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**BUNDLED PAYMENT:
AVOIDING SURPRISE PACKAGES**

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Bundled Payment: Avoiding Surprise Packages **by: Alice G. Gosfield**

Financial incentives to change care delivery have been a major focus of health care policy since at least the mid 1990s. From the time hospitals under Medicare began to be paid based on diagnosis-related groups (DRGs), while physicians continued to be paid fee-for-service, the need for 'aligned incentives' has been seen by many as the missing ingredient to limit increasing healthcare costs. Fundamental change has proven elusive though. Capitation tended to be limited to primary care, only under managed care contracts, and even then, in limited markets.¹ Percent of premium or global capitation paid to providers in the mid-1990s had disastrous results for provider networks with little infrastructure to manage and alter care delivery.² Pay-for-performance emerged as a jumpstart to improve quality, but did nothing to alter the fundamental incentives of fee-for-service payment.

Both in the health reform legislation and in commercial insurance, the implementation of bundled payment models is one of a new constellation of incentives designed to change what health care and how much is delivered to the American population. By putting multiple providers at financial risk in the same way in the same risk pool, so to speak, it is believed that improved value will result. To date, there is very little evidence to support that expectation,³ in part because there have been relatively few real world tests of bundled payment. This chapter looks at the basic concepts of bundled payment, touches on experiences to date with bundled payment initiatives, considers critical issues in constructing such payment models, elucidates competencies and infrastructures necessary to respond to bundled payment's incentives, and addresses governance and contractual issues between payors and providers and among providers to make bundled payment work. Throughout, particular attention is devoted to the PROMETHEUS Payment® model, which offers more diverse, already defined bundles than other reported experiences.

.1 Definitions, Conflations and Distinctions

As new payment models are being tested and demonstrated, there have emerged a range of confusions with respect to concepts which are distinct but related such as bundled risk, episode payments, gainsharing, and more. For the purposes of this chapter, I offer the following basic conceptual framework.

The most basic tenet of bundled payment in this chapter is that more than one provider is paid within the bundle. There are those who have referred to the Medicare hospital

¹ Frakt and Mayes, "Beyond Capitation: How New Payment Experiments Seek to Find the 'Sweet Spot' In Amount of Risk Providers and Payors Bears," Health Affairs (Sept. 2012) pp.1951-1957

² Burns and Pauly, "Accountable Care Organizations May Have Difficulty Avoiding The Failures Of Integrated Delivery Networks Of The 1990s," Health Affairs (Nov. 2012) pp. 2407-2415

³ Executive Summary, "Bundled Payment: Effects on Health Care Spending and Quality," Agency for Healthcare Research and Quality, Evidence Report/Technology Assessment, No. 208 (Aug. 2012)

prospective payment system, based on DRGs, as a bundled payment approach⁴ because instead of paying per day, as had been the case, now all the services in an admission were included in one payment. Similarly, in the end-stage renal disease payment program, where Medicare covers everyone with the disease, most of the services and supplies for dialysis, except for drugs, were paid for in one composite rate.⁵ But the leading edge of bundled payment initiatives is about aligning financial incentives among disparate providers, which is the type of payment addressed here.

Bundled payment is also used to describe payment where the physician and facility payments are combined, even if only around a single admission. This was the basic approach in the Medicare coronary artery bypass graft demonstration (see below). Another related concept is episode payment or case rates. To bundle payment for more services than a single admission to a hospital, boundaries in terms of time and the range of services to be included must be defined. Typically, this is around an episode of care which relates to a defined condition, like an acute myocardial infarction including the admission and subsequent cardiac rehabilitation. Episodes in chronic care -- such as diabetes, congestive heart failure or asthma -- typically extend for a full year to coincide with annual health insurance premiums. In addition, some episode payments, take into account a period before the admission as well as post-discharge care. Episode based payment, or case rates, need not entail bundling, but most bundled payment models today entail some episode definition -- a bounded clinical continuum of care used to address a specific medical condition over a defined period of time.

The payment amount of the bundle is determined in a variety of ways. Many programs merely take a historical average of the services paid for the condition and define the bundle or budget to include those services. How much money is paid to the providers depends on whether they must meet a cost reduction threshold or a quality performance threshold, before being eligible for any additional payments. Very few of these programs are paid on a prospective basis, since very few providers are in a position to take the financial risk of losses, although some of the oldest and largest physician groups in the country do take risk in this manner.⁶ In most bundled payment arrangements today, the providers are paid in the ordinary course of business (e.g., DRGs, fee for service) and what is paid is reconciled against the pre-determined bundled budget at the end of the episode. To the extent fewer services are provided, money which remains in the budget will be available to pay the providers.

⁴ Altman, "The Lessons of Medicare's Prospective Payment System Show That The Bundled Payment Program Faces Challenges," Health Affairs (Sept 2102) pp. 1923-1929

⁵ Swaminathan, Mor, Mehotra and Trivedi, "Medicare's Payment Strategy For End-Stage Renal Disease Now Embraces Bundled Payment and Pay-For-Performance To Cut Costs," Health Affairs (Sept 2012), pp. 2051-2057

⁶ Mechanic and Zinner, "Many Large Medical Groups Will Need To Acquire New Skills and Tools To Be Ready For Payment Reform," Health Affairs (Sept 2012) pp. 1984-1991

This raises the issue of how gainsharing or shared savings relates to bundled payments. The Medicare shared savings program using Accountable Care Organizations (ACOs) works on the basis of paying savings at the end of three years from both Part A and Part B dollars available from the historical basis of delivering care.⁷ The PROMETHEUS Payment® model ascribes to the bundled budget clinically appropriate services and their costs based on a payor's historical data. The bundle of services is determined by clinicians, with reference to the evidence base (Evidence-informed Case Rates® or ECRs), so that the bundle reflects what science says is appropriate treatment for the patient's condition, rather than whatever has been done historically regardless of appropriateness. In developing ECRs, the PROMETHEUS Payment design team discovered what is now more widely accepted--that we are spending a considerable amount of today's health care dollars on potentially avoidable complications (PACs). If some of the monies spent today on those complications which occur over time (such as diabetic stroke or diabetic amputations or diabetic eye procedures) were assigned to the diabetes budget for all the providers, they would have an incentive to avoid the complications by changing their care delivery earlier in the course of the patient's disease. What portion of those dollars is assigned to the provider bundle is a point of negotiation in that program.⁸

Incidence risk and bundled payment are frequently conflated in considerations of bundled payment, even by the American Hospital Association, which describes capitation as a bundled payment model.⁹ Capitation is not a bundled payment model. Capitation is an actuarially determined payment per assigned subscriber who may or may not use the physician's services or any other services. The same amount is paid regardless of the patient's condition or medical needs. Even if the capitation is global, meaning one entity gets all the payment and doles it out to other providers, this is only bundled payment in the sense that there is one payment. But capitation, no matter how broadly inclusive, is not based on any calculation of provider costs per se or patient clinical needs, but rather on actuarial assessments of historical payment factored by assumptions regarding incidence of disease. Capitation is a reflection of premium construction principles. It is an insurance concept and not a health care delivery concept. One of the premises of many bundled provider payment initiatives is that providers take the risk of managing care delivery effectively, but they are not at risk, as they are in capitation, for the incidence of disease in the assigned patient population. The best bundled payment models are risk adjusted to take into account the additional dollars needed to treat sicker patients.¹⁰

⁷ 42 CFR §425.604

⁸ In the original design, fifty percent of the money spent on PACs was assigned to the budget. Now, this is an issue to be negotiated by the plan with the providers. For more information about the PROMETHEUS Payment® model see, www.hci3.org

⁹ "Bundled Payment", AHA Research Synthesis Report (May 2010)
http://www.aha.org/research/cor/content/bundled_payment_cp.pdf

¹⁰ For an interesting colloquy between Francois de Brantes and Robert Berenson, on the relative merits of these distinctions see Robert Wood Johnson Foundation, "Payment Reform: Bundled Episodes vs. Global Payments" (Sept 1, 2012) <http://www.rwjf.org/en/research-publications/find-rwjf-research/2012/09/payment-reform--bundled-episodes-vs--global-payments.html>

Finally, policy discussions often refer to bundled payments with the expectation that the actual dollars to be paid will go from the payor to one recipient. The provider entity, however configured, then would have the responsibility to make the appropriate payments among the providers who are in the bundle. In contrast, the PROMETHEUS Payment model is actually a bundled budget, which means all the providers are at risk for their effective collaboration in delivering the continuum of care contemplated within the ECR, but payment can be made to the providers separately based on the contract they enter into with the payor and for what portion of the total budget they are responsible. Because the ECRs incorporate the costs of a range of services that reflect varying providers delivering different aspects of the care as analyzed from historical claims data, a software package had to be created to make these allocations; and it exists and is operational.

2 Medicare Bundled Payment

Medicare tried an experiment in bundled payment from 1991 to 1996 when seven hospitals received a single payment for hospital and physician services for coronary artery bypass graft surgery; and the hospitals determined how much to pay the physicians from the payment received from Medicare. The program was found to have saved Medicare \$42 million dollars on 10,000 procedures from lower lengths of stay, better pharmaceutical management and decreased post discharge care.¹¹ Less impressive results were achieved in a three year cataract bundled payment demonstration where for 4500 Medicare cataract procedures performed, \$500,000 were saved when all costs including physician fees, facility costs, and lens supply costs were bundled into one payment. CMS concluded that complex inpatient procedures with a bounded length of stay and standardized use of resources might be good candidates for bundled payment, but outpatient procedures involving few professional staff and limited supplies might not benefit as much from bundling.¹²

More recently, in 2009, CMS launched the three year Medicare Acute Care Episode (ACE) demonstration involving a discounted bundled payment for all hospital and physician services for a group of inpatient cardiovascular procedures (CABG, heart valve, defibrillator and pacemaker implant, and angioplasty) and orthopedic procedures (hip and knee joint replacement). Limited to physician-hospital organizations within one Medicare Administrative Contractor's jurisdiction, the hospitals were permitted to engage in gainsharing with physicians to motivate increased efficiency. "Unique to this demonstration is that Medicare will share 50 percent of the savings it realizes from the

¹¹ Thoumaian, Mango and Mason, "Medicare Bundled Payments" in Institute of Medicine (US) Roundtable on Evidence-Based Medicine; Yong PL, Saunders RS, Olsen LA, editors. *The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary*. Washington (DC): National Academies Press (US); 2010. 15, Payments for Value Over Volume. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK53930/>

¹² Id.

discounted prices with the Medicare beneficiary, up to the amount of the annual Part B premium, currently \$1,157. Sites are designated as “Value-Based Care Centers” and are encouraged to market their programs to referring physicians and Medicare beneficiaries.”¹³ Final reports are not yet in, but early results seem promising. The hospitals agree to a discounted bundled payment and physicians can get as much as a 25% increased bonus on top of their Medicare payment.

During the past 18 months, Baptist Health has reaped \$4 million total in device and supply savings, passing on \$558,000 to the 150 physicians participating. The nearly 2,000 patients who have received surgeries under the program have received \$600,000 back, or about \$300 a patient, Zucker says. “If you were to take the ACE program away today, people would resist,” he says.¹⁴

The health reform legislation contained a mandate for the Department of Health and Human Services to develop a demonstration around Medicare bundled payment to include physician services, hospital inpatient and outpatient services, post-acute care including home health, skilled nursing care, rehabilitation services and long-term care hospital services.¹⁵ The legislation called on the Secretary to focus on conditions that would be a mix of chronic and acute, surgical and medical, high volume, subject to significant variation and where there was evidence of an opportunity to improve quality while reducing total expenditures. To be focused around defined episodes, the legislation mandated that the episode include three days prior to admission to a hospital, the length of stay and thirty days following discharge. “A payment methodology to be tested and evaluated by a third party shall include payment for the clinical services delivered as well as other appropriate services: such as care coordination, medication reconciliation, discharge planning, transitional care services, and other patient centered activities as determined by the Secretary.”¹⁶

This mandate is being implemented through the Center for Medicare and Medicaid Innovations (CMMI) Bundled Payment for Care Improvement Initiative (BPCI).¹⁷ Originally the government proposed four models for which applicants could submit their proposals: (1) Model One was a retrospectively paid model to include the inpatient hospitalization only, permitting physicians to receive gainsharing payments from the hospital, but the physicians would continue to be paid fee for service. Here there was no

¹³ Id.

¹⁴ Vesely, "An ACE in the deck?, Bundled-payment demo shows returns for hospitals, physicians, patients" *Modern Healthcare* (Feb 7, 2011) <http://www.modernhealthcare.com/article/20110207/MAGAZINE/110209990#ixzz2BvzXwzg1?trk=tynt>

¹⁵ §3023, Patient Protection and Affordable Care Act, PL 111-148, 111-152 (PPACA) adding §1866D to the Social Security Act. There is also a demonstration program in Medicaid to bundle payment around a hospitalization. §2704, PPACA

¹⁶ §1866(D)(3)(B)

¹⁷ <http://www.innovations.cms.gov/initiatives/Bundled-Payments/index.html>

downside risk if the budget was exceeded. This represented very little 'bundling' per se, but rather a discounted hospital payment. (2) The second model was retrospective payment for an admission and post-acute care of either 30 or 90 days at the applicant's option with an opportunity for gainsharing by physicians (i.e., they share in savings) but also downside risk—a 'warranty' that the budget would not be exceeded, with repayment if it were. (3) The third model was for post-acute care only, beginning thirty days post discharge. Models 2 and 3 bundled the payment for all services -- physicians, facilities, laboratory, durable medical equipment, drugs, rehabilitation, and more, beginning with discounted facility payments and upside and downside risk. (4) The fourth option was for prospective payment for all services—physicians and hospital—associated with a hospital stay.

Initially it looked like this project would have enormous flexibility and would permit real diversity in bidding. CMMI chose to focus the initiative around anchoring the payments on MS-DRGs, a Medicare severity adjusted DRG payment to a hospital. But DRG payments are oriented around only the resource use in the hospital; and the DRGs combine a range of procedures which are clinically similar in the hospital, but which might reflect widely disparate patients with very different needs and costs both inside and outside the hospital. For example, a patient admitted for a percutaneous coronary intervention (PCI) with stable coronary artery disease would have different needs and costs than a patient with an acute myocardial infarction or an acute dysrhythmia.¹⁸ Cancer patients getting a hip replaced require different care from a patient getting a hip replaced because of trauma. In addition, for chronic conditions like congestive heart failure, Medicare pays far more for care outside the hospital than for a hospitalization. In addition, the small numbers of patients likely to be treated under each episode can give providers more risk than the calculation of the base period episode cost calculation will have anticipated.¹⁹ Then, after applications were submitted, CMMI announced that instead of letting applicants define their bundles, a critical feature of flexibility, CMMI would standardize the episode definitions to minimize operational complexity.²⁰ This would mean some of the proposals would no longer be acceptable. And then, CMMI announced that it was suspending Model 1 to evaluate how it fit with the other bundled payment concepts. At this writing, none of the awardees has been announced and the program was expected to be implemented in late spring of 2013.

¹⁸ For a deeper consideration of the methodological problems with the BPCI requirements see, Tompkins, "Ready?...Set?...No!", Healthcare Incentives Improvement Institute, Inc., and Tompkins, deBrantes et al, "Designing The BPCI For Success", Healthcare Incentives Improvement Institute Inc., <http://www.hci3.org/content/hci3-improving-incentives-issue-brief-designing-bpci-success>

¹⁹ For more information about methodological concerns regarding the program, see Mechanic and Tompkins, "Lessons Learned Providing for Medicare Bundled Payments," NEJM (Nov. 15, 2012) pp. 1873-1875

²⁰ Lazerow, "Bundled Payment Update: CMMI Converging Proposed Episode Definitions", The Advisory Board Company (Sept 13, 2012) <http://www.advisory.com/Research/Health-Care-Advisory-Board/Blogs/Toward-Accountable-Payment/2012/08/Bundled-payment-update-CMMI-converging-proposed-episode-definitions>

In addition to the stand-alone bundled payment concept in the law, as alluded to earlier, the Medicare shared savings program, is a form of bundled payment since the delivery system, an ACO must be able to accept Part A and Part B monies and allocate the dollars paid by Medicare among the participating providers. Unlike the BPCI program which focuses on specifically defined conditions, the ACO program applies to all Medicare patients assigned to the ACO for all of their medical conditions.

3 Commercial Bundled Payment Programs

While Medicare has been experimenting with bundled payment and is beginning demonstrations, commercial payors have already gotten their feet wet. One of the earliest commercial models of bundled payment was ProvenCare, a bundled payment model offered by the Geisinger Health System. Beginning in 2006 with elective coronary artery bypass graft (CABG) surgery, the system offered a single, bundled price to include preoperative evaluation and workup, hospital fees, professional fees, routine discharge care, cardiac rehabilitation services and management of CABG-related complications that occur within 90 days after the surgery.²¹ Because no additional payment is made for complications within that period, it is said that the system is offering a "warranty" on the care. The program lowered length of stay by a full day, improved the within thirty days readmission rate by 45% over 18 months, and enhanced compliance with clinical practice guidelines. The program then was extended to elective percutaneous angioplasty, perinatal care, bariatric surgery and then in an expansion outside the Geisinger system, extended the principles to non-small cell lung cancer as part of a ProvenCare Lung Cancer Collaborative with the American College of Surgeons Commission on Cancer.²² But many people dismiss these innovations because Geisinger is a fully integrated health system which not only employs its physicians but also has its own health plan which generates 30% of the patients treated at Geisinger hospitals.²³

In a report in early 2012, Bailit and Burns, identified 19 non-federal bundled payment initiatives that were in various stages of launch, among them the Geisinger initiatives.²⁴ Nine of the programs had fully operationalized at least one bundled payment, whereas the others were in observational studies with no payment involved during the process of developing bundled payments. Among the operational programs, by far most were

²¹ "Use of Clinical "Bundles", Fixed pricing and Patient Compact Enhances Adherence with Guidelines and Improves Outcomes in Bypass Surgery, Diabetes, and Other Areas" AHRQ Innovations Exchange, (last updated march 14, 2012), <http://www.innovations.ahrq.gov/content.aspx?id=2373>

²² "Geisinger participates in a national pilot study for treating lung cancer patients," The Express (July 30, 2010) <http://www.lockhaven.com/page/content.detail/id/519726/Geisinger-participates-in-national-pilot-study-for-treating-cancer-patients>

²³ McCarthy, Mueller and Wrenn, "Geisinger Health System: Achieving the potential of System Integration Through Innovation, Leadership, Measurement and Incentives," Case Study, (June 2009) The Commonwealth Fund, pub 1233 Vol. 9

²⁴ Burns and Bailit, "Bundled Payment Across the U.S. Today: Status of Implementations and Operational Findings," (May 2012) http://www.bailit-health.com/articles/052912_bhp_hci_issuebrief_4L7.pdf

focused around inpatient procedural conditions (9). Hip and knee replacement surgeries were the most common inpatient procedures since they are relatively easy to define. Because the costs of care occur mainly during the inpatient stay, providers have the ability to exhibit more control over costs.²⁵ With regard to outpatient procedures, percutaneous coronary intervention (PCI or coronary angioplasty), cataract removal and perinatal care were addressed by some bundles.

Chronic medical conditions may well offer the greatest opportunity to reduce avoidable complications. Diabetes care was the most common chronic medical condition for commercial bundled programs. Asthma, chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease and others were also being considered.

Reporters noted that the PROMETHEUS Payment® Model has been working on defining bundled payments since 2006 and, by May of 2012, had defined 7 chronic condition bundles, 3 acute medical bundles, 5 inpatient procedural bundles, and 6 outpatient procedural bundles. Some of the payors and providers in the study looked to those definitions, while others have used them as a starting point in creating their own. A far smaller number started from the ground up. Chronic care bundles extend for a year while procedural bundles were found to begin between 2 and 30 days prior to the procedure and extend beyond the procedure by 90 to 180 days. This is far longer than the Medicare bundle approach.

In the commercial arena, the degree of provider financial risk is generally seen as transitioning from shared savings to full risk. Under the shared savings approach, the incentive to the provider to reduce health care spending below the negotiated bundled payment rate comes from allowing the provider to share in any of the savings realized. Here, there is no downside risk. Some programs require providers to meet a minimum quality threshold in order to be able to share in any savings they have achieved. Shared risk is where the provider has an incentive to reduce health care spending to below the negotiated bundled payment rate as a result of being at risk for some of the costs above the negotiated rate while permitting gainsharing on the savings. Only one of the payors in the Burns and Bailit report indicated the desire to use this approach during the first year of bundled payment. Some of the commercial programs reported using a full risk strategy where the incentive for the provider to reduce health care spending below the negotiated payment rate is created by putting the provider at full risk for all of the costs above the negotiated rate but also allowing the provider to share in the savings. For those programs that reported using a full risk bundled payment approach, some providers negotiated to have outliers excluded or to have stop-loss insurance in place.

In terms of scope, the volume of bundled payments remains relatively small, often 10 to 50 bundles per year for a provider and payor. Although there was very little formal evaluation associated with the implementation of these programs, some preliminary results showed modest savings. “One large provider system reported a modest savings of \$600 per bundle and another reported reducing the average length of stay by half a day.

²⁵ Id. at page 4.

One well studied interviewee reported a 40% decrease in readmissions, 50% in complications, and reduction in mortality to nearly 0.²⁶

Since the Bailit and Burns report, as of November 2012, the sponsor of the PROMETHEUS Payment® model has calculated that 6,400 bundles have been triggered over the last three years. Most are chronic care bundles under The Priority Health (Grand Rapids, MI) plan, more than 300 total knee replacements by Horizon Health in New Jersey, several dozen by Independence Blue Cross in Philadelphia and a handful each in Blues plans in Western New York, North Carolina and South Carolina. Coronary artery bypass graft bundles are being deployed in Western New York and South Carolina. Colorado employers are also using PROMETHEUS Payment® bundles in a statewide pilot. Blue Cross Blue Shield of Florida is focusing on diabetes only.²⁷

4 Constructing Bundles

As we have seen from the criticisms of the CMMI Bundled Payment for Care Initiative approach to developing bundles, there are a host of issues associated with how bundles are constructed and what is included within them. The very first issue is what triggers the bundled payment. This may be an initial claim associated with a condition or a claim that verifies a diagnosis for which the bundle reaches back in time to include the diagnostic services that led to the condition. Typically, bundles are initiated by ICD-9 codes that are relevant to the condition the bundle will address. As we have seen from the Bailit and Burns report, many bundled payment programs to date have focused on total knee replacement, which represents a relatively simple set of challenges with concomitantly small impact. By contrast, the PROMETHEUS Payment® model has ECRs for chronic medical conditions, inpatient procedural cases, inpatient medical cases and outpatient procedural services. The chronic care ECRs are likely to produce the greatest change in delivery.

ECRs in Version 5		
Chronic Medical	Acute Medical	Procedural
<ul style="list-style-type: none"> ▪ Coronary Artery Disease ▪ Congestive Heart Failure ▪ Chronic Obstructive Pulmonary Disease ▪ Asthma 	<ul style="list-style-type: none"> ▪ Acute Myocardial Infarction ▪ Pneumonia ▪ Stroke 	<ul style="list-style-type: none"> ▪ Coronary Artery Bypass Graft ▪ Heart Valve Replacement ▪ Percutaneous Cardiac Intervention (angioplasty) ▪ Hip Replacement ▪ Hip Revision ▪ Knee Replacement
	Pregnancy & Delivery	

²⁶ Id. at page 12.

²⁷ Personal Communication, Francois de Brantes, Executive Director, Health Care Incentives Improvement Institute, Inc. (Nov. 15, 2012)

<ul style="list-style-type: none"> ▪ Diabetes ▪ Gastroesophageal Reflux Disease ▪ Hypertension 	<ul style="list-style-type: none"> ▪ High Risk Pregnancy ▪ Low Risk Pregnancy ▪ Normal Vaginal Pregnancy C-Section 	<ul style="list-style-type: none"> ▪ Knee Revision ▪ Knee Arthroscopy with ligament Repair ▪ Knee Arthroscopy without ligament Repair ▪ Esophagogastroduodenoscopy (Upper GI endoscopy) ▪ Colonoscopy ▪ Colon Resection ▪ Gall Bladder Surgery ▪ Hysterectomy
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A bundle might also be triggered by a CPT or HCPCS procedure code. For how long a the bundle will extend is a critical decision. For example, in Medicare, the options have been to include 30 days post-discharge or 90 days post-discharge. The PROMETHEUS ECRs extend for 180 days post-discharge, capturing more services that likely were associated with the original hospitalization. Which providers are included in the budget is also relevant. In the CMMI BPCI initiative, for Model 3, the post acute services model, included all post acute providers. Model 2 included physicians and hospitals plus post-discharge providers for 30 or 90 days. In the PROMETHEUS model, all providers, without exception, who treat the patient for the anchor condition are included in the bundled payment budget. This includes all inpatient stays during the episode period, all outpatient facility, professional and other ancillary claims during the episode period, all pharmacy claims during the episode period.

Most bundled payment programs to date simply reference historical data as the benchmark budget for the bundles. In PROMETHEUS Payment, the ECR was initially defined, in the earliest iterations, directly with reference to good clinical practice guidelines. Clinical Working Groups of physicians chose a good national guideline and then analyzed what specific services were necessary to deliver that care.²⁸ Today, in ECR version 5.0, the applicable services are defined by Clinical Working Groups of practicing physicians convened by the AMA and the America College of Physicians who take into account the evidence base, but determine those services which typically ought to be provided, in accordance with best evidence available or consensus judgment, as appropriate care. This is then referred to as the “Typical Budget.” Bundles are defined by diagnosis codes or procedure codes which trigger them, and then CPT codes which define the range of services included in the bundle.

One of the essential design features of the PROMETHEUS model which has enormous significance for the incentives to providers to change their clinical behavior came with the discovery of “Potentially Avoidable Complications” (PACs). This concept emerged when, having decided that ECRs would be based on what science said patients needed for their conditions, the PROMETHEUS methodologists began to analyze historical claims data. For the diagnosis of diabetes, many of the claims in the claims database the Design Team was accessing were for problems like diabetic stroke, admission to the hospital

²⁸ Gosfield, “Making PROMETHEUS Payment® Rates Real: Ya’Gotta’ Start Somewhere” (June 2008) 15pp <http://www.gosfield.com/PDF/MakingItReal-Final.pdf>

with a primary diagnosis of diabetes, diabetic amputations, and diabetic eye procedures. These are certainly complications of diabetes which can occur even when stellar care is being provided. However, when the Design Team realized the extent to which the system is already paying for PACs, the incentive to avoid those complications became one of the primary goals. In the first analysis of the data associated with the diabetes ECR, of the \$1.32 billion spent on diabetes services, \$515 million would be associated with Typical Budgets, with \$108 million paid for medical services and \$407 million for pharmacy; but \$813 million, fully 61% of the entire expenditure on diabetes, was spent on PACs. In congestive heart failure, the rate of PACs is about 80%. By allocating 50% of the dollars already spent on these Potentially Avoidable Complications into the bundled budgets, payment for those complications which would arise under any circumstances would be available, but providers would have a very clear incentive to change their clinical behavior to avoid these complications as much as possible. In today's version of ECRs, how much of the money currently spent on PACs is allocated to the provider budgets is a point of negotiation between the providers and the plans.

The extent to which any bundled payment is risk adjusted is a critical aspect of these programs. The less risk adjustment, the greater the transfer of insurance risk to the providers, which they are ill equipped to manage. The more sophisticated the risk adjustment, the more the budget will provide for those services which are clinically appropriate for the patient's constellation of clinical needs. In the PROMETHEUS Payment® model, some of the ECRs represent stand-alone case rates which can, at the same time, be considered as complications for other conditions. For example, if a patient being treated for coronary artery disease has an acute myocardial infarction, the heart attack ECR exists unto itself with all of the services associated with the admission calculated in that budget, but this is also a complication of the coronary artery disease. Similarly, diabetes can be complicated by a stroke. In the ECRs version 5, the stroke budget would be considered a complication of all of the applicable chronic conditions, including coronary artery disease, diabetes, and potentially congestive heart failure, so a portion of that budget would be assigned to all of the relevant bundles. Unlike many of the bundled payment programs so far, in PROMETHEUS Payment there is a clear expectation that a patient might have care assigned to multiple bundles. Those allocations are critical to make the payment reflect clinical reality. Very few patients present with heart failure alone. They likely also have coronary artery disease, hypertension and could have diabetes.

When the bundle expires or is broken is an important decision point. Chronic care bundles typically remain open year to year since the patient is never cured. Procedural or admission bundles expire at the pre-determined point. Most bundled payment programs today are paid retrospectively, so a reconciliation of actual expenditures to the pre-established budget occurs at the conclusion of the episode. But sometimes a bundle is "broken" in the sense that it no longer make sense for the patient's care to be paid on that basis. Where a patient who has three chronic care ECRs open gets injured in a catastrophic car accident, it no longer makes sense to continue to pay the providers for the chronic care on an ECR.

For lawyers, the methodological ins and outs of bundle construction is not where the primary focus lies. Rather, the fundamental issue is whether the relevant documents that established the bundled payment program effectively set forth the rules pertaining to how bundles are triggered, what is included within them, when they end, when reconciliation occurs, and dispute resolution (see below at 6).

5 Infrastructure and Competencies

Considerable attention has been devoted to the far larger proposition of accountable care organizations in their many varied iterations, both under the Medicare Shared Savings Program as well as commercially. Bundled payment alone without the risk of full accountable care requires a significant change in thinking, at a minimum, from hospitals on one hand, and physicians on the other. Ian Morrison, an iconoclastic futurist, has proposed three new techniques for health systems to consider in the move from volume to value based payment. Bundled payment encourages value by its emphasis on changed care delivery to realize the savings that can be found within the bundle from historical volume driven payment. Morrison suggests (1) develop a continuum of care partners; (2) eat your own cooking; and (3) find some new friends. A continuum of providers as partners is essential within the bundled payment structure to manage and prevent readmissions and use less expensive sites of care. Those who are beginning the process of moving to value driven models can eat their own cooking by starting to pilot new approaches with their self-insured employee population. For his third point, Morrison says, “Bridge building is not an amateur activity.”²⁹ He believes that most health systems need ‘adult supervision of spreadsheet migration,’ meaning what do the sources and uses of funds look like for the next 5 years and how do they sync with the unfolding market reality. While those big picture challenges certainly will have to be met in broader bundled payment programs, others have focused on far more granular problems.

The chasm between the financial administration of hospitals and health systems and physician clinical management of care has been significant. Under a bundled payment model, those involved in hospital finance and administration will have to be involved in valuation of clinical care delivery change. Buy in from physicians is essential, beginning with what is included in the bundle and the relevant care path to deliver the bundle. A clear understanding of the assumptions that create the bundle price is essential for physicians to understand how to change their behavior. The extent to which physicians are willing to follow the established care path will be critical.³⁰ Potential issues could arise under the medical staff bylaws, depending on how committed the hospital and physicians are to really effecting change. The variance within hospitalization costs that have been resistant to change can often be attributed to choice of medications, additional testing and other services associated with specific physicians. What to do about the recalcitrant resisters will be an issue. The extent to which health systems and physicians are willing to tackle these issues will determine success under a bundled payment model.

²⁹ Morrison, “The Bridge from Volume to Value Based Payment,” *Hospitals and Health Networks Daily* (Sept. 4, 2012)

³⁰ Abrams and Cummings, “The Bundled Payment Battle,” *Trustee* (Sept. 2011) pp. 25-26

Similarly, the entire concept of clinical integration, which requires physicians to work systematically with each other to deliver safe, timely, effective, and valued health care to their patients, will be an imperative under these models.³¹ The attributes of clinically integrated organizations include clarity of purpose and mission, respect for leadership and capacity for followership, consistent and supportive compensation mechanisms, issues associated with financial relationships with others, and above all, standardization—of guidelines and protocols, referrals and care coordination, relationships with referral sources, implementation of electronic health records and documentation; deployment of non-physician clinical personnel. Focus on capacity control (value as a value) with consistent measurement and transparency of performance data are directly relevant to the potential success of a bundled payment initiative. Teamwork and patient-centeredness will also characterize successful bundled payment programs.

Turning to what physicians can do to position themselves better under a bundled payment model, while there are a limited number of ways to reduce the cost of health care services, they can have significant impact. With regard to inpatient care, to reduce the costs of procedures, there has to be reduction of cost within existing facilities, moving procedures to lower cost facilities or to lower price facilities, reducing complications, infections and readmissions; reducing the number of elective or avoidable procedures and using lower cost procedures for the same condition.³² For ambulatory care, reduced costs can be found in reduced medication costs, reduced hospitalizations, reduced emergency room usage, and reduced need for expensive treatment through screening or prevention. Other opportunities for savings can be found in better scheduling of scarce resources such as surgery suites, coordination among multiple physicians and departments to avoid duplication and conflicts in scheduling; standardization of equipment and supplies; less wastage of expensive supplies; reduced length of stay and moving procedures to outpatient settings.³³

In bundled payment models, physicians can share in the savings generated by these changes in care delivery. To determine what changes are necessary and where the payment opportunities lie, physicians will have to have information regarding the rate of complications at the hospital or other facility, the cost of treating complications; the cost of changes in care to reduce complications, and the payments the hospital is currently receiving. They will have to communicate with each other and with their facility colleagues in explicit terms about what care should be delivered when. Saving physicians for their highest and best use can offer savings in these programs, too.

³¹ See Gosfield and Reinertsen, “Achieving Clinical Integration with Highly Engaged Physicians,” (Nov 2010), 31 pp., <http://www.gosfield.com/PDF/ACI-fnl-11-29.pdf>; Gosfield and Reinertsen, “Clinical Integration Self-Assessment Tool v.2.0,” (Nov. 2011) <http://www.uft-a.com/CISAT.pdf>; and Gosfield, “Clinical Integration Self Assessment Tool v.2.1 (Network/IPA Version),” Jan 2012 http://www.gosfield.com/PDF/CISAT_IPA_V.2.1.pdf

³² Miller, “Succeeding Under Shared Savings: Global Payment and Other Payment Reforms,” American Medical Association, PowerPoint (June 18, 2012)

³³ Id.

In the hospital context, the demands of bundled payment lead inevitably to co-management arrangements with physicians, where physicians engage far more directly with the hospital to improve its performance with regard to the applicable services line. In addition, given the emphasis on preventing costly readmissions, the role of primary care engagement, both with hospitals and specialists changes. The patient-centered medical home (PCMH) approach to primary care fits well in a bundled payment model because it, too, is focused on keeping patients out of the hospital, not as gatekeepers as in the mid-90s, but because physicians and patients are more engaged with each other far earlier; and better chronic care management is the result. How specialists relate to PCMH practices becomes more significant in bundled payment. NCQA, which certifies primary care PCMH, is launching a specialist recognition program.

6.6 Payor/Provider Contracts

In most bundled payment programs, the bundling occurs around selected episodes, procedures or conditions, to be rendered by providers who are already participating with the payor. Therefore, the bundling arrangement is typically addressed in an amendment to the basic provider contract. The most critical elements are defining the relevant episodes -- when they are triggered, how long they extend and how they are broken -- the price or budget associated with them, when and how payment will be made and since most of these programs begin with retrospective reconciliation, when and how that will occur. Depending on the scope of the program, some of these issues may be addressed in policies that are shared by the plan, much like a program manual; but the key issue is making sure the providers understand all the rules that will pertain to getting the new payment.

In some programs, particularly where a quality threshold must be met before the provider is eligible for the upside gains from changed care delivery, when and how data is made available to inform providers of their performance will be important. Whether financial data from claims submitted will be reported to providers during the episode and how often can be critical if the program is to accomplish its purposes. Release of data always raises the issue of the rights of the providers to challenge or correct the data. Because the most radical of these programs involve providers who are not part of the same organization, the incentives cannot truly work if all the participants do not have information about the performance of the others. This invariably leads to other potential disputes, all of which should be addressed in the amendment. Knowledge of who the other provider participants are and the expectations associated with the scope of their services within the bundle is an important foundation for bundling to be effective. These are not typical managed care contracting issues.

Because of the role of the incentives in bundled payment, where the program is initiated with sufficient buy in from physicians, a range of what otherwise apply as the plan's medical management programs may not be necessary for the bundles. Since bundled payment programs are rarely imposed across a payor's entire network, the selection process for provider participants can lead the parties to remove the bundled payments from prior authorization or utilization review programs. In other words, not all providers

are in a position to manage bundled payment effectively. Selection of the provider participants can obviate the need for the administrative controls that apply more broadly. Similarly, the role of pharmaceutical benefit managers, imaging benefit managers and behavioral health benefit managers may not be necessary either. Restrictions on the use of non-physician ancillary personnel become counter-productive in these programs; so the amendment should address those provisions in the basic provider participation agreement that do not pertain.

Dispute resolution is critical. What is appealable under the program and through what processes should be addressed. Because many of these programs are based on negotiations between the payor and the providers, the budget itself or the price of the episode once established, and how much is allocated in the budget to different providers ought not be subject to formal appeal. The rules for triggering, breaking or ending an episode payment are inherent in the determination of the budget and therefore should not be subject to appeal. Similarly the rules for severity adjustment in budgets would not be expected to be appealable. By contrast, whether an episode has been triggered or broken, whether a provider qualified for upside payment, what happens when two providers claim the same payment (see below) upon reconciliation are all financial determinations like any other payor determination and should be subject to dispute resolution. Whether a provider met quality or other thresholds to qualify for payment is also a potentially appealable subject. As in disputes among providers (see below), basic issues with respect to the process that is due under the circumstances should be clearly set forth in the payor-provider contracts.

If payment will be made to only one provider who will then have the responsibility to pay others, the payor needs to be indemnified for the failures of the paying provider. This is similar to the problems ACOs will confront in administering payments to providers within their network. These arrangements often look like network participation agreements of physician-hospital organizations (PHOs) and individual practice associations (IPAs) of the mid 1990s. This brings us to the issues of governance and contracting amount providers in bundled payment arrangements.

7 Provider Governance and Contracting Issues³⁴

³⁴ Some of these ideas were initially expressed in a piece I wrote for HCI3, Gosfield, "Here's How To Participate in CMMI's Bundled Payment for Care Initiative (Sept 2011) <http://www.hci3.org/content/improving-incentives-newsletter-heres-how-participate-cms-bundled-payment-pilot> which was the basis for CMMI's asking me to do a Technical Assistance webinar on the same subjects to those seeking to participate in the Bundled Payment for Care Improvement Initiative. (March 22, 2012) <http://www.innovations.cms.gov/resources/Bundled-Payments-ADLS-4-5.html> and then was further expounded in Gosfield, "Avoiding Food Fights: The Value of Good Drafting to ACO Physician Participants", American Health Lawyers Association, Physician Organizations Practice Group newsletter, Vol 15, No1, (June 2012) pp. 10-12, <http://www.gosfield.com/PDF/PhysOrg.Avoiding%20Food%20Fights.June%202012.pdf>. These ideas were further expanded in my teleconference on Governance and Contractual Issues in Bundled Payment (Sept 25, 2012) which is available as an MP3. <http://www.gosfield.com/teleconference/index.htm>

Because bundled payment in this chapter is about sharing a budget among disparate providers who are otherwise paid on differing bases, how the providers govern themselves under the payment rate becomes a real issue for lawyers. Relationships around payment may arise among physicians alone—primaries and specialists or among specialists, and certainly arise in hospital-physician interactions. Relationships among hospitals and other providers such as home health agencies and rehab agencies matter, too. Where physicians are managing chronic care in the community under bundled payment they may also have financial relationships that do not involve a hospital, but matter with home health agencies and rehabilitation centers. The types of entities that might be sharing bundled payments include physician groups, hospitals and health systems, IPAs, PHOs, ACOs and other integrated delivery systems, or a co-management entity created to help a hospital improve its performance. New networks are clearly being formed as well, given all the coalitions that came together to apply for the various Medicare ACO opportunities, particularly those that applied for the Advanced Payment model which provides dollars to develop infrastructure.³⁵

In establishing the governance of the payment there are many issues which are very reminiscent of the PHO governance arguments of the mid 1990s. The difference in bundled payment governance, however, is that unless you are an ACO taking all Medicare patients assigned to you, there are sub-networks of the members of a medical staff, or among physician groups, that are selectively involved, given their specialties and the conditions around which payment will be bundled. Even if no corporate entity is necessary to distribute dollars, per se, there will be issues of structure that will have to be addressed. How many people will sit in the governance that will handle disputes among the participants? Will they be one man one vote? How will larger medical groups and smaller ones be accommodated simultaneously? If there is an entity which is established, who has ownership, if anyone?

As decisions get made, supermajority topics have to be confronted. In a typical corporation, supermajorities are often necessary to determine dissolution, incurring debt, amending the governing documents, approval of a budget or change in legal form. In the context of bundled payment, supermajorities might be required to change the compensation or allocation metrics of the program. Adding providers or classes of providers can create disequilibrium if not handled effectively. Terminating a provider from participation or resolving an appeal might also be subject to supermajority vote.

Which clinical conditions are the subject of bundled payment can affect decisions on other matters including, if there is going to be ownership in an entity, who owns versus who can participate? Still further, participation in governance councils can be handled separately from ownership. Some providers are more important in some settings than others. For chronic care bundles, keeping people out of the hospital is important. Similarly in preventing readmissions to the hospital, home health agencies can be critical and might well be owners of a bundled payment entity. Certainly they should be considered for participation in governance councils that actually manage the standardization and performance measurement that makes bundled payment incentives

³⁵ <http://innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html>

work. For knee and hip repair, rehabilitation is essential. By contrast, if the bundled payment is about pneumonia, physical therapy may not be as critical. Physical therapists, if not employed by one of the participants, might participate only by contract rather than in ownership.

To make bundled payments work among providers, contracts are foundational. They address the expectations regarding performance as well as allocation of dollars among the participants, unless the model is a disaggregated bundled budget arrangement where payment is made after reconciliation of the actual expenditures, by the payor directly to the participating providers as in PROMETHEUS Payment, if the providers so choose. The rubber hits the road on the issues of downside risk (when budgets are exceeded) and how that is allocated versus upside distributions where dollars will be paid as rewards. In both issues there is a potential problem of attribution of responsibility. Many of these programs avoid this problem completely by putting everyone at risk for the same amount of money. In the past, in the few instances where there was risk or reward to be allocated within PHOs, disputes arose with respect to attribution. The easiest way to avoid these problems in today's bundled payment is to go back to the fundamental definition of the episode budget which takes into account clearly who is expected to share what portion of the budget. Presumably downside risk might be allocated similarly.

As to downside risk, in the mid-90's in the moment of PHOs, mostly hospitals took the downside risk. In Model 1 of the BPCI only the hospital has downside risk. There are potential Stark and anti-kickback issues if, upon reconciliation, the hospital makes up a debt that belonged to the physicians, but if there was never any expectation that the physicians would be financially responsible, then that legal issue is diminished. A different approach is to establish a risk pool set aside to protect against financial loss from mismanagement of care, but if the physicians are already being paid on a discounted fee for service basis, this is likely not going to be a popular approach. Even if the bundled payment is commercial only, the extent to which the hospital holds the physicians harmless from their ineffective behavior has to be confronted at the outset, to avoid Stark and anti-kickback risks from monies fronted for the physicians on the commercial side in order to garner Medicare admissions which aren't even part of the program. This would be in the nature of a reverse kickback.

On what basis to terminate participants in the bundled payment is another point of potential controversy. Obviously if the payor sponsoring the payment program takes action against the provider (e.g., putting them on prepayment review, seeking repayment of overpayments) although the payor may not be right, the predicates of the purpose of bundled payment would have been implicated in these actions. Providers who cherry-pick (taking only healthier patients) or lemon drop (getting rid of sicker patients) can undermine the viability of the program as well. If the bundled payment model is appropriately risk adjusted, these actions should not be necessary, nor tolerated by the other participants. Failure to comply with provider standards which go beyond basic credentials (e.g., licensure, participation status in Medicare, maintaining medical staff privileges as relevant) is the most significant challenge. Unless there has been clear agreement on the pathways or protocols to be utilized in a standardized approach to care,

or there are clear compacts which define the expectations of the participants in the program, it can be hard to get rid of someone who is simply not towing the mark. Depending on how attribution and allocation of dollars is handled, one miscreant can poison the waters for all. In fact, this is part of the point of bundled payment --- to put physicians and other providers at risk together for changing their behavior so they deliver safer, more valuable, cost effective, high quality care. Without clear statements at the outset of what that means, documented in ways that are meaningful to the participants, the positive potential of bundled payment will remain unrealized. Successful bundled payment programs will develop internal cultures, which is also the point of the incentives.

That said, when the network of providers who will initially participate is developed, there should be a theory of the right mix of specialties, institutions, non-physicians, etc. Terminating providers from participation can disrupt the delicate web of interrelationships which makes bundled payment different from disparate, siloed professionals doing whatever they think is in the patient's best interest. So, how termination is undertaken, and the appeal rights that pertain will be important. Voluntary termination by a provider can also be disruptive. This raises the additional concern of maintaining an effective network without having disgruntled participants putting the network at risk. Rules regarding when and how someone can voluntarily terminate need to be set forth in the contractual foundations or governance documents as well.

Once a bundled payment program is in place, who can join the participating network and how? Can they buy into the governance entity or just participate contractually? Will they be held to different standards to participate once the program has developed experience or will developmental participants be accepted as well? When new participants are added what happens to the financial risk of the other participants? New blood can dilute the extent of downside risk, but it also dilutes the effect of reward, again, depending on how the payouts of rewards are constructed.

All of these issues also raise the prospect of potential disputes. At the level of the network, below the payor, will arise the specter of a mirrored approach to dispute resolution or appeals of decisions made among the providers who are governing themselves around the bundled payment. The same issues that ought not be appealable to the payor (episode definition, rules for triggering, breaking and concluding, and the amount in the budget are all subject to negotiation and therefore ought not be appealable) ought not be subject to dispute resolution among the providers. But the same issues that might be appealed to the payor when payment is made directly to the providers will also emerge where the payment is managed by a provider governance structure. There is the additional issue as well as to what happens when two providers claim the same bonus payment. There are options here: (1) set rules that say who counts as the principal provider, often based on number of encounters; (2) go back to the fundamental calculations that stitched together which disparate providers would deliver what portion of the budget and allocate that way; (3) make the providers work it out among themselves or no one gets the payment. Surely there are other options as well, but the point is that in bundled payment involving environments where patients still see multiple independent providers, these issues are inevitable.

The nature and scope of the dispute resolution or appeals process will be a reflection of the culture of the bundled payment network. There might be a reconsideration by a leadership council of providers involving the same, different or more representatives than made the decision subject to appeal. There might be review by an entirely different internal body specifically established for this purpose. Whether the review is by peers or not, will likely have to be determined as well. Where bundled payment is focused around specific conditions, the input of those clinicians of similar disciplines would seem to be relevant. Some would argue that, depending on the nature of the problem, a full fair hearing as in a medical staff, should take place. I would not share that view. Whether to turn to external sources of review like the American Health Lawyers Association Alternative Dispute Resolution Service is another option to consider. Typical of dispute resolution processes, decisions about timeframes, whether attorneys are involved, whether there is a record review only, whether oral argument is permitted or a more informal face to face interchange, and the types of records to be maintained should be addressed. To ignore these potential problems can lead to disruptive difficulties.

8 Conclusion

The positive impact of bundling payment is by no means clear yet. The potential for improved care at lower cost when providers are at risk in the same way for results seems logical, at a minimum. But despite the healthcare system's typical response of taking the easy way out, by beginning with total knee replacements as the topic so far most often addressed by bundled payment, it seems inevitable that there must be real savings to be had in avoiding potentially avoidable complications, which avoidance itself represents better, higher quality care.

What is less obvious to many, though, is that for these programs to work well they must be designed with a clear eye toward the realities of clinical care, with budgets that support what science says patients should receive for their conditions, based upon open, fair and clear rules of engagement. Providers who would participate in these programs should understand they will need a different point of view, different skillsets and different styles of communication if they are to reap the rewards that bundled payment offers. Clinically integrating among themselves is a sine qua non for these initiatives to take hold.

One of the appeals of bundled payment programs, though, lies in the fact that unlike the Medicare ACO project, the participants need not play for all care for all patients. Payors and providers alike, can begin with programs that can make real change without too much financial risk, while everyone learns how to play the game differently and more collaboratively. There is much to be optimistic about.