Organizational Structure

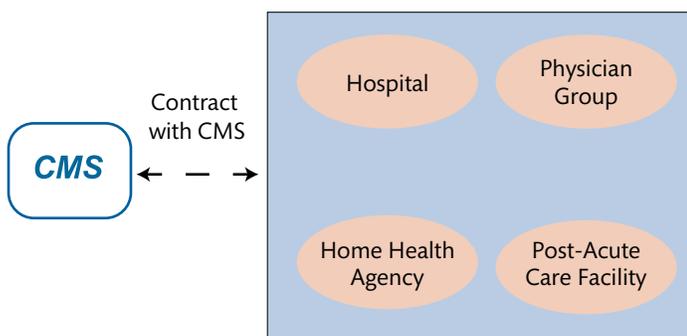


Figure 3. Example of Single Entity Organizational Structure

An organization may not need to change its structure to implement BP. Functional changes may suffice to accomplish the objectives of BP, or may be implemented in conjunction with changes to organizational structure. The following are types of functional changes that could facilitate BP.

- **Organizational Integration.** Organizations could consider how best to integrate their provider systems to align incentives across provider settings. This integration could promote greater efficiency, such as appropriate and efficient ways to transfer patients between provider settings without losing clinical data or performing duplicative services. Organizational integration might necessitate the creation of a new single entity, such as a physician-hospital organization, dedicated to serving the collaboration of the participating organizations.

- **Provider Cooperation.** Organizations could consider ways to foster cooperation between existing provider groups and settings without organizational integration. Improving relationships between existing providers may enable better care coordination. Such an approach could generate one or more contracts between or among the organizations.
- **Process Improvement.** Organizations could consider improvements to their clinical, administrative, patient, and other processes. Process improvements might result from changes to policies and procedures, and without fundamentally altering an organization's structure or even necessitating new contracts.

2.2.2. Governance

Providers should articulate and agree on governance of any BP program in advance of any contracts among providers. The contract should specify an agreed process for decision making, including who is authorized to make which sort of decisions, and how decisions will be made when parties disagree. A defined dispute resolution process is crucial to effective governance. The contract should specify the bounds of dispute resolution, whether by arbitration, mediation, or the use of a qualified third party.

2.3. Obtain and Analyze Price and Cost Data

Obtaining and analyzing price and cost data can be difficult, but it is essential for the development of a successful BP program. A detailed description of the methodology and techniques for acquiring this data is beyond the scope of this document; however, this subsection describes the importance of price and cost data for bundle creation.

2.3.1. Objectives of Price and Cost Data Collection and Analysis

The primary goal of price and cost data collection and analysis is to establish a baseline in a given clinical category for utilization rates, quality, revenue, and clinical and other costs. Establishing meaningful baselines may require regional data. If a provider system is large enough, internal data might be sufficient.

Cost data (not just related to inpatient stays) is quite important, but may prove particularly difficult to obtain. Cost data means the actual costs of delivering services, not the amount that an organization charges for its services. This process can be challenging because hospital clinical and cost systems are not typically integrated, and because cost systems manage overall costs in an area, such as an operating room, rather than the individual patient care that physicians are responsible for delivering.¹⁶

For example, to compare mitral valve replacement procedures, hospitals would need to exclude mitral repair, multivalve replacement, and valve replacement plus coronary artery bypass. The analysis also should include any other relevant clinical information, including outcome data and all products used on the case.

Some cost accounting systems also do not capture all items individually. Instead, some items, such as sutures, are divided across the usage of these products in the operating room. This procedure makes it difficult to compare practice patterns within the same hospital. It is also challenging for physicians to use the data in determining best practice patterns.¹⁷

Even when cost data is available, variations in how different hospitals categorize the same costs may complicate regional cost comparisons. Despite the difficulty, apples-to-apples comparisons of clinical costs and quality are necessary for BP program preparation. Only cost data can illuminate the impact of physician preference items on quality and cost, or demonstrate the financial impact of potentially avoidable complications.

In order to tease out and determine the impact of clinical costs, Geisinger Health System reports that their “patient care teams spend countless hours reassessing how they perform specific procedures. They examine patient care records. They also research best treatment recommendations from national experts, professional associations and databanks.”¹⁸ A robust data warehouse facilitates these efforts, clustering financial, clinical, and billing data together in a single location.¹⁹

A common strategy for effective data collection and analysis is to engage qualified experts, whether in house or externally, to analyze the best available information from all sources on costs, pricing, and care redesign. Expert engagement increases the probability that the platform for change is both sound and designed to best fit an organization’s needs.

2.3.2. Bundle Creation

Effective bundle creation and care redesign planning depend on the ability of an organization to establish cost, quality, and utilization baselines. Once baselines are established, an organization can evaluate how its providers perform on cost and quality metrics compared with others. Bundle creation and care redesign may focus on norming practice pathways, eliminating waste, improving quality, and, of course, lowering the cost of care. Key questions to ask when creating a bundle include:

1. To which conditions should BPs be applied?
2. What providers and services should be included in the BP?
3. How can provider accountability be defined, measured, and incentivized in a BP environment?
4. What should be the time frame of a BP?
5. What are the necessary capabilities for administering a BP?²⁰
6. How should BP payment amounts be determined?
7. How should the BP be risk adjusted?
8. What data is needed to support BP?²¹

(See subsection 3.1 for a detailed discussion of the related topic of care redesign.)

3. Plan Creation (Informs Contract Formation)

Participating in a BP program with CMS requires, at a minimum, that organizations have contracts in place with participating providers and non-providers such as vendors. Organizations may also want to have in place agreements among themselves that reflect their respective roles and

Contracting for Bundled Payment

responsibilities in patient care, data sharing, administration, and other areas.

The nature and structure of the contracts will depend in part on what types of arrangements are already in place among various providers. Some locations may already have a co-management program under which the participating entity receives co-management payments from the hospital.²² In other instances, there may already be a physician-hospital organization with established governance structures, or there may be existing direct contracts between the hospital and physicians as well as between the hospitals and other providers. In addition, there may be existing contracts between large physician groups and hospitals. To accommodate participation in a BP program, it may be necessary to develop one or more new contracts or modify existing agreements.

Regardless of the types of providers involved in a particular program and the nature of prior agreements, certain features should be considered when formulating the contracts that will introduce and govern a BP program. These features include care redesign, quality and other performance measures, data sharing arrangements, and gain and risk sharing.

As shown in Figure 4, in BP, the features relate to one another in specific symbiotic ways. Care redesign informs and is reinforced by gain and risk sharing, as well as quality and performance measurement. Gain and risk sharing reinforce and are informed by quality and performance measurement. Data sharing supports all of these activities and the information/reinforcement exchange between each activity. Contracts between provider organizations should reinforce organizational goals with respect to both these features and the symbiotic relationships between them.

3.1. Care Redesign

Care redesign is BP's objective and the key to its success. Meaningful care redesign can achieve efficiencies that will reduce the cost of healthcare, maintain or increase quality, and ensure effective risk mitigation. Care redesign must also drive gainsharing formulation, and so ensure financial rewards to providers who deliver care in accordance with the best practices targeted by the care redesign. All of this

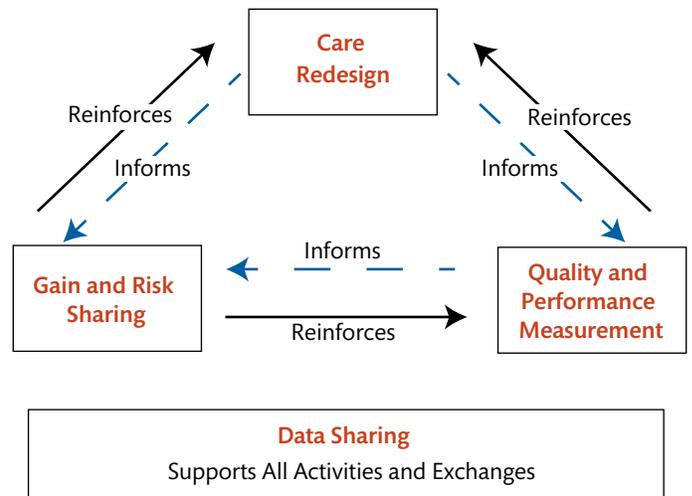


Figure 4. Relationships among Care Redesign, Quality and Performance Measurement, Gain and Risk Sharing, and Data Sharing in Bundled Payment

means that care redesign must be carefully planned and implemented. It must also be fully aligned with other essential contract features so that all parties understand their respective responsibilities. This subsection delineates the care redesign planning process and offers basic care redesign options.

3.1.1. Care Redesign Planning Process

The process for creating a plan for care redesign will vary depending on factors such as the type of organization involved, the patient population, the types of services provided, and what variation exists among provider practices. There are a few overarching steps and objectives that can be articulated. The Agency for Healthcare Research and Quality (AHRQ) suggests the following five-step process:

1. Assess the readiness for major redesign
2. Establish broad objectives for redesign
3. Create a structure for the redesign process
4. Gather external and internal data
5. Select tools to enable redesign implementation²³

The following subsections provide a discussion of each step.

3.1.1.1. Assess Readiness

The first step in creating a plan for care redesign is to ensure that an organization is ready for the undertaking. To make this assessment, the organization may investigate what other redesign projects it has completed, ascertain any lessons learned, and assess whether the workforce believes that the projects were beneficial. The organization may also confirm with its top administrative, physician, and nursing leaders the commitment to the process and the compelling reasons for redesign. Finally, the organization may assess whether it has a culture committed to data and information sharing, whether its workforce has the needed skills and tools to accomplish redesign, and whether the organization has the resources to undertake the redesign process.

A readiness assessment could also involve BP simulations, although these may be time intensive. Following 3 years of planning and preparation, in 2011, the Crozer-Keystone Health System (CKHS) launched a simulation of BP with Independence Blue Cross for knee and hip replacements.²⁴ “The payment simulation will close in March 2012. By July 2012, the 90-day clinical tail of the bundles, along with the 60-day administrative claims tail, will be complete.”²⁵

3.1.1.2. Establish Broad Objectives for Redesign

A second step in care redesign plan creation is to establish broad objectives evaluating the redesign process.²⁶ These objectives help to guide the redesign effort and focus process changes. For system-wide transformation, the objectives may touch upon quality, safety, customer service, efficiency, architecture/physical environment, and workforce development, including physician development.

Viewing care redesign with multiple objectives in mind can create feedback loops that positively affect the other objectives. For example, focusing on quality as an objective can result in process transformations that not only improve quality but also enhance customer service. In addition, while the various objectives may overlap, referring back to them during the care redesign process can help to prevent sub optimization. If a redesign initiative focused solely on efficiency, it could negatively affect customer service or workforce development.

3.1.1.3. Create the Structure

There are three basic components for the creation of care redesign. These components are similar to those discussed within the Initial Steps. The first is establishing a point person to lead the redesign. The point person should be an organizational and/or physician leader.

The second step is to develop a team to oversee the planning approach. The team should consist of individuals possessing the competency to gather, analyze, and interpret the data. Candidates might include, for example, an industrial engineer, a CEO, a medical director, a nurse with clinical experience, a director of health services research, and data and research analysts.

The third step is to form a broad-based internal group of leaders and champions to consult on the design and eventual implementation of the approach. This group is critical to ensuring the necessary provider buy-in to change the delivery of care. This group will presumably consist of some or all leaders who initially made a commitment to create a BP plan.

3.1.1.4. Gather Data

Data is essential to driving the care redesign and broader BP process; accordingly, its collection, analysis, and presentation are vital. (See subsection 2.3 for more information on cost and price data.) Sources of data that may inform the care redesign process may be external (from a literature review, external expert, database, or site visit), or internal (from employee or patient focus groups and observation of current processes). Data can be viewed in terms of health care processes and measured in terms of time and activity type. It is especially important to gather information on the cost and quality impact of clinical decisions made by clinicians.

Organizations can analyze data to identify waste, bottlenecks or other inefficiencies, and potential targets for quality improvement and/or cost reduction. The presentation of the data benefits from visual aids that clearly highlight the results. For example, pie charts typically offer effective representations of the relative size of a component compared to the whole and other components. By con-

trast, Pareto diagrams—bar graphs arranged in order from largest to smallest—are helpful for displaying and depicting the ranking of various activities.

3.1.1.5. Select Implementation Tools

Once optimal redesign targets are selected, the healthcare workforce may require implementation tools to accomplish system transformation. Two types of tools for redesign have been used by both health care and non-health care systems: those that facilitate process change, and those that facilitate change in the environment, culture, and/or workforce.

Tools that facilitate process change may, for example, provide a model for rapidly testing ideas for improvement (e.g., “Plan, Do, Study Act” or “PDSA”).²⁷ They may enable more efficient work while enhancing customer service (e.g., “Lean”).²⁸ These tools also may help to optimize and normalize processes to eliminate deficits (e.g., “Six Sigma”).²⁹

Tools that facilitate change in the environment, culture, and/or workforce may provide a business framework and help to improve organizational performance practices (e.g., “Baldrige Criteria for Performance Excellence”).³⁰ These tools may focus on and enhance the smallest replicable working unit that actually does the work, such as a team of people, a local information system, a client population, or a particular space or work design (i.e., “Clinical Microsystem”).³¹ They may focus on healthcare workers themselves, aiming to get the right person into the right job (i.e., “Talent Profiling”).

Once tools are selected, they should be made available and the workforce must be trained in their use. The tools should be utilized to achieve the primary objective of facilitating care redesign by the care redesign team, and eventually reducing costs and improving quality.

3.1.2. Care Redesign Options

Care redesign can encompass a wide array of actions. As with organizational structure, participating providers should not be limited in the care redesign options they consider to improve the quality and efficiency of healthcare services. The following examples of possible care redesign options exist:

- **Care Coordination.** Organizations should consider how best to smooth transitions across healthcare settings and among various providers. For example, this might entail focusing on improving follow-up care, eliminating redundant testing, and reducing expensive hospital readmissions.³² Alternatively, physicians and administrative leaders may team up to manage service lines.³³
- **Clinical Practice Improvement.** Organizations should consider mechanisms for improving clinical practices.³⁴ Examples include efforts to reduce preventable errors,³⁵ the use of checklists to reduce the incidence of nosocomial infections,³⁶ and the creation of incentives to adopt clinical practices that concord with evidence based medicine.
- **Supply Chain Optimization.** Organizations should explore ways in which quality-driven supply chain optimization can minimize supply chain tasks for clinicians, reduce supply-costs, and increase nurse and physician satisfaction.³⁷ Physician input is especially helpful in these efforts.
- **Patient Focused Interventions.** Organizations should consider interventions that improve communication and the engagement of patients in their care. Examples include patient education,³⁸ patient follow-up, and medication management.³⁹

Organizations should select care redesign options based on best available data; the effect on cost, quality, and efficiency; and on considerations specific to their organization’s environment.⁴⁰

3.2. Quality and Other Performance Measures

Once an organization has determined the desired elements of care redesign, it must establish quality and efficiency requirements to ensure that quality of care remains the same or improves while reducing costs. Performance measurement provides objective data necessary to assess the success of a BP program. Applicable measures may be selected based upon the medical condition(s) and services included in the bundle, the limitations imposed by the IT infrastructure supporting the collection and interpretation of the data, the intended purpose of the measures, and the care redesign processes and goals.

Performance measures are likely to be used in two BP-related settings: (a) for reporting to CMS,⁴¹ and (b) for gain/risk sharing and quality improvement efforts among providers. Each of these settings may have its own distinct set of performance measures. In each case, the contracts among providers should articulate the required quality measures together with their intended and potential use. The following subsections describe and highlight contractual considerations for reporting to CMS, use among providers, and measurement selection.

3.2.1. Reporting to CMS

Healthcare providers that conduct BP with CMS will likely need to report on CMS-specified quality measures and maintain minimum quality standards for continued participation in a BP program. Contractual agreements among participating providers should reflect any quality reporting requirements and minimum quality standards, and articulate any consequences for failure to report or perform as required.

3.2.2. Use Among Providers

In addition to information required for reporting to CMS, BP participants may use performance measures to determine gainsharing apportionments and inform quality improvement activities. The measures used by participating providers should reflect the length of the episode of care, the care included in the bundled payment, and the group of participating providers involved in the gainsharing agreement.⁴²

Performance data should be easily accessible to providers to ensure program transparency, possibly through the creation of performance reports. Transparent performance data bolsters trust between participating parties and facilitates improvement in the quality of care provided. In cases where providers are already top performers, it encourages a continued standard of high performance. (Subsection 3.3.2 discusses in further detail the benefits of data transparency.)

CKHS, which has implemented a BP pilot for hip and knee replacement, reported that its surgeons welcomed information on quality.⁴³ The participating surgeons were able to benchmark their performance against that of their col-

leagues, which provided an impetus for quality improvement. Benchmarking identified one physician with significantly lower transfusion rates than his peers. CKHS studied this physician's approach, shared the results with his peers, and significantly reduced the rate of transfusions.⁴⁴

Organizations should ensure that physicians obtain data regularly to support continued quality improvement. AHC provides information to physicians quarterly, allowing them to assess critical care processes and the impact that interventions have on process output.⁴⁵ Each practicing physician receives a report containing "patient satisfaction scores, care management scores, patient access statistics, coding, charge lag time, and production statistics."⁴⁶ In addition, AHC's physician leaders receive summary reports that give a "snapshot of key performance metrics... for all physicians in a group." These reports allow physician leaders to identify both individual physician problem areas and also broad "performance gaps" that may need to be addressed at a system level.

Contracts should reflect the understandings necessary to ensure that quality and performance data are collected and shared among providers, care settings and episodes of care. Contracts should specify the frequency for communicating performance standing to providers, the format for conveying this information, and the manner in which it can be accessed, and the consequence of noncompliance.

3.2.3. Selecting Quality Measures

Performance measures are instrumental in providing "information and feedback to providers to help improve patient care, to incorporate patients' feedback and insights into care delivery strategies, and to assure the public that any cost savings coincide with improvements in care."⁴⁷ There are currently a significant number of endorsed quality measures.⁴⁸ The Department of Health and Human Services (HHS) Measure Inventory, for example, contains all the measures HHS uses for "quality measurement, improvement, and reporting."⁴⁹ Many providers are familiar with quality metrics⁵⁰ based on participation in CMS quality initiatives including the Hospital Inpatient Quality Reporting (Hospital IQR) program, the Physician Quality Reporting Initiative (PQRI), or the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). Other providers may be participating in

Contracting for Bundled Payment

surveys created by non-public sources such as the Leapfrog Hospital Survey, created by The Leapfrog Group. Providers may easily adopt measures with which they are familiar. AHRQ provides a tutorial on selecting quality measures⁵¹ as well as an outline of questions to consider before starting the process of developing new measures.⁵²

While quality measures can help to drive care improvement, efficiency measures encourage the efficient use of resources. The development of efficiency measures has lagged behind the development of quality measures,⁵³ but there are numerous efficiency measures in use today. AHRQ has defined efficiency as “the relationship between a specific product (output) of the health care system and the resources (inputs) used to create the product.” Common outputs measured include hospital discharges, inpatient days, and outpatient procedures, while common inputs include physician labor, nursing labor, beds, and various financial inputs. Efficiency measures examine the ratio of an input over an output; however, there are measures that include multiple inputs and outputs. AHRQ’s literature review reveals there are currently 155 efficiency measures for hospitals, 35 measures for physicians, and a number of measures for other providers such as nurses.⁵⁴

Choosing the right measures means not only selecting the ones that best fit a BP program’s goals, but also selecting those measures that an organization can implement with relative ease. The consensus in the industry is that reliance on existing quality measures causes the least administrative burden^{55,56} because of the cost involved in designing and administering new measures. Moreover, designing new measures can be a very long process. Once participating providers agree on the measures, they need to determine their relative weight. Participants may decide on a weighting system based on prior practice or input from physicians, or they may elect to follow instructions from established quality assurance organizations.⁵⁷ Assistance from expert consultants may be beneficial during this process.

The contractual agreements should specify the measures chosen, their relative weight, the timing of the evaluations, and the methodology used to score providers against the measures. Alternatively, the agreements may cross-reference sources where providers can access performance-related information. Participants may consider using teaching mate-

rials or holding educational sessions to assist providers in understanding what they will be measured on and how performance will affect their ability to participate in gainsharing. In addition to specifying the performance measures, contractual agreements should identify measures that may be incorporated in the future to meet an organization’s evolving needs, adjust to advancement in technology that may affect performance, or to address adjustments in an organization’s goals.

3.3. Data Sharing Arrangements

Successful bundling arrangements require a high degree of information sharing and integration between participating providers. Given the sheer number of healthcare providers that participate in a given patient’s care, the potential for duplication of services, adverse drug reactions, and, at times, adverse and irreversible side effects is great.⁵⁸ Data sharing will help overcome many of these deficiencies and ultimately lead to better care (through integration) and lower cost (by avoiding treatment redundancy and adverse outcomes). A well-drafted data sharing agreement provides a framework for the secure transmission of necessary financial, clinical, and quality data that will assist in successful effectuation of the BP program. The following subsections address the major components in data sharing arrangements, starting with the systems required to support data sharing, transparency considerations, the laws and regulations affecting clinical data sharing, and considerations when sharing proprietary data.

3.3.1. Systems⁵⁹

Efficient methods for sharing clinical data and agreed-upon care pathways can enhance care quality and effectiveness, as well as reduce costs by eliminating redundancies and other sources of inefficiency. To facilitate collaboration among physicians and other members of the care team and to coordinate the best care for patients, each physician needs timely access to relevant patient information, especially information about treatments made by other providers.⁶⁰ Physician engagement may prove beneficial when designing or deciding on an information sharing system.⁶¹ For example, “after much experimentation” the leadership at CKHS found that “there was no ‘magic formula’ for displaying data to physicians.” They sat down with each

orthopedic group and created a “customized dashboard” that incorporated a particular group’s workflow and preferences.⁶² Participants may wish to specify any required systems in a formal agreement, particularly if a participant will need to transition systems or invest in additional IT resources as a condition for participation.

Although some investment in technological infrastructure may be necessary,⁶³ an organization’s existing technological capabilities will dictate the financial investment to facilitate data transfers. An increasing number of participants already use electronic health records (EHR).⁶⁴ Many smaller practices may not have adopted EHR; nevertheless, there are other ways to obtain and share this information.⁶⁵ Software and service vendors as well as off-the-shelf databases provide readily available data exchange and analytic capabilities. These relatively low-cost options can create a framework for storing and accessing data from many provider sites. Many organizations have created “data warehouses” for quality improvement and performance tracking. More recently, organizations have started adopting virtual data networks for accessing patient relevant data.⁶⁶ These solutions are examples of different approaches; providers should adapt their existing systems (or adopt new ones) as necessary to best facilitate data sharing and transfers.

3.3.2. Data Transparency

Transparency in many aspects of the BP program fosters trust in the program among providers and ensures their continued cooperation. A high level of transparency in financial and quality measures can enhance relationships between BP participants because it equips care providers with a common starting point for improving the efficiency, effectiveness, and quality of care. Organizations may make financial and performance data available to providers on a regular basis to streamline care and improve quality. (Subsection 3.2.2 provides examples from cases studies on this point.) Contractual agreements should, therefore, include provisions on how the data will be made available to participants, the frequency of such availability, and how providers’ identity will be protected (e.g., by providing information in a blinded⁶⁷ fashion).

3.3.3. HIPAA Privacy and Security Rules

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁶⁸ provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. The HIPAA Privacy Rule⁶⁹ is balanced; it permits the disclosure of personal health information needed for patient care and other important purposes.⁷⁰ The HIPAA Security Rule⁷¹ protects a subset of information covered by the Privacy Rule; this includes all individually identifiable health information a covered entity creates, receives, maintains, or transmits in electronic form, also called “electronic protected health information” (e-PHI).⁷² Covered entities must maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting e-PHI.⁷³

The Privacy and Security Rules contain requirements relevant to those seeking to receive claims data from CMS and seeking to exchange certain health information with organizations collaborating in BP. In these cases, HIPAA requirements should guide the construction of data sharing agreements. Organizations should engage competent legal counsel to ensure that data sharing arrangements are HIPAA compliant.

3.3.4. Business Confidentiality

Information shared as part of a bundling arrangement may be competition sensitive. In some cases, BP participants may have access to proprietary information from various providers. BP participants may wish to explicitly provide for the protection of this data through nondisclosure agreements (NDA) with other participants. NDAs should be drafted by competent legal counsel to specify what information is restricted, how restricted information may be used, to whom the restrictions apply, and what remedies are available for a breach of the agreement.

3.4. Gainsharing

As a general matter, the term “gainsharing” describes a team-based approach to improving quality and reducing costs that distributes gains to team members when certain pre-determined organizational objectives are achieved. In healthcare settings, gainsharing typically refers to the allo-

Contracting for Bundled Payment

cation among providers (e.g., hospitals, post-acute care providers, physicians, and non-physician practitioners) of money that represents a portion of the financial gains achieved due to more coordinated, efficient, and higher quality care.⁷⁴ Under gainsharing agreements, healthcare providers may distribute program savings to physician(s) and/or other practitioners according to jointly predetermined measures. These payments can help to align incentives for healthcare providers to coordinate care, improve quality and efficiency of care, and partner in the improvement of care delivery.

Although it is possible to engage in BPs without gainsharing, gainsharing agreements are often used to incentivize BP participation and quality improvement. Gainsharing agreements entered into as part of participation in a particular program may need to include additional program-specific provisions to ensure compliance.⁷⁵

3.4.1. Establish Gainsharing Systems and Data Requirements

As noted in subsection 3.3, successful BP and gainsharing agreements require data specific to each participant. For this reason, gainsharing contracts should take into consideration the reliability and integration between gainsharing participants of productivity measurement systems, financial measurement systems, quality measurement systems, performance management systems, and compensation systems. Because gainsharing requires a high degree of transparency and shared information, the integration and transparency of these systems become important considerations for gainsharing participants as they structure gainsharing targets and payment structures. Although the level of integration may be limited by the availability of certain IT resources, proper planning by the participants can ensure transparency. Regardless of how sophisticated the IT systems may be, it will be important for the participants to specify exactly how data will be made transparent. Participants should consider determining in advance exactly what quality, cost, or other reports will actually look like, how frequently they will be provided, and what specific data sources will be used to develop them.

3.4.2. Develop Gainsharing Performance and Quality Measures

Once the data requirements and system capabilities of the bundle are well understood, it will be necessary to establish quality and performance requirements. The context-specific nature of these decisions makes generalization difficult; however, there are several features common to most gainsharing arrangements that prospective participants may wish to take into consideration when drafting agreements.

There are two primary inputs that gainsharing programs can focus on to improve health and process outcomes. The first is the services provided by physicians, non-physician care providers, and health staff. The second is the tools and materials used to provide that care. In order for gains to be generated, the same or lower levels of services and material inputs will need to produce the same or higher quality.⁷⁶ Many redesigns in the care improvement process reduce both sets of inputs while improving health outcomes. For example, reducing re-operations means that less services and materials will be used and that the patient will not be required to undergo additional surgery.

In other cases, a targeted increase in one input can reduce other inputs and increase quality. For example, a program that increases the number of physician rounds to reduce PACs may require an initial increase in services provided, but may also result in an aggregate decrease in service and material inputs with higher care quality. For example, Geisinger Health System's ProvenCare program was able to reduce 30-day re-admissions for coronary artery bypass graft procedure patients by 44 percent after investing additional resources in developing evidence-based benchmarks and implementing industry best practices.⁷⁷ This approach required an upfront increase in program design and in services provided, but significantly reduced costly re-admissions.

Additional examples of gainsharing measures that track lower service inputs include reducing readmissions, reducing intensive care unit (ICU) utilization, and identifying and removing testing that does not improve quality of care. Measures that track reductions in material inputs include reducing the cost per test, care re-design to streamline medical device usage, and improving supply chain management to identify areas for savings.

Healthcare providers entering into BP arrangements will make gainsharing determinations based on their individual circumstances, but it is important to emphasize that accurate data from productivity measurement systems, financial measurement systems, quality measurement systems, performance management systems, and compensation systems is critical for evaluating the ratio of inputs to outputs to identify opportunities for care redesign and process improvement. It is also true that more measures are not necessarily better than fewer measures. In many cases, organizations are more successful in bringing about change incrementally by focusing on a few widely understood measurements with frequent feedback.⁷⁸ What is important is that the participants agree that the selected measures fairly measure how well care is provided under the redesigned procedures. For this reason, participants may wish to limit the complexity of the gainsharing distribution mechanism in their gainsharing agreements, depending on the maturity and the structure of existing relationships among the network of care providers.

Healthcare providers delivering care in a BP setting will also have to ensure that they maintain any minimum quality standards required by the participating payer. This will likely require a minimum set of quality measures and minimum quality thresholds. Participants could choose to reflect these requirements in agreements with participating providers, and maintenance of quality standards should be a condition for participation in gainsharing. This will help to ensure bundle participants are not provided with incentives to reduce quality of care to achieve savings. Participants in a gainsharing agreement may also define additional measures as a condition to providers to ensure that care redesign efforts are improving quality. Examples could include fewer re-operations and lower readmissions. Most participants in a gainsharing agreement will be familiar with these and other types of internal quality measures that are used for both aggregate quality reporting and individual performance management. Finally, many gainsharing programs will likely include additional quality measures as criteria for distributing gains.

Quality measures commonly used in gainsharing agreements include quality metrics that generally focus on the output of the healthcare process (better health and healthcare) and efficiency metrics, which tend to empha-

size making better use of the monetary and non-monetary inputs. Subsection 3.2 discusses quality and other performance measures that participants may consider in additional detail. A well-designed gainsharing program will incentivize participants to maximize the quality of care, while maintaining or reducing the inputs.⁷⁹

3.4.3. Creating Payment Structures

Gainsharing participants must also decide on a method for distributing gainsharing proceeds. Generally, payment and risk are closely linked under gainsharing and similar arrangements, including ACOs.

Key considerations related to gainsharing proceed distribution include:

- Each participant's impact on the goals of higher efficiency and quality of care
- The structure of the relationships between the participants
- The minimum quality performance targets

Participants in a gainsharing agreement have significant latitude in designing the precise criteria for receiving a gainsharing payment. While participants must be careful to follow any restrictions associated with a BP program requirement,⁸⁰ there are generally few restrictions regarding the minimum performance targets providers must reach to receive a gainsharing payment. Many participants in gainsharing agreements have used performance at the 75th percentile in their program or geographic area as a minimum target. Participants should focus on selecting a performance target that is both achievable for their provider population and will result in the necessary savings. Frequent payments are sometimes described as more effective incentives than larger and less frequent payments;⁸¹ however, a recent study in which doctors were provided with quarterly results, but not payments, found no significant differences in quality of care between physicians compensated quarterly and yearly under a P4P methodology.⁸² Where appropriate, participants and participating providers may find it useful to defer distribution of some portion of gainsharing proceeds as additional data is collected.⁸³

Contracting for Bundled Payment

An additional consideration is that providers who bear the larger portion of any risks are likely to require that they receive a commensurately larger share of gains. The sophistication of the various provider payment systems will also affect the structure of gainsharing payments, particularly where the BP is paid prospectively. All BP provider agreements should include a clear description of the process for determination and distribution of financial rewards (and risks) associated with the bundling activities.

3.4.4. Ensure Transparency for Gainsharing

Another key to gainsharing agreements is transparency. Gainsharing agreements should ensure two basic types of transparency. The first is transparency that enables auditing of the gainsharing agreement upon the request of payers involved in the BP. The second is transparency among care providers concerning how all gains and risks are to be distributed.

This second type of transparency depends on clarity in the agreement concerning what constitutes shared savings, how parties can obtain information regarding shared savings, and information on the methodology and frequency with which shared savings are distributed.⁸⁴ In some cases, handbooks including the details of the care redesign, all quality metrics, formulas for how apportionments will be calculated and detailed descriptions of sample reports have been distributed to providers to ensure the greatest possible transparency. For some organizations, this additional transparency may require a shift in attitude toward the sharing of data because, in many organizations, cost and quality data currently resides in silos. Nevertheless, both forms of transparency are important for gainsharing and BP more broadly because they enable a team-based approach to addressing concerns and difficulties as they arise.

3.4.5. Risk Sharing

Bundled payments provide an opportunity for cost savings that can be shared among participating providers, but also present risk if targets and minimum performance metrics are not met. Contracts among providers should reflect a clear understanding regarding how downside risks will be borne by each individual provider. Organizational structure may play a major role in determining how the risk associ-

ated with bundle participation is borne. A highly integrated organization with salaried physicians may decide to bear the risk and provide bonuses to their physicians based on savings and performance, whereas less integrated providers can share risk in a variety of ways. In some cases, specialists such as orthopedists have been willing to bear all the risk,⁸⁵ while in the recent ACE demonstrations, physicians were not required to bear any of the downside risk. This subsection describes how participants may assess the downside risk associated with participation in a BP program and how that risk can be mitigated. It also presents some considerations for risk sharing arrangements.

3.4.6. Assessing the Risk Involved

A risk assessment should be performed as a precursor to contracting activities. In all likelihood, organizations will engage in discussions and analysis of the risk involved with a specific BP program from the inception of their business plan. BP typically involves two types of risk: insurance risk and technical risk. “Insurance risk is the risk that an episode will occur. Technical risk is the risk that technical mistakes will be made during the services provided for an episode. It is also the risk incurred in selecting the types of services included in the episode.”⁸⁶

Some risks may be within various providers’ control, such as those having to do with avoidable errors. Others may be avoidable in some cases but not others; for instance, the risk of increased per-episode costs resulting from patient readmissions.⁸⁷ Quality and efficiency protocols will assist providers in reducing or avoiding these types of technical risks. Still other risks may be further outside the control of providers, such as those related to the general health of the population served during the duration of the BP program. For example, if hospitals are the recipients of the bundled payment,⁸⁸ their financial risk may increase due to wider variation in total costs across patients.⁸⁹ Once risks of various types are identified, a potential participant should assess its ability to bear the risk and agree on formulas for sharing it.

The risk involved with participation in a BP program is closely tied to the medical condition(s) and services involved in the bundle.⁹⁰ The process of risk identification should involve participants from the physician and hospital

administration communities who are best positioned to identify potential pitfalls as well as savings opportunities. Some services may contain more opportunities for savings than others.⁹¹ For example, the risks in acute care settings will differ in significant respects from the risks in post-acute or chronic care settings. Larger organizations may have sufficient data to run financial and clinical analyses to ascertain the risks involved, while others may need to develop other strategies for obtaining this information.

There are indications in the healthcare community that some providers feel at a disadvantage “in negotiating and managing shared-risk arrangements because of their lack of experience in understanding the overall financial risk of their populations and actuarial modeling to support negotiating and managing shared-risk contracts.”⁹² This underscores the importance of sharing all relevant information among providers and, if necessary, providing them with other tools to facilitate their assessment of risk and ability to bear risk.

3.4.7. Mitigating Risk

Based on the risks identified, provider organizations may develop a mitigation strategy. Such a strategy may include, for example, the use of certain quality and efficiency measure benchmarks to encourage desired behaviors and to ensure that providers do not reduce care. It may also involve stringent inclusion criteria for providers to participate in the BP program. In other cases, such as in the recent Alternative Quality Contract (AQC) initiative developed by Blue Cross Blue Shield (BCBS) of Massachusetts, providers may be required to get reinsurance for high-cost patients.⁹³ Effective risk mitigation strategies are likely to require collaboration between stakeholders with expertise in care redesign as well as in defining and pricing bundles. Where appropriate, provider contracts should reflect the responsibilities of each party as they relate to the mitigation strategy.

3.4.8. Sharing Risk

Once risk is assessed and mitigation strategies are identified, an organization needs to determine how providers will share the risk related with participation in a BP program. The structure of the organization and the condition included in

the bundle will play a major role in determining not only the nature of the risk involved, but also how the participants will bear the risk. As described previously, some highly integrated organizations with salaried physicians have decided to bear the risk of losses itself. Other providers may decide to share the risk. For example, under the AQC initiative, providers were permitted the option to assume anywhere between 50–100 percent of the risk.⁹⁴ Still other organizations might decide to bear the risk of loss to attract additional participants. This approach was adopted for the ACE Demonstrations at Hillcrest, where physicians were explicitly excluded from the risks of the gainsharing arrangement. Project participants cited this arrangement as a key to obtaining physician support for the project.⁹⁵ On the other hand, our interviews with experts have indicated that in some specialties, such as orthopedics, some independent surgeons have been willing to take on 100 percent of the risk. As the foregoing discussion illustrates, there are a wide variety of approaches to sharing risk among participants. Once participants agree on a risk sharing approach, the contractual agreements between the parties should reflect the formula or method for risk allocation as appropriate.

4. Contracting

Leadership typically reviews and approves the completed BP plan. During the review process, leadership will likely focus on the accuracy and flexibility of the measures and the mechanisms that control for extenuating circumstances (e.g., to avoid payouts when the hospital is performing poorly).⁹⁶

With a plan in place and leadership commitment reaffirmed, organizations use the BP plan to guide the development of one or more contracts, depending on the organization's structure. The key to success at the contracting stage is to engage competent legal counsel to assess the legal and regulatory landscape, and draft and execute an optimal contract (or contracts) to enable BP.

4.1. Engage Competent Counsel

Before engaging legal counsel for assistance with BP, an organization should evaluate their level of competence in the BP area. In doing so, the following questions may be useful:⁹⁷

Contracting for Bundled Payment

1. Before you engage an attorney for a problem, ask: How many of these cases have you handled? Over what period of time? What was the result?
2. Also ask the lawyer: If the work will be done by someone else in the firm, please describe the experience of the person who will do the work. How long has that person been with your firm? How many BP contracts has that attorney successfully negotiated and modified?
3. When inside counsel recommends outside counsel, ask: What is your prior relationship with the firm—former employer, associate, or colleague? If no prior relationship exists, ask: What was the basis for your recommendation? Who else did you consider? What was the reason for selecting one firm or counsel over the others?
4. When outside counsel recommends other technical legal counsel, ask: How did you learn of their technical expertise? What is their special expertise? Do they refer to you?

4.2. Assess the Legal and Regulatory Landscape

With legal counsel engaged, it is essential to assess the regulatory landscape to ensure compliance in the final design and execution of a BP plan. Legal requirements may influence BP plan construction and the resulting contracts. Such requirements fall into two broad categories, which are described in more detail in the following subsections: federal laws, and state laws and regulations.

4.2.1. Federal Laws

Four federal laws may prohibit certain types of gainsharing arrangements and affect decisions about organizational structure. These include Stark,⁹⁸ anti-kickback,⁹⁹ federal civil monetary penalties (CMP),¹⁰⁰ and tax code restrictions on private inurement in 501(c)(3) nonprofit organizations.¹⁰¹ As described at the end of this subsection, there is a process for waiving some of these requirements, or for obtaining an official opinion that the requirements will not be enforced in a specific scenario.

4.2.1.1. Stark Law

The Stark Law prohibits physician self-referrals (referral prohibition) and prohibits a healthcare provider from billing for improperly referred services (billing prohibition).¹⁰² This includes any referrals to an entity where the physician has a financial relationship for designated health services paid for by Medicare. The referral and billing prohibitions could prevent participants from engaging in gainsharing and could also create a disincentive for forming integrated delivery organizations. The Stark Law contains a number of safe-harbor exceptions,¹⁰³ and competent legal counsel is required to determine whether a particular arrangement is likely to qualify or whether a waiver is desirable.

4.2.1.2. Anti-Kickback Law

The anti-kickback law prohibits remunerations for inducing referrals or other health benefits.¹⁰⁴ As such, it may criminalize the act of gainsharing. Unlike the Stark Law and the federal CMP, this is a criminal statute. While conviction requires a knowing and willful violation, it could result in imprisonment and/or fines.

4.2.1.3. Federal CMPs

Federal CMPs prohibit a hospital from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care.¹⁰⁵ CMPs may prohibit gainsharing. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to \$2,000 per patient covered by the payments.

4.2.1.4. Prohibition Against Private Inurement in 501(c)(3) Nonprofits

Some hospitals operate as nonprofits under section 501(c)(3) of the Internal Revenue Code, which provides exemption from federal income tax for organizations that are “organized and operated exclusively” for religious, educational, or charitable purposes. This exemption is further conditioned on the organization being one where “no part of the net income of which inures to the benefit of any private shareholder or individual.”¹⁰⁶ Gainsharing arrangements in nonprofit facilities could potentially run afoul of

this prohibition if they result in payments that exceed fair market value for services. A violation of the private inurement prohibition could threaten an organization's nonprofit status.

4.2.1.5. Waivers and Opinions

There are two possible ways to gain permission to conduct gainsharing that may otherwise run afoul of federal Stark, antitrust, and anti-kickback requirements. One applies only to tests conducted through CMS' Center for Medicare and Medicaid Innovation (CMMI). The section of law that authorizes the CMMI also gives the Secretary of the Department of Health and Human Services the authority to waive "such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A) (iii) as may be necessary."¹⁰⁷ This new waiver authority encompasses federal Stark, antitrust, and anti-kickback requirements.

A second way to gain permission is to obtain an opinion from the HHS Office of the Inspector General (OIG) stating that it will not enforce legal prohibitions against a particular gain-sharing arrangement.¹⁰⁸ Joane Goodroe, who gained the first such OIG opinion, described the process as taking 2–3 years and involving the following steps:

1. Identify the opportunities to eliminate waste, improve quality, and reduce cost.
2. Create an initiative that articulates parameters for quality, cost, and utilization.
3. Establish a precise methodology for gainsharing that specifies the amount physicians may be paid, capped at fair market value.
4. Determine who is eligible to participate in gain-sharing, and define precisely the circumstances under which each provider will share in which part of the gains.

A detailed description of the results of each step is necessary to support a successful request for an OIG opinion.

4.2.2. State Laws and Regulations

State laws and regulations, which vary from state to state, may have significant implications for those wishing to

engage in a BP program with CMS. An exhaustive list of all such possible laws and regulations from every state and their potential impact on participants is beyond the scope of this document, but some examples include the following:

- State self-referral, anti-kickback, and similar fraud and abuse laws, which may mirror or differ from their federal counterparts, may have implications for gainsharing and organizational structure.
- Corporate practice of medicine laws, which may prohibit the practice of medicine or the employment of physicians by business corporations, may have implications for organizational structure and care redesign.
- Insurance or risk regulations, which may require organizations assuming financial risk in the provision of health services to be regulated as health insurers, could be implicated by a participant's assumption of risk through a BP program participation.
- Fee-splitting laws or regulations, which may limit the extent to which fees collected for professional services can be apportioned, may have implications for gainsharing arrangements.
- State tax laws, which have different liability triggers, may influence an applicant's selection of payment processes.

As in all legal matters, participants should engage competent legal counsel to help create an optimal, locality-specific BP program plan. Once the assessment is completed, the relevant plan terms can be set forth in the contract for execution and implementation.

4.3. Draft and Execute Contract

Once the parties have created an implementation plan and engaged competent counsel to ensure compliance with legal and regulatory requirements, the plans' terms can guide the construction of any contracts or contractual amendments. The resulting contracts should define key terms, set forth parties' rights and obligations, provide clarity with regard to the allocation of dollars, establish processes for decision making and dispute resolution, and address voluntary and

Contracting for Bundled Payment

involuntary termination. The following subsections provide a description of each of these topics.

4.3.1. Define Terms

The contract should carefully define common terms. For example, it will identify whom the agreement governs, which providers will participate in BP, which patients and services will be included in and excluded from the bundle, and the boundaries of any relevant episodes of care. These definitions are particularly important to formalize the precise meaning of each term, and will likely be very detailed and carefully worded to ensure that every facet of care that could be provided under the BP is specifically included or excluded from the definitions.

4.3.2. Set Forth Parties' Rights and Obligations

The contract should specify obligations related to the provision of services to patients, for example, requiring that providers treat patients using an accepted standard of practice, and without regard to patients' inclusion in or exclusion from a bundle. To that end, the contract may incorporate the terms of external documents, such as provider manuals, by reference.

The contract should clearly articulate the criteria for participation in BP, which might entail professional licensure, the treatment of a minimum number of bundle-related patients in the previous year, continued compliance with efforts to measure quality and utilization rates, and to share specific data. The contract should also specify parties' rights, such as that of a physician to view his or her own quality and utilization rates, and the commensurate obligation of an organization to collect such information and make it available.

4.3.3. Provide Clarity with Regard to the Allocation of Dollars

As described in subsection 3.4, the contract should also articulate how an organization will determine the amount that each provider (or group) will be paid, when those payments will be made, and what rights a provider will have to dispute the amount of his or her apportionment. For newly created organizations, additional administrative provisions

may be appropriate, for example, to specify how and by whom money will be received, held, and disbursed.

4.3.4. Establish Processes for Decision Making and Dispute Resolution

The contract should state how and by whom decisions may be made with respect to the BP program, including how the contract itself may be modified. The contract may specify how a party could protest a BP-related decision, and should articulate a dispute resolution process to resolve any persistent disagreements. The dispute resolution process could consist of moderation, judicial action, arbitration, or the intervention of another trusted third party. The inclusion of such a provision, and the use of a neutral third party, may help establish trust between the parties with the knowledge that any disputes will be resolved fairly.

4.3.5. Address Voluntary and Involuntary Termination

The contract should articulate the circumstances in which a specific provider or organization could be removed or remove oneself/itself from a BP initiative. To assuage fear about participation, a contract could allow for a complete unwinding early on, for example, by enabling parties to withdraw within the first six (6) months without cause or penalty. Typically, the contract will provide for a lock in after a specified period, making it more difficult for the parties to disengage. The specific lengths of these periods may be affected by specific conditions related to termination put in place by CMS or other payers or the length of the BP agreement.

The contract should contain an unwinding provision, specifying when and how a BP initiative (and any new entity created to conduct the initiative) could be terminated. The contract should also articulate the rights and obligations of the various parties post-termination.

The foregoing contract topics and descriptions are meant to serve as a starting point for the formation of agreements among organizations that want to partner to engage in BP with CMS. Like the contents of other sections of this document, these descriptions should not be construed as legal advice. As stated previously in this document, organiza-

tions seeking to create BP-related contracts should obtain legal advice from a competent attorney.

5. Conclusion

Success in BP requires careful attention to the relationships among provider organizations that will collaborate to provide services in a bundle. The terms of these relationships should be accurately described in one or more contracts (or other written agreements). At a minimum, each contract should define key terms, set forth parties' rights and obligations, provide clarity with regard to the allocation of dollars, establish processes for decision making and dispute resolution, and address voluntary and involuntary termination.

In order to determine contract contents, organizations may engage in a process that involves determining leadership commitment, assessing whether the organizational structure will support optimal BP implementation, and collecting and analyzing financial and clinical data. Organizations may then create a BP implementation plan, specifying processes for care redesign, data sharing, quality, and gain/risk sharing. Competent legal counsel should ensure that the plan complies with all applicable federal, state, and other laws and regulations, and create the contract to reflect and reinforce the terms of the plan.

Attention to contracts is an essential precursor of BP success that can help to reduce health care costs and improve health care quality across the United States.

Contracting for Bundled Payment

Acronyms

ACA	Patient Protection and Affordable Care Act of 2010
ACE	Acute Care Episode
ACO	Accountable Care Organization
AHC	Aurora Health Care
AHRQ	Agency for Healthcare Research and Quality
AQC	Alternative Quality Contract
BCBS	Blue Cross Blue Shield
BP	Bundled Payment
BPCI	Bundled Payments for Care Improvement
CKHS	Crozer-Keystone Health System
CMMI	Center for Medicare & Medicaid Innovation
CMP	Civil Monetary Penalty
CMS	Centers for Medicare & Medicaid Services
ECR	Evidence-based Case Rate
EHR	Electronic Health Records
e-PHI	Electronic Protected Health Information
FFS	Fee-for-Service
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health Maintenance Organization
IQR	Hospital Inpatient Quality Reporting
IT	Information Technology
NDA	Nondisclosure Agreement
PAC	Potentially Avoidable Complication
P4P	Pay for Performance
PQRI	Physician Quality Reporting Initiative
RFA	Request for Applications
SSA	Social Security Act

Endnotes

- 1 It is also possible to define BP simply as a single payment made to one locus to reimburse more than one provider. This definition differentiates BP from episode-based payment, defined as a single payment for an entire episode of care. The definition used for purposes of this document encompasses episode-based payment.
- 2 Section 1115 of the Social Security Act authorized the ACE demonstrations. The BPCI is authorized by Section 1115A of Title XI of the Social Security Act, as added by the Patient Protection and Affordable Care Act, P.L. 111-148 (March 2010) (ACA). Section 3021 of the ACA created the Center for Medicare and Medicaid Innovation.
- 3 “Bundling” Payment for Episodes of Hospital Care: Issues and Recommendations for the New Pilot Program in Medicare, Center for American Progress, http://www.americanprogress.org/issues/2011/07/pdf/medicare_bundling.pdf, Komisar, Harriet L., Feder, Judy, and Ginsburg, Paul (July 2011).
- 4 This document was not designed to support the creation of BP contracts between provider organizations and CMS or other payers. Although contracts with payers are necessary for BP, the focus of this document is on contracts between different provider organizations.
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- 11 R. Stone, The Medicare Acute Care Episode Demonstration Project: Regulatory and Legal Issues at <http://www.healthlawyers.org/Events/Programs/Materials/Documents/MM10/stone.pdf>
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- 14 See K. Romanoff and J. Williams, “Gainsharing: A Powerful and Proven Method for Improving Hospital Productivity and Quality,” at http://theperfectpayplan.typepad.com/Gainsharing_Article.pdf
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- 17 Goodroe supra.
- 18 Geisinger Health System, “About ProvenCare,” at <http://www.geisinger.org/provencare/index.html>.
- 19 The MITRE Corporation, “Information Technology for Bundled Payment,” December 16, 2011, at http://www.mitre.org/health/bundled_payments/.
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- 29 Additional information on Six Sigma can be found at <http://www.6-sigma.com>
- 30 Additional information on Baldrige can be found at <http://www.quality.nist.gov/>
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Contracting for Bundled Payment

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