Legal Issues in Designing Bundled Payments and Shared Savings Arrangements in the Commercial Payor Context

Nixon Peabody LLP
Jill Gordon, JD, MHA
David Martland, JD
Michele Masucci, JD
Jason Chimon, JD
Jennifer Cormano, JD
Carly Eisenberg, JD

The Camden Group
Deirdre Baggot, PhD(c), MBA

Pacific Business Group on Health
Kate Eresian Chenok, MBA
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Letter from the Authors

If you are confounded by the legal issues in setting up a bundled payment arrangement with a commercial payor, the good news is that you are not alone—the applicable laws and regulations were not designed to facilitate these types of arrangements. The bad news is we have to navigate often-competing policy objectives in achieving and maintaining compliance. Bundled payments are not a new idea, but historically have had limited adoption due to legal and practical obstacles. Many federal and state health care laws make bundled payments difficult to structure and implement.

However, now that both the Medicare program and commercial payors are looking to reduce cost, they have embraced bundled payments as a means for doing so. While there have been many publications and presentations on the requirements for Medicare bundled payments, there appears to be little guidance available to assist in facilitating and structuring contracts for bundled payments with commercial payors. This paper aims to address this issue and illustrate that, with the proper investment of time and resources, it is possible to create profitable and compliant bundled-payment and shared-savings arrangements with commercial payors.

This paper is divided into four sections: 1) An Introduction to the Structure of Bundled Payments and Incentive Payment Arrangements; 2) Antitrust Considerations and Legal Framework; 3) Fraud and Abuse Considerations and Legal Framework; and 4) Commercial Bundled Payment Program Creation.

It is important to note that although this document provides an analysis of the potential legal issues that organizations may encounter in designing a bundled payment program, this paper is not meant to be legal advice and it is not meant to be an exhaustive discussion of all of the potential legal issues that pertain to an individual organization. The key to successfully navigating the various legal issues involved in structuring a commercial bundled payment program is to engage competent legal counsel early in the process, as legal requirements will influence the program’s construction. Organizations should seek advice of counsel to fully analyze the issues as they apply to their specific bundled payment program and to ensure compliance with applicable federal and state laws. While the laws and regulations discussed in this paper present challenges in creating and implementing a compliant commercial bundled payment program, with the assistance of counsel these obstacles can be overcome.
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Introduction

If you are contemplating designing and implementing a bundled payment arrangement with a commercial payor, there are complex legal issues to consider, as the applicable laws and regulations were not designed to facilitate these types of arrangements. While successfully setting up a compliant bundled payment arrangement will require a significant amount of time and effort, it is possible to create such arrangements, and ultimately, the legal challenges can often be overcome. Bundled payments are not a new idea, but historically have had limited adoption due to legal and practical obstacles. Many federal and state health care laws make bundled payments difficult to structure and implement. However, both the Medicare program and commercial payors have embraced bundled payments as a means for reducing costs, and many providers view bundled payments as an effective market strategy and a gateway to population management and more complex value-based payment arrangements.

In contrast to traditional fee-for-service payments, where each service is billed separately, a bundled payment consists of a single payment for multiple services. This payment may cover multiple services furnished by either multiple providers or a single provider. Thus, in most instances, a bundled payment will be a single, global negotiated payment of a predetermined amount for all services furnished during an “episode of care” by a designated group of providers. For example, a bundled payment could include all services related to a hip replacement, from the pre-surgical workup all the way through rehabilitation. As you design your program, it is important to keep in mind your goals, as there are many reasons to develop commercial bundled payment arrangements.

Providers use bundled payments in an effort to attract more business—not only from commercial payors, but from self-insured employers, self-pay patients, and in the context of medical tourism as well. Providers also use these arrangements to engage with other providers, form networks, and build alliances. They use bundled payments to experiment with sharing risk to start cooperating better with their colleagues and to reduce hospital costs. Payors, on the other hand, often use bundled payments to reduce reimbursement, and to encourage patients to use lower-cost or higher-quality providers.

When considering how to manage legal and regulatory issues associated with the bundled payment program you are contemplating, it will be helpful to consider the components that will be included in the program. In addition to the financial payment for the “bundle,” many programs incorporate a gainsharing arrangement. “Gainsharing” often refers to a financial arrangement between a hospital and physicians whereby a hospital shares with physicians a portion of any reduction in the hospital’s costs attributable to the efforts of the physicians. If providers participating in a bundled payment program intend to share the “gains” based on these

2 ibid.
3 ibid.
efficiencies, they will need to create a methodology for sharing, including identifying with whom savings will be shared, the proportion of the savings to be shared, the mechanism for calculating savings (i.e., the “gains”), and the timing and method of distributing savings.

As you design your bundled payment program, a gainsharing arrangement may help achieve your goals, as it increases the direct incentives to providers for making cost-effective choices. Another commonly used incentive similar to a gainsharing arrangement is a bonus, or “pay-for-performance” program that rewards providers for achieving quality metrics (as opposed to cost-savings metrics). Pay-for-performance payments are distinct from gainsharing in that they are focused on quality and patient satisfaction, rather than the cost of care.

Bundled payment arrangements, including gainsharing and pay-for-performance incentives, have existed in various contexts for some time and have been tested in a number of Medicare demonstration projects. Bundled payment programs in the commercial space, however, are a more recent development. While there are examples of successful bundled payment arrangements in the commercial space, most have been limited to hip and knee replacement or certain cardiac episodes of care. This is true even with the advent of advanced actuarial tools and predictive modeling techniques that assist with many of the difficulties associated with bundled payment implementation. When designing a bundled payment program, it’s important to remember that while the practical challenges have become less daunting, the legal framework for compliance has not become more flexible for bundled payments in the commercial payor context.

Recently, the Bundled Payments for Care Improvement initiative (“BPCI”), introduced by the Center for Medicare and Medicaid Innovation (“CMMI”), created a bundled payment program for participating providers caring for Medicare beneficiaries. There are also opportunities outside the BPCI context to implement successful bundled payment programs in the commercial space. While there have been many publications and presentations on the requirements for Medicare bundled payments, there appears to be little guidance available to assist in facilitating and structuring contracts for bundled payments with commercial payors. This paper aims to provide a discussion of some of the possible legal issues to consider as you create profitable and compliant bundled payment and shared savings arrangements with commercial payors.

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4 Although single-provider bundled payment plans have been used for quite some time (e.g., hospitals bundling facility-only services for a given inpatient stay, and global obstetrical fees that include prenatal, delivery, and post-partum obstetrical physician services), bundled payment plans grouping the services of multiple providers have not emerged until recently. Painter MW, Burns ME and Bailit MH. Bundled Payments Across the U.S. Today: Status of Implementations and Operational Findings, Newtown, Conn.: Health Care Incentives Improvement Institute, 2012, www.hci3.org/sites/default/files/files/HCI-IssueBrief-4-2012.pdf (accessed August 2013).

5 Traditionally, an obstacle for bundled payment implementation has been the difficulty in evaluating a budget. A viable bundled payment plan requires a detailed analysis of the projected costs associated with the covered episodes in order to be profitable. This, in turn, requires gathering large amounts of historical billing data to make accurate projections. Now, however, with advanced actuarial tools and predictive modeling techniques, cost projections are more accurate and easier to calculate. Further, with the increased use of electronic medical records, and with cooperation among multiple providers and hospitals growing more and more commonplace, the necessary historical data is becoming more accessible. To be sure, budgeting is still an important concern, but there are potential solutions.
This paper is divided into four sections: 1) An Introduction to the Structure of Bundled Payments and Incentive Payment Arrangements; 2) Antitrust Considerations and Legal Framework; 3) Fraud and Abuse Considerations and Legal Framework; and 4) Commercial Bundled Payment Program Creation.

**Section I: An Introduction to the Structure of Bundled Payments and Incentive Payment Arrangements**

In order to discuss the potential legal issues related to a commercial bundled payment program and design a compliant program, it is necessary to examine some operational issues first, such as whether a particular law will even apply depending on the structure of the program. Implementing a successful commercial bundled payment program requires that all participants initially define the “episode of care” for which all of the participants will be accepting a global payment, the contract structure, and the possible methods used to distribute the single payment among the provider participants.

**Episode of Care**

The provider entity administering the bundled payment program will receive one bundled payment for all hospital and physician services furnished to a patient during an “episode of care.” The first step in fashioning a bundled payment program is to define the “episode of care,” or the set of services and the time period included in the bundle. Though any set of services can be deemed an “episode,” selecting a group of services naturally bound by a medical condition enables physicians to arbitrage the supply chain and treatment options to increase efficiency. Further, determining what services ought to be included should also involve an analysis of historical reimbursement data and a determination that there is an opportunity to reduce costs on those services. The episode of care for a hip replacement bundle, for example, might cover pre-surgical preparation and diagnostic tests, anesthesiology, the surgical procedure, operating room fees, the hip implant itself, intra- and post-operative radiological examinations, laboratory tests, and rehabilitation. Thus, in the designing the program, cost and effectiveness of various care pathways, including the supply costs and other inputs, would be reviewed to determine whether a particular option could reduce costs but remain just as effective as higher-cost options.

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7 Morrison EC. “Bundled Payments.” In Evaluating and Negotiating Emerging Payment Options, Chicago: American Medical Association, 2012, www.ama-assn.org/resources/doc/psa/payment-options.pdf (accessed August 2013). Note that though this example provides a good overall structure for the episode, but further refinement would be required before implementing a bundled payment plan relying on it. For instance, we know that “diagnostic tests” are covered, but exactly which tests are included would be required in any properly functioning bundle.
In addition, clearly defining the duration of the episode is critical, as it will determine both reimbursement and contractual obligations. Setting clear episode triggers and endpoints defines what services are included in the single payment and what services for which the providers will receive additional payments. As an example, the BPCI initiative includes four models for defining the episode, each with clear triggers and endpoints. Model 1, for example, covers the inpatient stay at an acute care hospital and no more. By contrast, Model 2 begins with the inpatient stay, but does not end there; instead the “episode” ends either 30, 60, or 90 days after discharge. Models 3 and 4 likewise define the “episode” with similarly clear time frames. Though these models were designed for Medicare, there is no reason bundled payment arrangements in the commercial space cannot utilize them as well. Indeed, in the commercial space, acute-care episode bundles typically begin between two and 30 days prior to the procedure and extend afterwards for 90 to 180 days. Bundles for chronic disease management have been found to cover a standard time period—one year, for example—and begin with either the first diagnosis on a claim or “simply include the entirety of the time period for someone with a diagnosis on a claim.”

A properly defined episode of care must also delineate what factors (such as comorbidities) would cause a patient or service to be excluded from the bundle. Factors that providers know increase a patient’s risk for complications ought to exclude a patient from the bundle, as those complications often mean additional care for which the costs will be difficult or impossible for providers to control. This determination is important for limiting provider risk,

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8 Dong et al.
9 Information Technology for Bundled Payment. McLean, Va.: The MITRE Corporation 2011, www.mitre.org/work/health/news/bundled_payments/IT_Bundled_Payment.pdf (accessed August 2013). It is likely for this reason that at this time, most bundled payment plans cover acute-care episodes, such as surgeries, rather than the management of chronic diseases. The ambiguities inherent in chronic care, as compared to those in acute care episodes, make it more difficult to define a trigger or an endpoint. See ibid.
13 Model 3 is triggered, like Models 1 and 2, by an acute-care hospital stay, but only post-acute care services with a participating skilled nursing facility, inpatient rehabilitation facility, long-term care hospital, or home health agency are covered. BPCI Model 3: Retrospective Post-Acute Care Only. Baltimore, Md.: Centers for Medicare and Medicaid Services, 2013, innovation.cms.gov/initiatives/BPCI-Model-3/index.html (accessed August 2013). Further, these services must begin within 30 days of discharge from the hospital, and extend for a minimum of either 30, 60, or 90 days after initiation of the episode. Model 4 covers only the inpatient stay, and differs from Model 1 in that it involves a single payment that covers all services furnished by the hospital, physicians, and other practitioners. BPCI Model 4: Prospective Acute Care Hospital Stay Only, Baltimore, Md.: Centers for Medicare and Medicaid Services, 2013, innovation.cms.gov/initiatives/BPCI-Model-4/index.html (accessed August 2013). Model 1, on the other hand, pays the hospital a lump sum, and then pays the practitioners separately.
14 Painter et al.
15 ibid.
16 ibid. A patient’s age and gaps in health insurance coverage during a bundle’s established time period are also common reasons to exclude patients from a bundle.
as, the more severe a case, the higher the outlier risk associated with that case.\textsuperscript{18} For example, the American Society of Anesthesiologists (“ASA”) classifies patients into severity levels based on comorbidities.\textsuperscript{19} By recommending that only patients considered to have mild or moderate risks be part of the bundle, the ASA minimizes the risk of catastrophic loss from outlier cases.\textsuperscript{20} Some orthopedic surgeons reduce outlier risk by excluding patients with certain complications, such as surgical site infections and venous thromboembolism, from the bundle.\textsuperscript{21} In the maternity care bundled payment context, providers can reduce their financial risk by having additional payment for care and treatment of complications in labor and delivery, such as infants with preexisting conditions, premature infants, and infants with congenital abnormalities, paid outside the standard maternity bundle.\textsuperscript{22} In this regard, bundled payments in the commercial payor context are very flexible. As long as the arrangement does not run afoul of any laws or regulations, payors and providers are free to tailor their episodes and bundles as they see fit.\textsuperscript{23}

\textit{Participating Providers}

A second important step in designing a bundled payment plan is to identify the participating providers. Potential providers include hospitals, physicians (both primary care physicians and specialists), other institutions (imaging centers and skilled nursing facilities, for example), and ancillaries (such as physical therapy). Some payors find it useful to set qualifying criteria for participation in a bundled payment plan.\textsuperscript{24} Most insurance companies have Centers of Excellence programs, for which participants qualify based on facility accreditation, physician credentialing requirements, and the use of specific surgical safety and verification processes.\textsuperscript{25} Some large, self-insured employers are now qualifying providers through review of detailed quality and outcomes measures.

\textit{Contracting with Payors}

Once the episode of care has been defined and the participating parties identified, the structure and flow of funds within the bundled payment and shared savings arrangements must

\textsuperscript{18} Dong et al.
\textsuperscript{19} ibid. The severity levels used in the ASA system range from 1-6. However, only levels 1 and 2, considered mild and moderate cases, would be included in a bundled payment program.
\textsuperscript{20} ibid.
\textsuperscript{22} Elective cesarean delivery prior to 39 weeks of gestation may also be excluded from a maternity bundle because it may often cause infections, lead to five or more days of hospitalization, and require infant cardiac resuscitation. \textit{Action Brief: Maternity Care Payment}. Washington: Catalyst for Payment Reform, 2012, \texttt{www.pbgh.org/storage/documents/CPRMaternity.pdf} (accessed August 2013).
\textsuperscript{23} See the discussion below regarding compliance with federal and state laws. In the bundled payment context, it is most often more efficient to design the bundle and propose the flow of funds and contractual arrangements and then work with legal counsel to ensure that the proposed arrangement is compliant. There is no standard “right” way to approach an arrangement, which can create compliance challenges, but often allows for more customized programs that are structured to meet specific stakeholder needs.
\textsuperscript{24} Painter et al.
\textsuperscript{25} ibid.
be delineated. In the most basic form, a payor will make a single bundled payment of a pre-determined amount to a central provider entity that has an agreement with the payor to assume financial risk and receive the bundled payment. The central provider entity is responsible for distributing the payment among all physicians, non-physician practitioners (e.g., nurses, physical therapists, etc.), and all other organizations caring for the patient (e.g., hospitals, skilled nursing facilities, home health agencies, etc.). Therefore, the central provider entity acts as a hub and executes a series of contracts with other organizations regarding provider participation in the bundled payment program, and distributes payment from the global bundled payment. Figure 1 illustrates this structure with both physicians in an independent practice association (“IPA”) and physical therapists participating with the hospital, which is acting as the central provider or “hub.”

**Figure 1: Simple “Hub” Contract Structure with Hospital**
This hub arrangement may also be used by an IPA or other physician entity wishing to coordinate a bundled group payment program. This structure is illustrated in Figure 2.

**Figure 2: Simple “Hub” Contract Structure with IPA**

In addition, an arrangement could make certain services optional. For example, a hip replacement bundled payment arrangement may want to make the inclusion of physical therapy services optional to a payor. This means there would be two different bundled payment amounts a payor could pay, one that included the physical therapy services and one that did not, depending on the course of the patient’s treatment. It’s also important to note that a bundled payment arrangement does not always need a single “hub” entity to receive the payment. There may be business or compliance reasons why providers may negotiate a single bundled payment and then separately contract for their respective portions with the payor. This arrangement is described in more detail under the “Corporate Practice of Medicine” and “Fee Splitting” sections below.

**Allocating the Bundled Payment**

The “hub” provider entity and the other bundled payment participants must develop the financial and logistical mechanisms necessary to accept single bundled payments for each episode of care, and to distribute the bundled payments among themselves. This distribution could include a gainsharing and/or pay-for-performance arrangement to incentivize cost
reduction and increase quality of care. There are generally three types of methodologies for distributing the bundled payment among bundled payment participants that include gainsharing/pay-for-performance concepts and that also comply with federal law. These methodologies are: (1) a two-part payment comprised of a fixed amount plus a bonus arrangement based on cost and quality metrics; (2) a payment based on an average inpatient length of stay (“LOS”), or some other allocation of risk between physicians and the entity/institutional services; or (3) a combination of the two.

The first methodology is a fixed-payment-plus-incentive bonus based on gainsharing and/or pay-for-performance-type bonuses. Under gainsharing and pay-for-performance models, providers either share the financial gains achieved in part due to the efforts to reduce inefficiencies, or they set aside a portion of the bundled payment to reward participants for improved quality and patient satisfaction. Provider compensation is comprised of two parts—flat-fee payments and incentive payments. The parties would first establish guaranteed flat-fee payment amounts for each provider, payable from the bundled payment. Then, pursuant to a shared savings and/or pay-for-performance agreement, another portion of the bundled payment would be allocated to each participating provider—if such provider achieves predetermined quality and efficiency criteria. To the extent that services furnished to patients are included in the episode of care, providers may not independently bill the payor for those services. This flow of funds is illustrated in Figure 3. In a slightly different context, Blue Cross Blue Shield of Massachusetts (“BCBSMA”) employs an incentive payment arrangement layered on top of a fixed fee in some of its global payment contracts. Contracted providers are given their base payment on a per-member, per-month amount. The providers are then also eligible for 10 percent bonus of the global payment, which is centered on inpatient and outpatient performance measures. These incentive payments are designed with “five thresholds or ‘gates’ to recognize different performance levels.” For example, if a physician has met the quality metrics of Gate 1, then that physician will get a 2 percent incentive payout. Satisfying the quality metrics of Gate 3 will result in a 5 percent incentive payout, while the final gate (Gate 5) will result in the full 10 percent incentive payout.
The second methodology splits the bundled payment into a hospital (or institution) share and a physician (or professional) share, defined by percentages, and each party’s share could increase or decrease based on performance. For example, the parties could split the bundled payment for one episode of care into equal parts (50 percent payable to the hospital and 50 percent payable to the physicians), and then adjust their shares based on average inpatient LOS or other treatment or clinical basis. To the extent a specific patient’s LOS exceeds the average number of days for that patient’s condition, the physicians’ share of the bundled payment would decrease. Conversely, if a patient is discharged in less time than the average LOS for a given diagnosis, the physicians’ share of the bundled payment would increase. Of course, this payment would also be tied to readmission rates in order to provide a safeguard against premature discharges. This flow of funds is demonstrated in Figure 4.
Lastly, the parties could adopt a hybrid approach. For example, instead of establishing fixed fees for services, the providers could agree to split the bundled payment into percentages. Those percentages could increase or decrease according to a performance metric, such as patient LOS. In this hybrid approach, the parties could carve out a portion of the bundled payment for an incentive pool that is paid out based on shared savings and/or quality criteria. This flow of funds is demonstrated in Figure 5.31

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31 Note that, as discussed in Section III, for compliance reasons, incentive payments based on cost savings are typically contingent on meeting quality targets as well. In the absence of meeting certain quality metrics, generally providers will not receive any bonus, regardless of cost savings.
As may be evident from the discussion above, providers participating in a bundled payment arrangement may take on varying degrees of financial risk. This is determined by the contracts among the parties. Absent a limitation under state insurance law and as long as the amounts ultimately paid to each provider are fair market value for the provider’s goods or services, the hospital, physicians, and other providers participating in the bundle may allocate risk in any way that meets their business needs.

**Contract Structure**

Once the parties determine the flow of funds and allocation of risk, they must ensure all of the financial relationships are documented by a written agreement. If pre-existing contracts are in place, new agreements are unnecessary or even inappropriate, and amendments are required instead. The structure of the contracts documenting the bundled payment program will depend, in part, on what types of arrangements are already in place among the various providers and how the providers are currently affiliated.

If none of the parties have an established relationship, then all of the contractual arrangements among the program’s participants will need to be drafted to create the bundled payment. These new contracts must:
• define the episode of care;
• define the types of patients to receive care under the bundled payment arrangement;
• require the provider to provide services in the bundle to patients identified as participating in the bundle; and
• describe the allocation of revenue, including incentive payments like pay-for-performance and/or gainsharing bonuses.

These contractual arrangements are highlighted in Figure 6.

**Figure 6: New Contracts for Bundled Payment Program**

If the parties have an existing relationship, then they must amend the current contracts to carve out the services covered by the bundled payment (i.e., the episode of care) from the existing payment terms. The amendments must:

• define the episode of care (including what medical and other services are included in the episode of care);
• carve out the episode of care from the existing contracts,
• state the payment terms; and
• set forth any incentive payment terms among the parties (e.g., pay-for-performance and/or gainsharing bonuses).
For example, existing contracts may specify how much the health plan will pay a surgeon for a type of surgery, and for follow-up post-surgical care. If all of those services are covered under the bundled payment, the surgeon’s contract with the payor should be amended to specify that those services will no longer be covered by the payor for qualifying patients; instead, for applicable patients, the physician would seek payment solely from the hospital (i.e., the “hub” provider). However, if the bundle only includes the surgery, then the surgeon will be compensated for all post-surgical care, per the terms of his or her payor contract, and not as part of the bundled payment arrangement. The contract amendments must clearly identify these distinctions. These amendments are highlighted in Figure 7.

**Figure 7: Existing Contracts with Bundled Payment Amendment**

Existing ACO Arrangements

If the parties participating in the bundled payment arrangement are also participating in a Medicare Shared Savings Program accountable care organization (“ACO”), they may continue to do so; there is no prohibition on participating in both. Under Medicare regulations, ACO participants are not permitted to participate in other shared savings programs. However, bundled payment arrangements—both the BPCI initiative and commercial bundled payment programs—are not deemed to be “shared savings programs” under the regulations. Therefore, the parties
should simply ensure that the agreements defining the bundled payment arrangement and the ACO participation agreement(s) do not conflict. There is no inherent reason why they should.

Section II: Antitrust Considerations and Legal Framework

When designing a bundled payment arrangement, it is important to consider several antitrust issues, and address these issues from the start. The primary issue, which arises if independent providers (such as distinct physician groups or independent hospitals) join together to negotiate bundled payment agreements with payors, is whether that joint activity constitutes illegal “price fixing” or is, instead, permissible, potentially pro-competitive joint activity. Courts and regulators will engage in a two-step analysis in addressing this issue.

First, they will consider whether it is permissible for the independent providers to negotiate and enter into bundled payment agreements at all. Over the past two decades the Department of Justice (“DOJ”) and Federal Trade Commission (“FTC”), through over 25 successful enforcement actions, more than five advisory opinions, and multiple public statements, have articulated the view that providers who are actual or potential competitors may only jointly negotiate prices with payors if the providers are financially or clinically integrated. Financial integration requires that the providers share “substantial” financial risk, while clinical integration requires that the providers are sufficiently integrated to demonstrate that they are likely to produce significant efficiencies (i.e., lower prices and/or higher-quality care). Clinically integrated provider groups generally have established mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; have selectively chosen network participants who are likely to further those efficiency objectives; and have made significant investments of capital in the necessary infrastructure and capability to realize those efficiencies.

Provider groups should consider whether their proposed negotiation of a bundled payment program would pass antitrust muster under the financial or clinical integration standard. It certainly appears that properly structured bundled payments can constitute the sharing of financial risk. Indeed, the FTC and DOJ Healthcare Statements provide that an agreement by [independent providers] to provide a complex or extended course of treatment that requires the substantial coordination of care by [providers] in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient’s condition, the choice, complexity, or length of treatment, or other factors [can constitute the sharing of financial risk provided that the providers jointly] assume the risk or benefit that the treatment provided through the network [as the cost] may either exceed, or cost less than, the predetermined payment.”32

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Similarly, one would anticipate that providers jointly negotiating and implementing bundled payment programs could be clinically integrated. Indeed a provider network would be well-advised to be integrated before embarking on a bundled payment program; while being clinically integrated does not eliminate all compliance risk, it greatly mitigates potential antitrust issues.

Second, if a court or regulator determines that the provider organization is sufficiently financially or clinically integrated to be able to negotiate a bundled payment program, it will then apply the so-called “rule of reason” to determine whether, on balance, the program is pro-competitive (i.e., results in lower prices and/or higher quality care) or anti-competitive (i.e., results in higher prices and/or lower-quality care). The program will only fail scrutiny if the court or regulator concludes that it will have an anti-competitive effect in the relevant market. If its effect will be neutral (i.e., it will have no effect, perhaps because the participating providers lack sufficient market power to influence the market) or pro-competitive, it will withstand scrutiny. To help ensure that programs will withstand scrutiny, provider organizations should adopt antitrust protocols to safeguard against network participants making anti-competitive side agreements or sharing pricing information in a manner that could reduce price competition in the market.

The question of whether the providers negotiating a bundled payment agreement are sufficiently financially or clinically integrated to do so does not arise if the provider network is a single entity (a network of commonly controlled hospitals and employed physicians, for example) because, in that situation, independent “competitors” would not be jointly “agreeing” on prices. There are miscellaneous other antitrust issues that could arise in a bundled payment agreement, however, such as “tying” (if the provider network has market power and the bundled payment was used to coerce a payor or patient into paying for a service they did not want in order to obtain a service they wanted) or “predatory pricing” (if the services were priced below cost as a means to put competitors out of business). However, these issues are only likely to arise in extreme factual scenarios.

Antitrust issues would also be implicated if payors jointly agree on the terms of bundled payment programs they will offer in the market or work together to influence state or federal regulators. Generally, it is illegal for competitors to agree to limit the terms on which they will compete, as would be the case if they agreed to only offer a standardized product to the market. In the insurance context, however, the McCarran Ferguson Act exempts certain components of “the business of insurance” from antitrust scrutiny. This Act has been held to permit insurers to agree on standardized policies they will offer in the market and a similar analysis might protect payors who agree on standardized bundled payment programs. As to joint efforts to influence regulators, a series of judicial decisions have established that joint, good faith action by competitors to solicit government or regulatory action is not subject to antitrust challenge.
Section III: Fraud and Abuse Considerations and Legal Framework

Confusion over the legal and regulatory requirements surrounding the creation of a bundled payment and shared savings arrangement is one of the primary roadblocks to widespread commercial use of these models. There are multiple federal and state fraud and abuse laws and regulations that must be considered when designing a commercial bundled payment plan. While the legal framework is certainly navigable, it will require a significant amount of time and effort to analyze the applicable legal issues and design a compliant program. This section provides a summary of the common legal issues involved in bundled payment programs. The applicable state laws and regulations vary on a state-by-state basis, but typical prohibitions are discussed in this section as well as the typically applicable federal laws and regulations. The laws, regulations, and legal issues discussed in this section are:

- **Civil Monetary Penalty (Federal)**—This law prohibits a hospital from knowingly making a payment, directly or indirectly, to an individual physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries.

- **Self-Referral Prohibitions (Federal and State)**—These prohibitions forbid physicians from referring patients to hospitals or other providers for specific services where the physician and the recipient of the referral have a financial relationship. Most of these prohibitions also provide exceptions to permit certain financial relationships.

- **Anti-Kickback Prohibitions (Federal and State)**—These laws prohibit payments to physicians and others that are intended to induce patient referrals of, or otherwise generate business from, beneficiaries of specific payor sources. Similar to the Self-Referral Prohibitions, Anti-Kickback Prohibitions often provide for certain types of payments to be acceptable and not violate the law.

- **Tax Issues (Federal)**—If any of the provider entities is a nonprofit entity, there are several federal tax requirements that these entities need to ensure are still fulfilled after the creation of the new bundled payment arrangement.

- **Corporate Practice of Medicine (State)**—This doctrine generally prohibits lay entities (i.e., entities that are not owned by physicians) from providing professional medical services. These prohibitions generally prevent hospitals and other corporate entities from directly employing physicians. Often these prohibitions will include exceptions as to when a corporate entity may employ a physician.

- **Fee Splitting (State)**—In general, these laws prohibit physicians from splitting fees for professional services with any non-physician.

- **Insurance Laws (State)**—Since a bundled payment program can, and often does, shift financial risk from a payor to the providers, it is possible that provider organizations assuming financial risk under the bundled payment model will be regulated as health insurers, “risk-bearing organizations,” or that the financial risk will trigger reporting requirements to the state.

- **Special Rules for Self-Insured Employees (Federal)**—If the payor paying the global payment is an employer-sponsored benefit plan, there are other federal laws and regulations to be considered when designing the bundled payment arrangement.
Note on Federal Fraud and Abuse Laws and Regulations

It is important to note that typically, federal fraud and abuse laws and regulations only apply to programs providing care to federal health care payment program beneficiaries. Thus, it may seem unnecessary to comply with these regulations, given that commercial bundled payments by definition do not include the federal government as a payor and therefore, theoretically, do not have an impact on federal program beneficiaries. However, these legal constraints can be applicable to commercial bundled payment programs.

From a practical standpoint, a commercial bundled payment program could find it more efficient to comply with these federal requirements if the participants are running a concurrent government-payor bundled payment program. Currently, CMMI has several bundled payment programs under the BPCI initiative. The Patient Protection and Affordable Care Act (“ACA”) granted CMMI the authority to waive federal health care fraud and abuse laws as may be necessary for purposes of carrying out CMMI initiatives such as the BPCI initiative. Applicants may propose waivers in their application and explain why waivers are necessary for their BPCI-model design. Any such waiver, if granted, would be included in the terms and conditions of the agreement between the Centers for Medicare and Medicaid Services (“CMS”) and BPCI participants. It is important for all BPCI participants engaging in gainsharing to request and obtain a waiver.

However, commercial bundled payment programs are unable to qualify for these waivers. This can lead to some odd results. For example, certain incentives paid to physicians by hospitals for cost savings under a BPCI program, may not be appropriate in a commercial-payor bundled payment program to the extent any of the beneficiaries have Medicare or Medicaid fee-for-service coverage (i.e., as secondary coverage). Even more likely, physicians’ behavior will be influenced by appropriate financial incentives in a commercial payor context, but such care decisions will impact care to Medicare and/or Medicaid fee-for-service beneficiaries who are also being treated by that physician outside the context of the bundle. In a Medicare/Medicaid fee-for-service context, such incentives may not be lawful. Even if physician incentives are paid only to influence the care of commercial patients, if the payments indirectly impact the care provided to the Medicare and/or Medicaid fee-for-service patients, then the plan must still be structured in compliance with the federal laws and regulations.

Any hospital initiative to pay physicians based on potential cost savings must be sensitive to, and determine whether, such payments could implicate services furnished to Medicare and/or

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33 Although Medicare Advantage Plans may be involved in bundled payment arrangements, generally there are Stark law exceptions, federal anti-kickback statute safe harbors, and exceptions from gainsharing prohibitions that apply to managed care arrangements. Therefore, the focus of this discussion is with respect to compliance issues raised by fee for service federal payment programs.
Medicaid fee-for-service patients. If this is the case, then the program should be structured in accordance with Office of Inspector General’s (“OIG”) guidance regarding acceptable physician incentive arrangements (discussed in further detail below).

Civil Monetary Penalty (Federal)

The Civil Monetary Penalty (“CMP”) law is most often viewed as the biggest barrier to gainsharing because it prohibits a hospital from knowingly making a payment, directly or indirectly, to an individual physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries. Under the CMP law, the OIG may bring an administrative action against parties in possible violation and seek to fine those parties.

A “hospital or critical access hospital” that makes a payment in violation of the CMP law shall be subject to a “civil money penalty of not more than $2,000 for each such individual with respect to whom the payment is made.” A physician who “knowingly accepts” a payment prohibited by the CMP law shall also be subject to a civil money penalty. By its own terms, the CMP law applies to payments knowingly made only by a “hospital or critical access hospital” to physicians as an inducement to reduce or limit services. Accordingly, incentive payments from any source other than a hospital are unlikely to implicate the CMP law.

In a bundled payment context, incentive payments from hospitals to physicians and the payment of physicians’ fees calculated on the basis of a cost analysis (like LOS) could violate the CMP law. If there is a gainsharing component within a bundled payment program, typically it is structured so the hospital participant pays physicians an incentive payment or a higher service fee, in part, for successfully keeping costs below a certain level. Physicians typically reduce costs by implementing cost-saving measures. For example, physicians may standardize or use less costly devices or supplies when the replacement products do not impact the quality of care, or they may only use surgical trays or comparable sealed supplies as needed. In this context, the OIG has concluded that these monetary incentives have the potential to induce physicians to limit or reduce care and therefore, they implicate the CMP law. The CMP law prohibits such payments even when they are not intended to reduce or limit services to a specific patient or to reduce or limit care that may not be medically reasonable or necessary. Thus, even if the bundled payment program’s incentive payment or higher services fee is compensation to the physicians for the increased efficiency of care, if the program affects care to Medicare or Medicaid fee-for-service beneficiaries, it must be structured in accordance with OIG guidance regarding acceptable physician-incentive arrangements.

The OIG has evaluated cost-saving measures in gainsharing programs in several Advisory Opinions for compliance with the CMP law. While the OIG has declined to recognize incentive formulas or program elements that are always permissible or prohibited, the parameters established by the Advisory Opinions provide a useful evaluative framework to be considered.

35 ibid.
36 ibid.
when designing a commercial bundled payment model. Generally speaking, the cost-saving measures approved by the OIG through the advisory opinion process fall into the following categories:

- Incentive payments based on meeting quality benchmarks only—not tied to cost savings;
- Substitution of less-costly products for products previously in use;
- Product standardization;
- Opening supplies only when needed; and
- Eliminating or limiting the use of certain items and supplies.

In a series of Advisory Opinions beginning in 2005 addressing gainsharing arrangements, the OIG found that gainsharing arrangements implicated federal fraud and abuse laws when payments are made by hospitals to physicians. However, the OIG declined to impose

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37 OIG Advisory Opinion No. 05-01. Washington: U.S. Department of Health and Human Services, 2005, oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0501.pdf (accessed August 2013). This report pertains to a proposed arrangement in which a hospital would share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons opening packaged items only as needed during a procedure, substituting some less-costly items for some higher ones, and standardizing certain cardiac devices; OIG Advisory Opinion No. 05-02. Washington: U.S. Department of Health and Human Services, 2005, oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0502.pdf (accessed August 2013). This report pertains to a proposed arrangement in which a hospital would share with five cardiology groups a percentage of the hospital's cost savings arising from the cardiologists using standardized types of cardiac catheterization devices and vascular closure devices as needed; OIG Advisory Opinion No. 05-03. Washington: U.S. Department of Health and Human Services, 2005, oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0503.pdf (accessed August 2013). This report pertains to a proposed arrangement in which a hospital would share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from surgeons opening packaged items as needed during a procedure, performing blood cross-matching only as needed, substituting less-costly contrast agents in certain cardiac catheterization laboratory procedures; OIG Advisory Opinion No. 05-04. Washington: U.S. Department of Health and Human Services, 2005, oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0504.pdf (accessed August 2013). This report pertains to a proposed arrangement in which a hospital would share with each of eight cardiology groups a percentage of the hospital's cost savings resulting from the cardiologists’ implementation of a number of cost reduction measures, including standardizing products, limiting use of certain vascular closure devices, and substituting less-costly contrast agents in certain cardiac catheterization laboratory procedures; OIG Advisory Opinion No. 05-05. Washington: U.S. Department of Health and Human Services, 2005, oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0505.pdf (accessed August 2013). This report pertains to an arrangement in which a hospital would share with a group of cardiologists a percentage of the hospital's cost savings arising from the cardiologists' product standardization and limit of use for certain devices, on an “as needed” basis, for inpatient coronary interventional procedures and diagnostic procedures; OIG Advisory Opinion No. 05-06. Washington: U.S. Department of Health and Human Services, 2005, oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0506.pdf (accessed August 2013). This report pertains to a proposed arrangement in which a hospital would share with a group of cardiac surgeons a percentage of the hospital's cost savings resulting from the surgeons making certain less-costly product substitutions, opening surgical trays or comparable supplies only as needed, limiting the use of specific supplies, and agreeing to use selected standardized products of some cardiac devices and supplies when medically appropriate; OIG Advisory Opinion No. 06-22. Washington: U.S. Department of Health and Human Services, 2006, oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-22NewA.pdf (accessed August 2013). This report pertains to a proposed arrangement in which a hospital would share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons limiting the use of certain surgical supplies, using less-costly substitutes for some items, and agreeing to standardization of certain cardiac heart valves; OIG Advisory Opinion No. 08-15. Washington: U.S. Department of Health and Human Services, 2008, oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-15.pdf (accessed August 2013). This report pertains to an existing multiple-year arrangement in which a hospital would share with groups of cardiologists a percentage of the hospital's cost savings arising from the cardiologists standardizing the type of catheterization devices, limiting the use of specific vascular closure devices to an “as needed” basis, and substituting less costly anti-thrombotic medications when appropriate; OIG Advisory Opinion No. 08-16. Washington: U.S. Department of Health and Human Services, 2008, oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-16A.pdf (accessed August 2013). This report pertains to a proposed arrangement by which a hospital would share with an osteopathic physician-owned entity certain performance-based
administrative sanctions when certain safeguards are incorporated into each arrangement. Specifically, the OIG identified the following safeguards:

- **Transparency.** The program mechanics permitted clear identification of specific cost-saving measures and resulting savings, and in each instance, the hospital and physicians shared equally in identified savings as compared to historical practices. For instance, in one agreement between a hospital and a group of cardiac surgeons, the arrangement specifically identified that costs would be reduced by the surgeons making certain product substitutions (e.g., using less-costly disposable head support for patients), opening packing items during surgery as needed, etc. In another proposed agreement, a hospital clearly identified which cardiac catheterization devices should be standardized to decrease costs—stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators—to its cardiology group. In both agreements, the physician groups were entitled to a maximum of 50 percent of the hospital’s cost savings.

- **Credible Medical Support.** The parties offered credible medical support to demonstrate that the arrangement would not adversely impact clinical care. Promised periodic updates of the review were also important. All of the proposed agreements had a program administrator, internal staff, a committee, or an external third-party who would measure the quality, cost, and utilization of the implemented agreement to ensure that the hospital’s and physicians’ care of the patient was not unfavorably affected. For example, with respect to product-standardization recommendations in one agreement, the physicians were required to make patient-by-patient determinations of the most appropriate care. In addition, to protect against inappropriate reduction of the services outlined in the agreement as potential cost-saving areas, the services were monitored to ensure that use did not fall below a designated floor. In another agreement, in which bonus compensation depended on the physician’s performance, the physicians were directly incentivized to improve patient care in order to yield a monetary benefit. Therefore, an adverse effect would be unlikely.

- **Uniform Application Subject to Federal Cap.** The measure for savings included all surgeries, regardless of patients’ insurance coverage. In addition, the programs excluded shared cost savings to the extent that procedures payable by the Medicare and Medicaid programs in the measured year exceeded the volume of like procedures performed during the base year. Savings were measured by referring to actual acquisition costs rather than

38 OIG Advisory Opinion No. 05-06.
39 OIG Advisory Opinion No. 05-05.
40 OIG Advisory Opinion Nos. 05-05; OIG Advisory Opinion No. 05-06.
41 OIG Advisory Opinion No. 05-01.
42 ibid.
43 OIG Advisory Opinion No. 08-16.
an abstract accounting formulation. One proposed agreement between a hospital and a cardiac surgical group followed this safeguard by ensuring that the costs savings from additional procedures payable by a federal health care program during the contract year would not be shared if the volume of procedures exceeded that of the base year. In addition, the payment under the agreement was based on all surgeries, irrespective of the patients’ insurance coverage, and the measurement of savings was made calculating the hospital’s actual out-of-pocket acquisition costs.44

• **Protection Against Inappropriate Reductions.** The programs used objective historic and clinical measures to establish baselines beyond which no savings would accrue to the physicians, thereby removing the incentive to implement cost-saving measures where inappropriate. A cardiology group that would share in costs savings from making changes to its cardiac catheterization laboratory practice, for example, would receive no share of savings resulting from the reduction of use of vascular closure devices beyond 15 percent, based on national data establishing this as the floor in which reduction would not adversely impact patient care.45 In an agreement between a hospital and another cardiology group with a bonus payment based on performance, the agreement ensured that there would not be inappropriate reductions by basing cost-saving measures and standardization procedures on clinical outcomes and by obtaining an independent, third-party valuation.46

• **Written Disclosure.** The hospital and physicians would make written disclosure of the arrangement to patients before their admission to the hospital. Where impractical prior to admission, the parties would make the disclosure prior to obtaining surgical consent. For example, in a proposed arrangement between a hospital and five cardiology groups, the cost-saving agreement would be disclosed to the patient pre-admission for procedure, and if that was impractical, the disclosure would be made before surgical consent. Thus, the patient was privy to the fact that the cardiology group’s compensation was based on some of the hospital’s savings.47

• **Reasonableness in Amount.** The financial incentives were deemed reasonable in amount and duration. As with a proposed agreement between an acute care hospital and its cardiology group, the inducements were deemed proper because the payment to the group would represent a portion of only the first year’s cost savings and the group would only receive up to 50 percent of the cost savings. Furthermore, the savings payment would be adjusted if any inappropriate reductions in use of items were made beyond the target floor, which was based on historical and clinical measures determined by the program administrator.48 With a performance-based bonus agreement, the incentive bonus amount was also deemed reasonable because it was limited to three years and subject to a maximum annual cap.49

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44 OIG Advisory Opinion No. 05-03.
45 OIG Advisory Opinion No. 05-05.
46 OIG Advisory Opinion No. 12-22.
47 OIG Advisory Opinion No. 05-02.
48 OIG Advisory Opinion No. 05-04.
49 OIG Advisory Opinion No. 12-22.
• **Per Capita Distribution of Profits.** In each case, the contracting physician group agreed to distribute profits from the arrangement on a per capita basis. As a result, no single physician was incentivized by personal productivity to seek excessive remuneration from the program.

The OIG has identified certain features that were not present in the analyzed gainsharing arrangements and that would lead to a risk of program abuse. These features include the following:

- **No Demonstrated Connection.** No demonstrable direct connection between individual actions and any reduction in the hospital’s out-of-pocket costs (and any corresponding “gainsharing” payment);
- **Lack of Specific Requirements.** Failure to identify with specificity the individual actions giving rise to the savings;
- **Insufficient Safeguards.** Insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any “savings”;
- **Dubious Quality Indicators.** Quality-of-care indicators of questionable validity and statistical significance; and
- **Lack of Independent Oversight.** No independent verification of cost savings, quality-of-care indicators, or other essential aspects of the arrangement.

Although the CMP law is an important factor when structuring a commercial bundled payment model with a gainsharing arrangement, it is certainly not an insurmountable obstacle. It is important to remember that the prohibition is triggered when the gainsharing incentive payments are made with respect to care for Medicare or Medicaid fee-for-service beneficiaries. Because providers can limit the beneficiaries participating in the bundled payment arrangement, such coverage can sometimes be a factor for excluding beneficiary participation and designing the bundle. Another approach is to exclude Medicare and Medicaid fee-for-service beneficiaries when calculating the shared savings or other incentive payment that could fall under the CMP law. Specifically, beneficiaries would be included for purposes of care; however, no provider would receive an incentive payment based on such care. On the other hand, if the incentive payments exclude care to Medicare and Medicaid fee-for-service beneficiaries, but the outcome is the same (i.e., their care is similarly affected because providers are not distinguishing care protocols by payor type), the providers run a potential compliance risk that they are indirectly implicating the CMP law. It’s important to note that neither one of these approaches is without some compliance risk, and providers should be sensitive to potential discrimination or other unintended consequences when running care models that specifically exclude Medicare and Medicaid fee-for-service beneficiaries.

Further, it is important to highlight that the CMP law is implicated by incentive payments paid by hospitals to physicians. There could be ways to structure payment arrangements whereby incentive payments are not paid or influenced by the hospital; for example, payments could be made directly by the health plan, avoiding the CMP law issue altogether.
Self-Referral Prohibitions (Federal and State)

As previously discussed, commercial bundled payment programs will need to comply not only with the federal self-referral prohibition (the “Stark law”), but also with state self-referral laws. The Stark law applies to physicians who make referrals for Medicare patients to hospitals or other providers for specific services, where the physician and the recipient of the referral have a “financial relationship” and the law does not provide an exception-permitting arrangement.

The term “financial relationship” includes direct and indirect ownership or investment interests in the recipient of the referral or any compensation arrangement between the recipient of the referral and the physician.\(^50\)

The Stark law is a technical statute that is strictly applied. In other words, parties either comply or they do not—their intent is not considered for enforcement purposes. Because of its breadth and mechanical application, the amount of the potential repayment liability arising out of a Stark law violation is often grossly disproportionate to the conduct that gave rise to the violation.

Penalties for violating the Stark law include denial of payment, repayment of amounts paid in violation of the law, exclusion from the Medicare program, and substantial civil monetary penalties (up to $15,000 per service, $100,000 for each arrangement or scheme intended to circumvent or violate the statute, or $10,000 per day for false reporting or failure to report certain information required under the law).\(^51\) Violation of the Stark law may also provide the basis for liability under the Federal False Claims Act (“FCA”).\(^52\)

Almost all commercial bundled payment programs must be designed to fit under a Stark law exception because all inpatient and outpatient hospital services qualify as “designated health services,” and physicians and hospitals will establish a financial relationship by virtue of participating in the bundled payment arrangement. So, when a physician refers a patient to the hospital, by virtue of the bundled payment program itself, he or she is referring that patient to an entity with which he or she has a financial relationship and the Stark law is implicated.

There are exceptions to the Stark law that permit referrals where the hospital and physician have a financial relationship. Many exceptions require, among other things, that compensation not vary based on the volume or value of referrals or other business generated

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\(^{50}\) Financial Relationship, Compensation, and Ownership or Investment Interest. 42 C.F.R. § 411.354(a), 2012.

\(^{51}\) Limitation on Certain Physician Referrals. 42 U.S.C. § 1395nn(g), 2012.

\(^{52}\) The FCA provides that anyone who “knowingly” submits false claims to the government is liable for damages up to three times the amount of the erroneous payment plus mandatory penalties between $5,500 and $11,000 for each false claim submitted. False Claims. 31 U.S.C. §§ 3729-3733, 2012. At least one court has determined that an alleged violation of the Stark law was actionable under the FCA. United States ex rel. Thompson v. Columbia/HCA Healthcare Corp. 20 F. Supp. 2d 1017, 1020, 1047, Southern District of Texas, 1998. Further, under ACA, providers must report and return all overpayments under Medicare and Medicaid (including amounts received during any “period of disallowance” [i.e., noncompliance]) under the Stark law within 60 days of discovery or risk exposure under the FCA. The Patient Protection and Affordable Care Act. § 6402(d), 2010.
between the parties. This requirement often makes it difficult to make payments based on reductions in the cost of services or the achievement of efficiencies. However, certain arrangements, such as an employment relationship provides more flexibility.

There are several other exceptions to the Stark law that potentially apply in a bundled payment context. These exceptions include those for personal service contracts, arrangements paid at fair market value, referrals of Medicare Advantage and other beneficiaries of prepaid health plans, indirect compensation arrangements, and risk sharing arrangements. It is important to note that in the commercial payor context, the Stark law is implicated and applies to all referrals made by physicians to entities that bill Medicare for certain designated health services if a financial relationship exists between the parties and if the physician also refers Medicare patients to that entity for designated health services in any context.

When considering a commercial-payor bundled payment model, it is also necessary to look at state self-referral statutes. Many states have “all-payor” statutes, meaning they apply to beneficiaries from multiple payor sources, not just Medicare and/or Medicaid beneficiaries. In addition, certain state self-referral laws are implicated by services other than those regulated under the Stark law. For this analysis, it is important to consider whether a favorable exception exists under state law, since some state self-referral prohibitions do not mirror the Stark law.

Anti-Kickback Prohibitions (Federal and State)

Commercial-payor bundled payment programs will need to comply both with the federal anti-kickback statute, and any applicable state anti-kickback statutes as well. The federal anti-kickback law prohibits payments to physicians and others that are intended to induce patient referrals of, or otherwise generate business from, federal payment program beneficiaries. 53

Violations of the statute are punishable as a felony with a maximum fine of $25,000 and five years’ imprisonment. 54 Violation of the federal anti-kickback statute is also grounds for substantial civil monetary penalties and/or exclusion from the Medicare program, and according to ACA, now also provides a basis for liability under the FCA. 55

The OIG promulgated regulations providing for “safe harbors,” which, if complied with, prevent a payment practice from violating the federal anti-kickback statute. 56 Safe harbors most likely to apply to a bundled payment arrangement include employment agreements, 57 personal services agreements, 58 and the safe harbor for discounts. 59 Compliance with a safe harbor generally requires that there be a written agreement, that the arrangement be commercially

54 Criminal Penalties for Acts Involving Federal Health Care Programs. 42 U.S.C. § 1320a-7b(b).
55 Patient Protection and Affordable Care Act. § 6402(f)(1); Criminal Penalties for Acts Involving Federal Health Care Programs. § 1320a-7b(g).
57 42 C.F.R. § 1001.952(i).
58 42 C.F.R. § 1001.952(d).
59 42 C.F.R. § 1001.952(b)(1)(i); 42 C.F.R. § 1001.952(b)(2)(i).
reasonable absent any patient referrals or expectation of business, and that all remuneration exchanged between the parties is fair market value for the goods and/or services received.

Similar to the analysis of the application of the Stark law above, in the commercial-payor bundled payment context, the parties need to be concerned about the federal (and state) anti-kickback statutes because all payments among participants in the bundle, to the extent that the participants refer federal payment program beneficiaries to each other in any context, must be fair market value, and if possible, structured to fit under a safe harbor to the federal anti-kickback statute, lest they be deemed inappropriate inducements for referrals.

Unlike the Stark law, however, the federal anti-kickback statute is focused on the intent of the parties and therefore, strict compliance with the anti-kickback safe harbors is not required. On the one hand, strict compliance with a safe harbor provides comfort that an arrangement does not violate the law. On the other hand, failure to fit within a safe harbor does not mean that an arrangement is illegal. To the contrary, failure to fit within a safe harbor merely means that all facts and circumstances must be reviewed to determine whether the parties had the requisite intent to violate the anti-kickback statute. The parties’ intent to comply with a safe harbor can be relevant to showing that they did not intend to violate the law. For example, if all of the compensation relationships within a bundled payment program comply with the criteria for the personal services safe harbor except some of the payments have a variable aspect and are not fixed in advance, regulators would take this into account in looking at the parties’ motivations and determining intent. Thus, the entities involved in a bundled payment program can reduce compliance risk by adopting as many of the safe harbor provisions as possible.

When considering a commercial-payor bundled payment model, it is also necessary to look at state anti-kickback statutes. Many states have their own anti-kickback statutes applicable to beneficiaries from multiple payor sources, not just federal payment program beneficiaries. With respect to state anti-kickback statutes, similar to the federal prohibition, the typical focus is on the fair market value of the compensation. When implementing the commercial-payor bundled payment model, it is necessary to structure the financial relationships in a way that complies with state law. For this analysis, it is important to consider whether a favorable exception or safe harbor exists under state law and to watch out for elements of state law that do not mirror the federal prohibition. As a general rule, it is critical that all payments within the bundle are fair market value for the goods and services received.

**Tax Issues—Private Benefit (Federal)**

When considering a commercial bundled payment model, it is important to understand possible tax implications as well. Specifically, nonprofit entities need to be conscious of any payments to for-profit entities. Nonprofit organizations are exempt from paying federal income tax if they comply with certain requirements, including: (1) that they are “organized and operated exclusively” for religious, educational, or charitable purposes; and (2) that “no part of the
[organization’s] net income . . . inures to the benefit of any private shareholder or individual.\textsuperscript{60} This means that similar to the analysis for anti-kickback, the nonprofit entity may not provide the for-profit entity a benefit that is in excess of the for-profit’s contribution of goods and/or services.

\textit{Corporate Practice of Medicine (State)}

The corporate practice of medicine doctrine generally prohibits lay entities (i.e., entities that are not owned by physicians) from providing professional medical services. The doctrine also prohibits lay entities and often licensed facilities from employing a physician to provide medical services absent specific authorization. This state law doctrine may impact the organizational and contractual structures of a commercial bundled payment model because, typically, there is one entity that accepts payment from the health plan and allocates it to all of the participating providers. Depending on the particular corporate practice prohibitions in the state, a hospital, for example, may not be permitted to accept payment for physician services. Typically, parties can address this concern by making clear in the payor agreement that the “hub provider” is accepting payment on behalf of itself for certain services and as a billing agent of the physician entities for others. Some plans may require two separate contracts that cross-reference each other (i.e., one with the institutional providers and one with the physician providers) or specifically designate a bifurcated payment amount in a single contract; however, many plans have not required that level of financial transparency among provider participants, and arguably it is not required to comply with corporate practice prohibitions. Additionally, even with a bifurcated contract or payment mechanism, the provider participants may reallocate dollars and risk within the bundle, through gainsharing or other forms of risk-sharing agreements. This is illustrated in Figure 8 below.

\textsuperscript{60} Exemption from Tax on Corporations, Certain Trusts, etc. 26 U.S.C. § 501(c)(3), 2012.
Fee Splitting (State)

In general, state fee-splitting laws prohibit physicians from splitting fees for professional services with any non-physician. Violations of state fee-splitting laws can lead to the revocation or suspension of a physician’s medical license. Each state defines fee-splitting differently. Some states prohibit engaging in fee-splitting arrangements regardless of the form, while others prohibit fee-splitting among certain types of providers, such as physical therapists and physicians, or physicians and laboratories. Certain states have non-statutory fee-splitting prohibitions articulated in medical board advisories or position statements. Depending on the state, fee-splitting laws may restrict the structure of a commercial bundled payment model. In these instances, it would be necessary to structure the arrangement so that one entity is not collecting professional-service fees on behalf of another in violation of the state’s fee-splitting prohibition.

In a bundled payment arrangement, again, this could be accomplished by having the payor pay both the physicians and the hospital directly, similar to the solution to the corporate practice prohibition in Figure 8, or explicitly state in the payor contract with the “hub provider”
that the hub provider is acting both as a provider of services and as a billing and collections agent on behalf of the other provider participants in the bundle.

*Insurance Laws (State)*

The interplay between commercial-payor bundled payment models and state insurance laws is constantly evolving. Since a bundled payment program can, and often does, shift financial risk to the providers, it is possible that provider organizations assuming financial risk under the bundled payment model will be regulated as health insurers or “risk-bearing organizations,” or that the financial risk will trigger reporting or other requirements. Another concern is whether providers participating in the bundle are deemed to assume financial risk for services they do not directly provide. Many states regulate providers’ ability to do so. Finally, it is important to consider, particularly in a commercial-payor bundle, that commercial plans are regulated by state agencies, and typically, those agencies will require some level of review and approval of the bundled payment program and/or proposed agreements entered into by the health plans. For agencies, bundled payment arrangements are considered new, and parties should factor in time to work with the applicable state authority to obtain approvals and address concerns. Parties should also expect that state agencies may want specific requirements built into agreements or the overall payment model, and therefore should remain flexible when negotiating the bundle and the documents, as state regulators’ requirements are not always foreseeable.

*Special Rules for Self-Insured Employees*

When an employer-sponsored benefit plan is at issue, application of the Employee Retirement Income Security Act (“ERISA”) may change the state and federal law analysis. First, state insurance laws that might otherwise place restrictions on a bundled product will often have

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61 For example, in California, a professional medical corporation, other forms of corporations controlled by physicians and surgeons, a medical partnership, certain medical foundations exempt from licensure, or another lawfully organized group of physicians that delivers, furnishes, or otherwise arranges for or provides health care services may be deemed a risk-based organization (“RBO”) if it:

1. Contracts directly with a health care service plan or arranges for health care services for the health care service plan’s enrollees;
2. Receives compensation for those services on any capitated or fixed periodic payment basis; and
3. Is responsible for the processing and payment of claims made by providers for services rendered by those providers on behalf of a health care service plan that are covered under the capitation or fixed periodic payment made by the plan to the organization. California Health and Safety Code Section 1375.4 and 1375.5. 28 CCR § 1300.75.4.

Entities that qualify as RBOs under this definition in California or corollary definitions in other states are generally subject to specific licensing or certification and reporting requirements. For example, among other requirements, California mandates that entities submit specific quarterly and annual financial reports, maintain a minimum cash-to-claims ratio, and submit a corrective action plan should the RBOs not meet specified requirements. Ibid. The state of Massachusetts, which similarly defines and regulates RBOs, requires RBOs to apply for a risk certificate with its Division of Insurance. Massachusetts General Laws Annotated Code, Ch. 176T. A Massachusetts RBO may renew its certificate every year by submitting required annual filings, including financial statements, a financial plan, a utilization plan, an actuarial certification, and other information that the Division may request. Ibid. Thus, when assessing the compliance issues of a bundled payment arrangement, it is critical to determine whether the program triggers its respective state’s health insurers, RBO, or other potentially applicable statutes or regulations for entities that assume this type of financial risk. Atchinson BK. *The Regulation of Risk-Bearing Entities.* Washington: American Health Law Association, 1996; Brewster LR, Jackson LA and Lesser CS. *Insolvency & Challenges of Regulating Providers that Bear Risk.* Washington: Center for Studying Health System Change, 2000, www.hschange.com/CONTENT/56/ (accessed August 2013).
carve-outs for self-funded ERISA plans because of ERISA’s broad preemption of state laws. Second, if ERISA plan assets are used to pay for bundled products, ERISA’s fiduciary rules may come into play. So, self-funded plans must consider two issues: whether they are exempt from certain restrictions under state insurance laws (which they may be), and whether they have any additional responsibility to structure any discounts/rebates in premiums or other payments due to the reduced costs of services in a trust or other fiduciary arrangement pursuant to ERISA.

Section IV: Commercial Bundled Payment Program Creation

To better illustrate the design of a bundled payment program, and specifically, variations of the episode of care and contracting, we have outlined two examples below, as follows: (1) where providers and a payor collaborate on a bundled payment arrangement and (2) where providers design the bundle and offer it to payors.

Provider-Payor Collaboration—“XYZ” Health Plan and “Community Hospital”

Community Hospital is a regional, independent, not-for-profit health system that is located in a suburban area of the East Coast. Community Hospital wanted to cut costs while it increased the quality of patient care and improved the health of the population. It had plans to develop an accountable care organization (ACO). In conjunction with this initiative, Community Hospital sought to collaborate with one of the major commercial payors in its service area, XYZ Health Plan. XYZ Health Plan is one of the state’s largest health insurers and has processed over $20 billion worth of claims annually.62 XYZ Health Plan’s provider network covers 90 percent of the physicians and 100 percent of the hospitals in the state. Community Hospital and XYZ Health Plan formed a collaborative bundled payment agreement with the objective to identify new ways to cut costs and improve care for patients that needed a total knee replacement. Two other entities, the surgeons (Community Orthopedic Group) and the anesthesiologists (Community Anesthesia Associates) participated in the bundled payment arrangement, each having separate agreements directly with XYZ Health Plan, to allocate the bundled payment.

Forming the Bundle

In its work with XYZ Health Plan, Community Hospital applied a systematic process to analyze five different inpatient procedural episodes with the intent of selecting one that they could bundle. XYZ Health Plan evaluated the episode’s complication rates, provider-level costs, and quality, among other factors. The parameters of the analysis included: surgical activity occurring between April 2009 and March 2010; patient ages 18 to 64; 30-day allowable gap in coverage; and exclusion of Medicare cases and bilateral knee replacements.

Community Hospital and XYZ Health Plan agreed that total knee replacement (TKR) was best suited for the bundling pilot because its complication rate was near the national average,

62 Bundled Payment Case Study. Newtown, Conn.: Health Care Incentives Improvement Institute, 2010.
and the episode had an opportunity for cost savings and quality improvements. Moreover, Community Hospital believed physicians would be more willing to participate and take risks with the TKR episode. XYZ Health Plan and the three provider organizations agreed that the bundled payment for TKR would include pre-op tests, office visits, services during the inpatient stay (including physical therapy and care-related complications), and all outpatient services within a certain time frame. XYZ Health Plan’s review of the allowable historical claims revealed that Community Hospital was responsible for 86 percent of the episode’s costs; the Orthopedic Group was responsible for 10 percent of the episode’s costs; and the Anesthesia Group contributed the remaining 4 percent of the episode costs. 63

Creating the Agreement

Once TKR was selected as the episode, achieving physician buy-in was important in order to form the agreement. XYZ Health Plan leveraged its existing relationships and contracts with providers to inform them of the bundling pilot. The participating groups had to decide on an episodic price formula where all participants clearly understood and accepted the financial implications. This episodic price was determined on the basis of the historical costs plus 50 percent of observed complications, a formula that gave a set price for each patient instead of a severity-adjusted price. 64

Next, XYZ Health Plan and the three provider organizations agreed that the method for dividing the gains should not depend on the distribution of current costs among the organizations. Instead, the sharing of gains from each bundle procedure should be correlated to the provider’s influence on the resulting costs. Once all parties were satisfied with the TKR bundle agreement, XYZ Health Plan amended its current contracts with each of the three participating providers. This amendment defined the scope of the bundle, budget accountabilities among the providers, gainsharing, and the period of reconciliation and adjudication of the variances to the budgeted episodes.

From a legal perspective, because the health plan contracted directly with each of the participants for the bundle, many regulatory issues were avoided. As described above, since the gainsharing payments were made directly by XYZ Health Plan, CMP was not a concern, and similarly self-referral and anti-kickback issues were more easily resolvable since the hospital and physicians did not have a direct financial relationship created by the bundle. Further, each provider participant was responsible for its own financial risk directly with the health plan. This limited potential insurance regulation of the providers and obviated any corporate practice of medicine issues.

On the other hand, not every health plan is willing to structure its contracts this way—either because there are too many provider participants or the logistics are otherwise not feasible. Further, not all providers are interested in collaborating with health plans to this extent and

63 ibid.
64 ibid.
engage in this level of pricing transparency. Notwithstanding, a high degree of collaboration between a payor and the providers, and in particular, driving payments directly from the payor, often takes many of the more challenging compliance issues off the table.

Lessons Learned

Three factors were important to the success of the bundling arrangement between Community Hospital and XYZ Health Plan. First, both parties committed to finding ways to reduce costs and improve the quality of care. As a result, both were proponents of care redesign specific to the TKR episode. Together, they sought to cut costs by reducing fragmentation and allowing providers to be compensated for creating efficiencies in the system and supporting better patient outcomes. Second, the leadership of Community Hospital and the physician leaders of the Orthopedic Group and the Anesthesia Group worked collaboratively to agree on the adaption of protocols and best practices enabling clinical integration. This resulted in enhanced care coordination, better clinical outcomes, and reduced costs. Finally, the bundling pilot was viewed as an essential step in Community Hospital becoming an ACO, as well as a valuable investment for the XYZ Health Plan in achieving its goals.

Providers Reaching Out to Multiple Payors - “Hospital A”

As a nationally recognized leader in musculoskeletal (“MSK”) services, performing more than 10,000 orthopedic procedures annually, “Hospital A” was very clear from the outset in its goals with respect to bundled payment. It was committed to building on its position as an expert in the field of orthopedic and musculoskeletal care. It also aimed to develop an array of bundled payment products that could be offered to commercial payers, Medicare, ACOs, and other organizations taking population-based risk. Hospital A believed it needed a solid strategy and consistent approach to conversations with payors to ensure it was recognized for the value it could provide. Hospital A’s leadership team was focused on optimizing political, market, and strategic considerations, and the hospital’s participating physicians supported these goals. In furtherance of these goals, Hospital A redefined its mission as follows,

In partnership with our physicians we will deliver on the promise to provide patients with the highest-quality orthopedic and musculoskeletal care, distinguished by exceptional outcomes and a superlative patient experience, all delivered at a reasonable price.

Hospital A established aggressive goals and a timeline, and its initial efforts began in March 2012 with the formation of a Bundled Payment Steering Committee to spearhead the development of a risk-adjusted bundled payment product. Hospital A approached the major payors in its market with a proposal, and three out of four of the payors contracted with Hospital A under a bundled payment reimbursement system starting June 1, 2013.

Hospital A profiled the payors in its market based on the strength of their existing relationship, the number of enrollees by payor, and the perceived “fit” with Hospital A as a long-
term strategic partner. When Hospital A met with payors, it focused on the unique value proposition Hospital A could provide to each payor. Consistently, payors were interested in Hospital A’s ability to deliver the highest quality, manage costs related to readmission and post-acute services, and manage to a mutually-agreed-upon “price” for the pre-defined scope of services.

Hospital A created a jointly-owned physician-hospital organization (PHO) with the participating physicians to act as the “hub” and contract with the payors for the bundled payments. The individual provider participants (i.e., Hospital A and the physicians) maintain independent contracts with the payors; however, the services subject to bundled payment are carved out and paid through the contract with the PHO. The PHO then allocates the bundled payment to each of the participating providers. This organizational structure is illustrated below.

**Figure 9: Hospital A Bundled Payment Organizational Structure**

Membership of the Bundled Payment Steering Committee is comprised of selected members of the PHO Board, PHO Contract Committee, Hospital A’s President’s Council, and important physician advisors. A recommended final model and approach to commercial bundling was prepared by the Steering Committee and approved by the PHO Board.

The primary legal issues facing Hospital A, as a tax-exempt entity, were the tax-exemption issues in establishing the PHO and creating the governance structure. Hospital A also had to look at the tax impact of running the bundled reimbursement through the PHO, rather than directly to the hospital. Further, Hospital A had challenges in deciding not to be inclusive in
forming the PHO; instead of making the opportunity available to all medical staff, Hospital A narrowed it to only those providers who historically provided high-quality care and were efficient with resources. With respect to compliance issues, all payment flowing into the PHO and distribution of revenues had to be analyzed under CMP, self-referral prohibitions (the Stark law) and anti-kickback statutes; however, much of the risk was mitigated by screening eligible patients for participation in the bundle and ensuring that such patients did not have Medicare or Medicaid secondary coverage. Further, the PHO had to ensure that it did not run afoul of any state insurance regulations since it was taking both institutional and professional risk. Finally, Hospital A was not located in a state with corporate practice of medicine prohibitions, which alleviated any concern with the organizational structure under such prohibitions.

Conclusion

As you design your commercial bundled payment program, it is important to keep in mind the laws and regulations discussed above as they present challenges in creating and implementing a compliant program. For further guidance, and as an example only, sample contract provisions are attached as Exhibits A–E.65

The key to successfully navigating the various legal issues involved in structuring a commercial bundled payment program is to engage competent legal counsel early in the process, as legal requirements will influence the program’s construction. Although this document provides an analysis of the potential legal issues that organizations may encounter in designing a bundled payment program, this paper is not meant to be legal advice and it is not meant to be an exhaustive discussion of all of the potential legal issues that pertain to an individual organization. Organizations should seek advice of counsel to fully analyze the issues as they apply to their specific bundled payment program and to ensure compliance with applicable federal and state laws.

65 Note that the attached samples were previously created as part of a California commercial bundled payment pilot program sponsored and initiated by the Integrated Healthcare Association (www.iha.org). The authors would like to thank IHA for its generosity in making such materials available for purposes of this paper.
Exhibit A: Episode of Care/Patient Qualification

The following is a general framework for constructing contract terms to identify/define the episode of care and patient qualifications for participation:

1. Episodes

   (a) Hospital receives a bundled payment with respect to the following DRG bundles:

<table>
<thead>
<tr>
<th>DRG</th>
<th>MS-DRG</th>
<th>[enter description]</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRG</td>
<td>MS-DRG</td>
<td>[enter description]</td>
</tr>
<tr>
<td>DRG</td>
<td>MS-DRG</td>
<td>[enter description]</td>
</tr>
</tbody>
</table>

   The above DRG bundles include the following services:
   - inpatient stay and associated care;
   - professional fees for surgeons and assistants, cardiologists, cardiac rehab, anesthesiologists, and radiologists;
   - consultations related to the patient’s cause for admission; and
   - all related post-procedure services for thirty (30) days after discharge.

   (b) Hospital specifically excludes from the bundled payment in (1) above the following DRG and diagnostic codes:

<table>
<thead>
<tr>
<th>DRG</th>
<th>MS-DRG</th>
<th>[enter description]</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRG</td>
<td>MS-DRG</td>
<td>[enter description]</td>
</tr>
<tr>
<td>DRG</td>
<td>MS-DRG</td>
<td>[enter description]</td>
</tr>
<tr>
<td>DRG</td>
<td>MS-DRG</td>
<td>[enter description]</td>
</tr>
</tbody>
</table>

2. Patient Qualification

   (a) For inclusion in the Program, the member must:
   - Be covered by [Plan] on the date of surgery and for the duration of the episode.
   - Be over the age of [x] and under the age of [x].
   - Have a BMI less than or equal to [x].
   - Be treated at [Hospital].

   (b) Patients are excluded from the Program when:
   - Patient requests a custom implant.
   - Patient is transferred at any time during initial hospital stay to another acute care facility for further intervention.
• Patient is readmitted to the Hospital, not directly associated with the primary surgery.
• Patient’s primary coverage with [Plan] ends at any time during the episode.
• Patient’s BMI is greater than [x].
• Patient’s age is greater than [x], less than [y].
• Patient is pregnant.
**Exhibit B: Incentive Payment**

The following is a general framework for constructing contract terms to describe incentive payments:

Hospital and Physicians agree that there shall be a performance-based incentive system for Physicians. Such system shall be created by Hospital in the form of an incentive pool, which shall be funded by carving out fifteen percent (15%) of the bundled payment received by Hospital from Health Plan (the “Incentive Pool”).

The Incentive Pool shall be comprised of three (3) pools, each of which has specific targets (“Incentive Criteria”) that trigger all or a portion of potential payout. If any funds remain in the Incentive Pool at the end of an Incentive Period due to Physicians either collectively or individually not meeting Incentive Criteria, the unused portion of the Incentive Pool shall be retained by Hospital.

For purposes of this Section, “Incentive Period” is defined as [three month period]. On a [quarterly] basis during the term of this Agreement, Hospital shall review Physicians’ performance in light of the Incentive Criteria and pay to Physicians such monies contained in the Incentive Pool, as earned in accordance with the Incentive Criteria below.

The Incentive Pool shall be comprised of the following Incentive Criteria:

**Cost Pool (50%)**

Based on individual physician case-mix-adjusted performance against historical baseline average hospital costs by DRG. Cost pool incentives are not awarded if any of the clinical outcome targets are not met. Specific clinical targets shall be: [define]

**Quality (30%)**

Based on collective performance against national benchmarks for specific outcome measures of mortality/morbidity and clinical process measures. All outcome measures must be met in order for any of the outcome incentive pool funds to be distributed. The outcome measures are as follows:

- **Outcome measures (15%)**
  [Define, e.g., mortality rates, rates of certain diseases or complications, etc.]

- **Process measures (15%)**
  [Define specific desired clinical pathways related to condition]
Satisfaction (20%)

Based on collective performance for both patient and provider satisfaction

Patient satisfaction (10%)
[Define, e.g., overall rating of care, physician concern, physician skill, etc.]

Physician satisfaction (5%)
[Define, e.g., hospital has quality staff, staff is responsive to requests, hospital is a great place to practice, etc.]

Hospital satisfaction (5%)
[Define, e.g., hospital has quality staff, staff is responsive to requests, etc.]
Exhibit C: Sample PPO Contract Amendment for Bundled Payment

THIS BUNDLED PAYMENT ADDENDUM (this “Addendum”) is made and entered into by and between _____________________________________, a __________________ (“Provider”) and ________________________________, a ______________________________________ (“Plan”), as of ____________, 20__. (Provider and Plan are referred to herein individually as a “Party” and collectively as the “Parties”).

This Addendum sets forth the terms and conditions under which Provider will participate in the bundled payment demonstration program sponsored by ____________________ and supported by Plan (“Bundled Payment Program”). Pursuant to the Bundled Payment Program, Provider has contracted with other providers to accept one case rate from Plan for specified services, which include both hospital and post-acute services.

This Addendum effective date (“Bundled Payment Addendum Effective Date”) is listed below and binds this Addendum to the Parties’ [PPO Agreement] dated _____________ (the “Agreement”). This Addendum shall have a term coterminous with Agreement.

Bundled Payment Addendum Effective Date:
________________________________________.

A. Introduction

The intent of the Parties is that the negotiated bundled episode payment should include all Covered Services provided to a Covered Person during the Episode Period for:

1. An Index Procedure of total knee or total hip replacement for patient with degenerative osteoarthritis;

2. Routine Care appropriate to the Index Procedure; and

3. Patient Complications arising during the stay for Index Procedure or during the Episode Warranty Period following the surgery, Included Readmissions and Revision Procedures performed during the Episode Period because of complications associated with the original procedure or for mechanical failure.

Provider and Plan may mutually agree to include an optional rehabilitation package for an additional negotiated fee.

B. Definitions

1. Covered Services. The following services are included in the episode definition and negotiated episode payment. They may not be separately billed by Provider when treating a Covered Person during the Episode Period.
• During the Episode Period, and for any included Readmission, Covered Services include:
  o All physicians, anesthesiologists, other attending and consulting physicians, and all professional technical and ancillary services;
  o Preoperative visits after the decision is made to operate beginning with the day of surgery;
  o Intra-operative services that are normally a usual and necessary part of a surgical procedure;
  o All additional medical or surgical services required of the surgeon during the postoperative period of the surgery because of complications which do not require additional trips to the operating room;
  o Follow-up visits during the postoperative period of the surgery that are related to recovery from the surgery;
  o Postsurgical pain management by the surgeon;
  o Supplies, except for those identified as exclusions;
  o Miscellaneous Services (items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal tubes; and changes and removal of tracheostomy tubes);
  o All other medically necessary services and supplies;
  o All inpatient and outpatient professional services;
  o All services provided by Provider or its contracting providers under the Bundled Payment Program.

• During the Episode Warranty Period (including Readmission), Covered Services include:
  o All Covered Services above: outpatient institutional and professional follow-up care, consultations, and related services, including but not limited to medical care, or similar services; and
  o All other related episode covered services will be included unless they are clearly caused by injury or disease other than the underlying disease for which the Index

This exhibit is not a legal form, and is provided by the Integrated Healthcare Association for purposes of example only.
Procedure is being undertaken. For example, injuries due to an automobile accident or disease unrelated to the diagnosis of degenerative osteoarthritis (for example, primary care or specialist visits for a dermatologic condition).

- Covered Services do NOT include the following:
  - The initial consultation or evaluation of the problem by the surgeon to determine the need for surgery;
  - Outpatient prescription drugs;
  - Professional charges for treatment in a skilled nursing facility;
  - Outpatient services clearly unrelated to the Index Procedure or underlying condition, for example, pregnancy or, for osteoarthritis treatment, surgical evaluation and planning for a procedure on a different joint than the one on which the Index Procedure was performed (knee replacement on the other leg); and
  - Inpatient services not provided during the admission for the Index Procedure or an Included Readmission (for example, admission for an appendectomy).

2. **Episode Period**:

- The Episode Period begins on the date of admission for the Index Procedure and continues to the 90th day following the date of the original admission.

- Readmissions (as defined) that begin within the Episode Period are included in the episode price (and may not be separately billed), even if the period of readmission extends beyond 90 days following the date of the original admission. For example, if a patient were readmitted for a surgical site infection on the 89th day of the Episode Period, the Episode Period would be extended until that patient is discharged.

- Covered Persons who elect to have a second Index Procedure (i.e., total knee replacement on the other knee) during the first Episode Period, begin a new 90-day Episode Period on the date of admission for the second surgery.

- For purposes of determining Covered Services, the Episode Period is divided into:
  - The *acute period*, which begins on the date of admission to the Provider or its partner hospital under the Bundled Payment Program for the Index Procedure and continues to the date of discharge from the Provider or its partner hospital for the Index Procedure;
The warranty period, which begins on the date of discharge from the Provider or its partner hospital for the Index Procedure and continues through the 90th day following date of admission for the Index Procedure; and

The rehabilitation period, which only applies to participants contracting for the optional rehabilitation package and begins on the date of discharge for the Index Procedure and continues through the 21st day following discharge for the Index Procedure.

3. Readmissions. For purposes of the Bundled Payment Program, a Readmission is defined to mean any subsequent admission to an acute care facility that occurs within the Episode Period. However, whether a Readmission is included in the contracted episode rate (and thus may not be separately billed) depends on: a) the facility where the patient is readmitted, and b) whether the readmission is considered to have been caused by or related to the Index Procedure (according to rules below).

- The Provider agrees that Covered Persons will be readmitted to the applicable hospital (i.e., the hospital participating under the Bundled Payment Program (the “Participating Hospital”)) except when: the Covered Person requires emergency admission to a closer facility, the Covered Person requires care that cannot be provided at the Participating Hospital, or the Covered Person refuses to be readmitted to the Participating Hospital.

- A readmission at the Participating Hospital is assumed to be related to the Index Procedure and is included in the episode price (may not be separately billed) if the readmission groups to one of the defined set of DRGs below.

Defined DRGs for Index Procedure of Total Knee Replacement

- 175, 176—Pulmonary embolism
- 294, 295—Deep vein thrombophlebitis
- 463, 464, 465—Wound debrid & skin grft, exc hand, for musculo-conn tiss dis
- 466, 467, 468—Revision of hip or knee replacement
- 485, 486, 487, 488, 489—Knee Procedures with and without pdx of Infection
- 539, 540, 541—Osteomyelitis
- 553, 554—Bone diseases & arthropathies
- 555, 556—Signs & symptoms of musculoskeletal system & conn tissue
- 559, 560, 561—Aftercare, musculoskeletal system & connective tissue
- 564, 565, 566—Other musculoskeletal sys & connective tissues diagnoses
- 602, 603—Cellulitis
- 856, 857, 858, 862, 863—Post-operative or post-traumatic infections
- 870, 871, 872—Septicemia or severe sepsis (note: these DRGs are included only if septicemia is related to a septic joint or central line infection)
- 901, 902, 903—Wound debridements for injuries
- 919, 920, 921—Complications of treatment

This exhibit is not a legal form, and is provided by the Integrated Healthcare Association for purposes of example only.
939, 940, 941—O.R. procedure with diagnosis of other contact w health services

Defined DRGs for Index Procedure of Total Hip Replacement

- 175, 176—Pulmonary embolism
- 294, 295—Deep vein thrombophlebitis
- 463, 464, 465—Wnd debrid & skn grft, exc hand, for musculo-conn tiss dis
- 466, 467, 468—Revision of hip or knee replacement
- 480, 481, 482—Hip & Femur procedures except major joint
- 533, 534—Fractures of Femur
- 535, 536—Fractures hip and pelvis
- 537, 538—Sprains, strains, dislocation hip, pelvis, thigh
- 539, 540, 541—Osteomyelitis
- 553, 554—Bone diseases & arthropathies
- 555, 556—Signs & symptoms of musculoskeletal system & conn tissue
- 559, 560, 561—Aftercare, musculoskeletal system & connective tissue
- 564, 565, 566—Other musculoskeletal sys & connective tissues diagnoses
- 602, 603—Cellulitis
- 856, 857, 858, 862, 863—Post-operative or post-traumatic infections
- 870, 871, 872—Septicemia or severe sepsis (note: these DRGs are included only if septicemia is related to a septic joint or central line infection)
- 901, 902, 903—Wound debridements for injuries
- 919, 920, 921—Complications of treatment
- 939, 940, 941—O.R. procedure with diagnosis of other contact w health services

4. **Index procedures.** The tables below outline the primary procedure codes (i.e., are in the primary position on the billing code) that will trigger the provisions of this Addendum. Revision procedures other than those occurring within 90-days of an Index Procedure for a Covered Person participating in this Program are also excluded.
### Definition of Total Knee Replacement Index Procedure

<table>
<thead>
<tr>
<th>Index Procedure Code:</th>
<th>DRG:</th>
<th>Diagnosis Exclusions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>This procedure must exist to trigger the episode.</td>
<td>Episode must map to one of these DRGs.</td>
<td>Diagnosis (any position) must NOT equal one of the following:</td>
</tr>
<tr>
<td>CPT:</td>
<td></td>
<td>714.0x—Rheumatoid Arthritis</td>
</tr>
<tr>
<td>27447—Arthroplasty, knee condyle and plateau, medical and lateral compartments</td>
<td>MS DRG 470 Major Joint Replacement or Reattachment of Lower Extremity without MCC</td>
<td>736.89—Other acquired deformities, lower limb</td>
</tr>
<tr>
<td>ICD-9 Px:</td>
<td></td>
<td>170.7—Malignant neoplasm of long bones of lower limb</td>
</tr>
<tr>
<td>81.54—Total Knee replacement</td>
<td>AND</td>
<td>171.3—Malignant neoplasm of soft tissue, lower limb, hip</td>
</tr>
<tr>
<td></td>
<td>APR DRG SOI of 1 or 2</td>
<td>198.5—Secondary malignant neoplasm of bone, marrow</td>
</tr>
<tr>
<td></td>
<td></td>
<td>822, 823, 827, 828. 836, 891—Fractures, dislocations and open wounds</td>
</tr>
<tr>
<td></td>
<td></td>
<td>928—Crushing injury</td>
</tr>
</tbody>
</table>

### Definition of Total Hip Replacement Index Procedure

<table>
<thead>
<tr>
<th>Index Procedure Code:</th>
<th>DRG:</th>
<th>Diagnosis Exclusions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>This procedure must exist to trigger the episode.</td>
<td>Episode must map to one of these DRGs.</td>
<td>Diagnosis (any position) must NOT equal one of the following:</td>
</tr>
<tr>
<td>CPT:</td>
<td></td>
<td>714.0x—Rheumatoid Arthritis</td>
</tr>
<tr>
<td>27130—Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft, or</td>
<td>MS DRG 470 Major Joint Replacement or Reattachment of Lower Extremity without MCC</td>
<td>736.89—Other acquired deformities, lower limb</td>
</tr>
<tr>
<td>27125—Hemiarthroplasty, hip, partial (e.g., femoral stem prosthesis, bipolar arthroplasty) (when performed for reasons other than fracture)</td>
<td>AND</td>
<td>170.7—Malignant neoplasm of long bones of lower limb</td>
</tr>
<tr>
<td>ICD-9 Px:</td>
<td>APR DRG SOI of 1 or 2</td>
<td>171.3—Malignant neoplasm of soft tissue, lower limb, hip</td>
</tr>
<tr>
<td>81.51—Total hip replacement</td>
<td></td>
<td>198.5—Secondary malignant neoplasm of bone, marrow</td>
</tr>
<tr>
<td>81.52—Partial hip replacement (when performed for reasons other than fracture)</td>
<td></td>
<td>822, 823, 827, 828. 836, 891—Fractures, dislocations and open wounds</td>
</tr>
<tr>
<td>00.85—Resurfacing hip, total, acetabulum and femoral head</td>
<td></td>
<td>928—Crushing injury</td>
</tr>
<tr>
<td>00.86—Resurfacing hip, partial, femoral head</td>
<td></td>
<td>928—Crushing injury</td>
</tr>
</tbody>
</table>

*This exhibit is not a legal form, and is provided by the Integrated Healthcare Association for purposes of example only.*
5. **Optional rehabilitation package.** If the Parties agree, the episode may include an optional package of rehabilitation services that will be provided during the rehabilitation period (defined above under *Episode Period*). This package will include:

- Initial evaluation by a physical therapist, including development of a recommended physical therapy plan;
- All physical therapy visits provided during the rehabilitation period;
- Evaluation by a home health aide or occupational therapist of the Covered Person’s physical environment and need for durable medical equipment; and
- All home health visits and/or blood draws to calculate the international normalized ratio (INR) for Covered Persons receiving anti-coagulant therapy provided during the rehabilitation period.

6. **Covered Person.** For inclusion in the Bundled Payment Program, a patient must be:

- Undergoing surgery provided by an orthopedic surgeon contracting directly or indirectly with the Plan to provide services under the Bundled Payment Program;
- Admitted to the Participating Hospital under the Bundled Payment Program to provide specified services under the Participating Hospital’s applicable payor agreement;
- Presenting for the Index Procedure with an American Society of Anesthesiologists (ASA) rating of <3 (and post-discharge assignment to APR-DRG SOI level of 1 or 2);
- Presenting for the Index Procedure without:
  - Clinical history that demonstrates a clinical condition of active cancer, HIV/AIDS, or End-Stage Renal Disease
  - Body Mass Index (BMI) of 40 or greater;
- Over age 18 and under age 65 on the date of surgery; and
- Covered (as primary plan) by a participating employer and health plan on date of surgery.

7. **Patient complications.** All Covered Services provided to treat patient complications that arise during the Episode Period are included in the negotiated episode rate, and may not be separately billed through the end of the Episode Period. Examples of complications include patients with infections, wound issues, or cellulitis. Service examples include joint injection,
pain management, X-Ray or MRI, dislocation, incision and drainage of hip joint, or removal of hip prosthesis. (All outpatient services after the end of the Episode Period will be excluded from Covered Services; e.g., treatment for infections that continues for 12 months. However, all costs of an included readmission that begins within the Episode Period even if the readmission extends beyond the 90-day window will be included as a Covered Service.)

8. Revision Procedures. Revision procedures are included in the episode payment only if performed within the 90-day Episode Period as a result of patient complications or device failure.

### Revision Procedures for Knee Replacement

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>DRG: Admission must map to one of these DRGs.</th>
<th>Included Diagnoses:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>▪ All</td>
</tr>
<tr>
<td><strong>CPT:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27486 — Revision joint total knee arthroplasty with or without allograft 1 component</td>
<td>MS DRGs 466 — Revision of hip or knee replacement with MCC</td>
<td></td>
</tr>
<tr>
<td>27487 — Revision joint total knee arthroplasty fem and entire tibl component</td>
<td>467 — Revision of hip or knee replacement with CC</td>
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<td>APR SOI limitation does not apply if patient was included in the pilot for the Index Procedure.</td>
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<tr>
<td><strong>ICD-9 Px:</strong></td>
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<tr>
<td>00.80 — Revision of knee repl, total (all components)</td>
<td>468 — Revision of hip or knee replacement without CC/MCC</td>
<td></td>
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<tr>
<td>00.81 — Revision of knee repl, tibial component</td>
<td></td>
<td></td>
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<tr>
<td>00.82 — Revision of knee repl, femoral component 00.83 — Revision of knee replacement, patellar component</td>
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<tr>
<td>00.84 — Revision of knee replacement, tibial insert (linear)</td>
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<tr>
<td>81.55 — Revision of knee replacement, NOS</td>
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### Revision Procedures for Hip Replacement

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>DRG: Admission must map to one of these DRGs.</th>
<th>Included Diagnoses:</th>
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<tbody>
<tr>
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<td>▪ All</td>
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<tr>
<td><strong>CPT:</strong></td>
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<tr>
<td>27134 — Revision of total hip arthroplasty; both components, with or without autograft or allograft</td>
<td>MS DRGs 466 — Revision of hip or knee replacement with MCC</td>
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</tr>
<tr>
<td>27137 — Revision total hip</td>
<td>467 — Revision of hip or knee replacement with CC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>468 — Revision of hip or knee replacement</td>
<td></td>
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<td>NOS</td>
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</table>

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arthroplasty, acetabular component only, with or without autograft or allograft

- 27138—Revision total hip arthroplasty, femoral component only, with or without autograft or allograft

ICD-9 Px:
- 00.70—Revision of hip repl, both acetabular and femoral components
- 00.71—Revision of hip repl, acetabular component
- 00.72—Revision of hip repl, femoral component
- 00.73—Revision of hip replacement, acetabular liner and/or femoral head only
- 00.87—Resurfacing hip, partial, acetabulum

<table>
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<tr>
<th>replacement without CC/MCC</th>
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<tbody>
<tr>
<td>APR SOI limitation does not apply if patient was included in the pilot for the Index Procedure.</td>
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</table>

9. **Routine care appropriate to the Index Procedure.** This includes:

- Preoperative Visits—Preoperative visits after the decision is made to operate beginning with the day before the day of surgery for major procedures and the day of surgery for minor procedures;

- Postoperative Visits—Follow-up visits during the postoperative period of the surgery that are related to recovery from the surgery;

- Postsurgical Pain Management—By the surgeon;

- Supplies (except for those identified as exclusions and Miscellaneous Services)—Items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal tubes; and changes and removal of tracheostomy tubes; and

- Diagnostic tests and procedures, including diagnostic radiological procedures.

C. **Referrals and Provider Qualification Criteria**

1. **Patient Referral.** Once a patient is identified as a qualified candidate for the Bundled Payment Program, the Provider will follow the authorization requirements as described in the Agreement.
2. **Qualification Criteria.** The Provider must at all times meet the Plan’s qualification criteria for Bundled Payment Program participation.

D. **Payment Terms**

1. **General Payment Terms.** For the provision of Covered Services to a patient, the Plan will pay the Provider under the terms of this Addendum, subject to any benefit plan limitations as described in the Parties’ Agreement. The obligation for payment under this Addendum is solely that of the Plan. The Provider will accept as payment in full for Covered Services rendered the total of amounts payable by the Plan pursuant to this Agreement, plus allowed patient charges pursuant to the terms of the Agreement, as may be amended.

2. **The Case Rate Payment.** Claims for Covered Services included in the case rate for the Episode Period will be paid to the Provider at ______________________________ and will be paid pursuant to Section D.3 below. The Provider and its provider affiliates under the Bundled Payment Program will look solely to the Plan for payment of all Covered Services rendered pursuant to this Agreement. This Addendum shall not apply to any services, including, without limitation, Covered Services that are the financial responsibility of a third party that is not a Plan under this Agreement.

   a) Price: Knee (with or without optional rehab package)
   b) Price: Hip (with or without optional rehab package)
   c) Stop loss or catastrophic claim provisions if any

3. **Payment Schedule.** For cases paid pursuant to the Bundled Payment Program, the Provider will bill the Plan for the full bundled amount no more than sixty (60) days from the date that the applicable Covered Person was discharged from the Participating Hospital for the Index Procedure. The Plan will pay the Provider within 30 days after receipt of the claim. Notwithstanding the foregoing, in addition to the claim above, the Provider shall submit to the Plan a Final Claim at the end of the Episode Period for purposes of data reporting only. For purposes of this Section D.3., a “Final Claim” means an invoice, reasonably detailed, that illustrates all health care services provided to the Covered Person pursuant to the Bundled Payment Program during the Episode Period.

4. **Refunds.** Provider will refund any overpayment to the Plan within 30 days of the Provider’s receipt of a notice from the Plan, if such overpayment is not a disputed amount. In the event that the overpayment is disputed, the Parties will resolve such dispute pursuant to the terms of the Agreement.

5. **Late Payment Penalty.** If payment is not received by the Provider within 30 days from the date the Plan receives a claim from the Provider, the Plan shall pay the Provider interest at a rate of one and one-half percent (1.5%) on any unpaid balance each month the

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balance is overdue. The Provider will make best efforts to notify the Plan in writing of its intent to assess this late payment penalty.

6. **Referrals to Non-Participating Providers.** In the event that a Participating Hospital or other provider under the Bundled Payment Program refers a Covered Person to another facility or provider not participating in the Bundled Payment Program (collectively, “Non-Participating Providers”) during the Episode Period, and the Participating Hospital or other provider intends to continue treating such Covered Person and does not relinquish ultimate responsibility for such Covered Person’s care, the payment for Covered Services provided by the Non-Participating Providers during the Episode Period will be the responsibility of the Provider, and such amount will be included in the bundled payment made to the Provider by the Plan, and no additional payments will be made from the Plan to the Provider to cover such expenses.

7. **Premature Closure of Case.** No bundled payments will be made, and the payment terms under the Agreement will control, if:

   - A Covered Person loses coverage with the Plan during the Episode Period for any reason (e.g., due to death, becoming covered by Medicare, employer switching health plans); or
   - A Covered Person is transferred or referred to a Non-Participating Provider without the expectation that such Covered Person will return to the Participating Hospital or other provider at any time during the Episode Period.

Note that a readmission to a hospital other than the Participating Hospital during the Episode Period does not constitute a reason for premature closure of the case. Under such circumstances, a bundled payment will still be made to the Provider pursuant to the terms of this Addendum. Except as set forth under Section 6 above, the Provider assumes no liability for payments that may be due to Non-Participating Providers under the Plan’s contract with such Non-Participating Providers or the Covered Person’s benefit plan.

Additionally, the case will not be subject to premature closure if the Covered Person leaves the Participating Hospital or otherwise discontinues treatment during the Episode Period “against medical advice.”

**E. Miscellaneous Provisions**

1. **Quality Improvement.** The Provider agrees to participate and cooperate with the Plan and others as desirable or appropriate for purposes of furthering quality improvement and reporting processes as developed for the Bundled Payment Program (e.g., quality measure development and reporting, patient education, and/or shared-decision making processes). These processes will not include public reporting of quality information unless such reporting is mutually agreed upon in advance by the Provider.

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2. **Grievance Procedure.** The grievance procedure outlined in the Agreement will apply to the processing of any patient complaint regarding Covered Services furnished by the Provider.

3. **Coordination of Benefits.** The Provider agrees to coordinate with the Plan for proper determination of the coordination of benefits and to bill and collect from other payors such charges for which the other payor is responsible. Such coordination is intended to preclude the Provider from receiving or a Covered Person from paying an aggregate of more than one hundred percent (100%) of the rates set forth in this Addendum for Covered Services.

4. **Continuation of Services.** Upon any termination of this Addendum and the Provider’s participation in the Bundled Payment Program, the Provider, at the Plan’s request, shall remain obligated to furnish those Covered Services that the Provider is qualified to provide to any Covered Person under the Provider’s care at the time of termination; however, compensation for such services provided after the termination of this Addendum shall be pursuant to the Agreement, and not this Addendum.

5. **Effect of Addendum.** This Addendum and associated Agreement supersede any prior written or unwritten agreements between the parties or their affiliates with regard to the same subject matter. As to any particular patient who has accessed the Provider for Covered Services under the terms of a prior agreement, the terms of that prior agreement will continue to apply to that patient’s care through the duration of treatment for which terms are included under the prior agreement.

[Signature page follows]
Exhibit D: Sample Exception Language Excluding Bundled Services From Existing PPO Agreement

[PROVIDER] agrees to look solely to [PAYOR] for payment for [PROVIDER] Services, subject only to:

[(1)]

[(2)]

(3) any written agreement between [PROVIDER] and a [Participating Hospital, Participating Medical Group or IPA that is a Participating Provider] for such [PROVIDER] Services, including any written agreement for bundled payments; provided that, [PROVIDER] has entered into an agreement with such [Participating Hospital, Participating Medical Group or IPA] prior to [PROVIDER’s] provision of such [PROVIDER] Services, which agreement sets forth the express rates at which [PROVIDER] is to be reimbursed for the provision of such [PROVIDER] Services; and

[(4)]
Exhibit E: Sample Participating Provider Agreement

THIS PHYSICIAN PARTICIPATION AGREEMENT (this “Agreement”) is made and entered into by and between ________________________________, a ____________________ (“Physician Group”) and ________________________________, a ______________________ (“Hospital”), as of the effective date stated on the execution page of this Agreement (the “Effective Date”). (Physician Group and Hospital are referred to herein individually as a “Party” and collectively as the “Parties”).

RECITALS

WHEREAS, Hospital is a _________________ that owns and operates a licensed hospital facility which provides health care services to, among others, persons entitled to such services under particular plan(s) of health care benefits offered by Payors (as defined below) pursuant to agreements between Hospital and such Payors (each agreement respectively, “Hospital Payor Agreement”);

WHEREAS, Physician Group is a _________________, that employs or otherwise contracts with California-licensed physicians to provide professional health care services to, among others, Covered Persons (defined below) pursuant to agreements between Physician Group and such Payors (each agreement respectively, “Physician Payor Agreement”);

WHEREAS, Hospital has implemented a program to market certain services to Payors subject to the terms and conditions specified in the Program Description (as defined below) applicable to the particular Program (as defined below), and seeks to contract with Physician Group in order to facilitate the provision of the professional services related to such Programs;

WHEREAS, pursuant to the terms of this Agreement, Physician Group desires to provide the professional services related to such Programs in conjunction with Hospital; and

WHEREAS, each of Hospital and Physician Group will continue to provide services to Covered Persons pursuant to its own Hospital Payor Agreements and Physician Payor Agreements, respectively, except as modified by the Program Description and the terms as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and promises recited herein, the receipt and sufficiency of which are acknowledged hereby, the Parties, intending to be legally bound, agree as follows:

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1. **DEFINITIONS**

For the purpose of this Agreement and each Program Description attached hereto, the following terms shall have the meanings specified unless defined otherwise in the Program Description.

1.1 **Confidential Information** means the information made available to or developed by the Hospital or Physician Group, including, but not limited to, compensation schedules, mailing lists, employer lists, utilization management procedures, total quality assurance policies and programs, internal risk management programs and policies, programmatic information and structure, and related information and documents concerning the planning, structure, and operation of either the Hospital or Physician Group or a particular Program.

1.2 **Covered Person** means any person who has entered into, or on whose behalf there has been entered into, an agreement with a Payor for the provision to such person of Covered Services.

1.3 **Covered Services** means those health care services that a Covered Person is entitled to receive as set forth in the applicable Program Description.

1.4 **Credential, Credentialing, Re-Credential, or Re-Credentialing** means the process, whether performed by the Hospital, Physician Group, Hospital or Physician Group’s designee, and/or the applicable Payor, for verifying that each Physician Group Participating Physician is adequately trained, licensed in the jurisdiction in which such Physician Group Participating Physician maintains his or her practice, of good professional reputation, and capable of working with others to provide health care services to Covered Persons.

1.5 **Emergency** means a Covered Person’s medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

1.5.1 placing the Covered Person’s health in serious jeopardy; or

1.5.2 serious impairment to the Covered Person’s bodily function; or

1.5.3 serious dysfunction of any of the Covered Person’s bodily organs or parts.

1.6 **Medically Necessary or Medical Necessity** refers to or means:

1.6.1 a determination by the Hospital, Physician Group, Hospital or Physician Group’s designee, and/or Payor that the services and supplies provided or to be provided to a Covered Person are:

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1.6.1.1 appropriate and necessary for the symptoms, diagnosis, or
treatment of the Covered Person’s medical condition, illness,
disease, or injury; and

1.6.1.2 required for the diagnosis or direct care and treatment of the
Covered Person’s medical condition, illness, disease, or injury; and

1.6.1.3 within standards of good medical practice as recognized and
accepted by the medical community in which the Hospital and
Physician Group operate; and

1.6.1.4 not primarily for the convenience of the Covered Person, the
Covered Person’s physician, or another provider of health
services; and

1.6.1.5 the most efficient, economic, and appropriate service or supply
which can be safely provided; and

1.6.2 in the case of a hospital stay, a determination by the Hospital, Physician
Group, Hospital or Physician Group’s designee, or the applicable Payor
that the Covered Person has a condition in which acute care as an inpatient
is timely and appropriate, and that safe and adequate care cannot be
received as an outpatient or in a less-intensive treatment setting.

1.7 **Non-Routine Coverage** means the assumption of a Physician Group Participating
Physician’s responsibility for providing care to Covered Persons pursuant to this
Agreement in instances where the physician is ill, on vacation, or temporarily
absent for professional or personal purposes.

1.8 **Payor** means any third-party payor or combination of third-party payors,
including but not limited to, an insurance company, self-funded employer,
Medicare, or Medi-Cal, that has entered into an agreement with each of the
Hospital and Physician Group for the provision of Covered Services to Covered
Persons by the Physician Group and Hospital.

1.9 **Physician Group Participating Physician** means a physician who (i) is
employed by or under contract with the Physician Group and (ii) meets all of the
criteria for participation as set forth in this Agreement.

1.10 **Program** means a program offered and financed by a Payor or combination of
Payors which utilizes the Hospital and Physician Group to render Covered

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Services to Covered Persons under the terms and conditions described in the applicable Program Description.

1.11 **Program Description** means a written description of a Program negotiated and entered into between each of the Hospital and the Payor, and the Physician Group and the Payor, respectively. The Program Description includes terms and conditions under which, the Physician Group and Hospital shall provide Covered Services to Covered Persons enrolled in that Program. Each Program Description approved by the Physician Group will be included in Exhibit A of this Agreement.

1.12 **Provider Manual** means the compilation of policies and procedures to be jointly developed by the Hospital and Physician Group and applicable to both the Hospital and Physician Group with respect to their provision of Covered Services to Covered Persons under any Program.

1.13 **Quality Assurance** means an ongoing program designed to objectively and systematically monitor and evaluate the quality and appropriateness of health care services delivered to Covered Persons and to resolve identified problems based on the prevailing professional and hospital standards of care. Such a program identifies quality issues and recommends corrective actions to be taken by the Physician Group and/or Hospital.

1.14 **Routine Coverage** means the assumption of a Physician Group Participating Physician’s responsibility for providing care to Covered Persons pursuant to this Agreement based on a routine, anticipated, and predetermined basis (e.g., one Saturday a month).

2. **PHYSICIAN GROUP PARTICIPATION**

2.1 **Participation Generally.** Upon the execution by the Physician Group of the Execution Page of this Agreement, each of the Physician Group Participating Physicians shall be deemed to be participating hereunder.

2.2 **Criteria for Participation.** To qualify as a Physician Group Participating Physician throughout the term of this Agreement, each physician employed by or contracting with the Physician Group must:

   2.2.1 Possess a valid and unrestricted license to practice medicine in the State of California;
   2.2.2 Remain in strict compliance with all applicable state and federal laws;
   2.2.3 Be licensed or certified to prescribe medications and controlled substances and have and maintain in good standing a controlled substance certificate from the Drug Enforcement Administration (“DEA”);
   2.2.4 Be eligible to participate in the Medicare and/or Medi-Cal programs;

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2.2.5 Have and maintain in good standing clinical privileges at the Hospital and membership on the Active Staff or Courtesy Staff of the Hospital;

2.2.6 Be insured against professional liability at a level not less than the level of coverage required by the Medical Staff Bylaws of the Hospital; and

2.2.7 Comply with any additional criteria mutually established by the Hospital and Physician Group.

2.3 **Physician Group Participating Physicians.** Each Physician Group Participating Physician is subject to the terms and conditions of this Agreement. The Physician Group hereby represents and warrants to the Hospital that the Physician Group has the power and authority to cause, and will cause, each of the Physician Group Participating Physicians to be bound by the terms and conditions of this Agreement.

2.4 **Licenses.** The Physician Group agrees to submit for each Physician Group Participating Physician all licenses, certifications, and any other credentials as required by the Hospital for verification and approval, provide medical services to Covered Persons within the limits of such verification and approval, and notify the Hospital immediately upon any change or the initiation of proceedings that could result in a change in good standing of any Physician Group Participating Physician’s license or other certificate to practice his/her profession as represented herein.

2.5 **Credentialing.** The Physician Group agrees to submit for verification all required information necessary to Credential or to Re-credential the Physician Group Participating Physicians in accordance with the standards, as amended from time-to-time, subscribed to by the Hospital. The Physician Group and the Physician Group Participating Physicians will cooperate with the Hospital’s designee as necessary to conduct Credentialing and Re-Credentialing pursuant to the Hospital’s Credentialing and Re-Credentialing programs. The Physician Group will ensure that the Hospital has authorization from each Physician Group Participating Physician for the release of any and all information compiled, maintained, or otherwise assembled by the Hospital. In addition, the Physician Group will ensure that all Physician Group Participating Physicians remain credentialed and preferred by the applicable Payor at all times.

2.6 **Non-Physician Providers.** The Physician Group acknowledges that it may, in the course of providing Covered Services hereunder, utilize employed or contracted nurse practitioners, physician assistants, allied health professionals, technologists, and/or other non-physician health care professionals. To the extent that it does, the Physician Group will ensure at all times that such individuals are appropriately licensed and credentialed, are covered by adequate professional liability insurance, and are otherwise qualified to perform all services as requested by the Physician Group on behalf of Covered Persons hereunder. The Physician

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Group shall be responsible for all care provided by such individuals pursuant to this Agreement.

3. RELATIONSHIP AMONG THE HOSPITAL, PHYSICIAN GROUP, AND COVERED PERSONS

3.1 Independent Contractors. The Physician Group and Hospital are independent legal entities. Except as otherwise expressly set forth in this Agreement, nothing in this Agreement shall be construed or be deemed to create between them any relationship of principal and agent, partnership, joint venture, or any relationship other than that of independent parties. The Parties acknowledge that the Physician Group and Hospital do not have an employee-employer relationship and the Physician Group shall be responsible for complying with all tax, social security, and other local, state, and federal requirements applicable to funds received by Physician Group pursuant to this Agreement. No Party, nor the respective agents or employees of either Party, shall be required to assume or bear any responsibility for the acts or omissions, or any consequences thereof of the other Party under this Agreement. No Party hereto, nor the respective agents or employees of either Party, shall be liable to other persons for any act or omission of the other Party in performance of his, her, or its respective responsibilities under this Agreement.

3.2 Physician/Patient Relationship. It shall be the sole right and responsibility of the Physician Group and the Physician Group Participating Physicians to create and maintain a physician/patient relationship with each Covered Person that the Physician Group treats, and the Physician Group and the Physician Group Participating Physicians shall be solely responsible to each such Covered Person for all aspects of medical care and treatment within the scope of a physician’s professional competence and license, including the quality and levels of such care and treatment.

3.3 Physician Practice Closings. The Physician Group may, in its sole discretion close the medical practice of any Physician Group Participating Physician to Covered Persons due to lack of adequate resources to accept any additional Covered Persons; provided, however, that such Physician Group Participating Physician shall close his or her practice to all patients, not just Covered Persons, for all purposes, without regard to race, sex, national origin, religion, source of payment, prior medical history, or current medical condition, and for only such time as is reasonable in light of physician’s lack of resources. If the Physician Group and Hospital determine that a Physician Group Participating Physician should not provide services to a particular Covered Person due to a personality conflict or other personal reasons, the Hospital and/or Physician Group will arrange to have such Covered Person treated by another physician.
3.4 **Coverage by Other Physicians.** The Physician Group may rely on a non-Physician Group Participating Physician for Non-Routine Coverage only (i) in an Emergency, or (ii) with the Hospital’s prior written consent. The Physician Group agrees that, should it arrange for Non-Routine Coverage with a non-Physician Group Participating Physician, the Physician Group shall ensure that such physician: (a) shall accept as full payment for services to Covered Persons, the lesser of such physician’s usual and customary charge or such fee to be paid to the Physician Group for the service, as determined pursuant to this Agreement; (b) shall comply with the quality assurance, referral, and admission requirements, and all other policies and procedures set forth in the applicable Program Description and/or mutually established by the Hospital and Physician Group; and (c) has, at a minimum, clinical privileges at the Hospital. Further, the Physician Group may use a non-Physician Group Participating Physician only for Non-Routine Coverage. The Physician Group shall have all Routine Coverage performed by a Physician Group Participating Physician.

4. **COVENANTS RELATING TO PARTICIPATION**

4.1 **Provision of Services.** For each Program approved by the Hospital and Physician Group respectively, both the Hospital and Physician Group agree to comply with the terms of the Program Description, and to provide to Covered Persons those Medically Necessary Covered Services as set forth in the Program Description that the Hospital and Physician Group Participating Physicians are licensed and credentialed to provide. The Hospital and Physician Group each further agree to provide such services to all Covered Persons in a nondiscriminatory manner consistent with the care and services that each of the Hospital and Physician Group provides to its patients who are not covered under this Agreement.

4.2 **Standard of Practice.** For Programs approved by the Hospital and Physician Group, both the Hospital and Physician Group agree that they shall conduct their practice in accordance with recognized standards in the health care community in which the Hospital and Physician Group operate, and ensure that health care services are provided in accordance with the Hospital’s and Physician Group’s objectives of comprehensive quality care, cost containment, and effective utilization of inpatient, ambulatory, and emergency services.

4.3 **Insurance.** Both the Hospital and Physician Group agree to maintain: (i) a professional liability insurance policy for itself (and with respect to the Physician Group, for each of the Physician Group Participating Physicians) in an amount at least equal to one million dollars ($1 million) per occurrence and three million dollars ($3 million) in the aggregate; and (ii) any other types of insurance required under California law or as mutually agreed to by the Parties. The Physician Group and Hospital each agrees to provide the other with evidence of such coverage and immediate notice of any adverse changes to such insurance coverage. In the event
that a Party’s policy is a “claims-made” policy and is terminated for any reason, such Party shall purchase extended reporting coverage (e.g., “tail coverage”) or retroactive coverage for a period of not less than five (5) years following the effective termination date. Said “tail” policy shall have the same policy limits as the expired primary professional liability policy. In furtherance of the above, the Physician Group shall be responsible for ensuring that all Physician Group Participating Physicians have adequate coverage, including tail coverage, as specified above.

4.4 **Network Roster and Marketing.** For each Program approved by the Parties, each Party authorizes the other and/or the applicable Payor to include such Party’s contact information as well as each Physician Group Participating Physician’s name, business address, business telephone number, medical specialty, medical education information, hospital affiliations, and other similar information in its provider directory or other similar material, which may be included in various marketing materials. Other than the above, each Party agrees not to use the name of the other in any form of advertisement or publication without prior written permission of the other.

5. **PHYSICIAN COMPENSATION**

5.1 **Compensation Generally.** For each Program approved by the Physician Group, the Physician Group agrees to accept as payment in full for Covered Services the compensation set forth in the applicable Program Description. The Physician Group understands and agrees that it will invoice and receive payment directly from the Hospital; however, the Hospital is acting merely as an administrator of payment on behalf of the Payors for physician services hereunder, and the Hospital is not responsible for compensation or reimbursement due under any Program Description, unless expressly stated otherwise in such Program Description, in the event a Payor fails to pay the Hospital and/or Physician Group for services. In furtherance of the above, the Physician Group agrees that it will invoice only the Hospital for Covered Services hereunder, unless otherwise specifically stated in the Program Description, and in doing so, the Physician Group shall comply with the applicable Provider Manual. The Hospital and/or Physician Group, as appropriate, shall take all necessary action to enforce the Payor’s payment obligations under applicable Program Descriptions. The Physician Group hereby waives, releases, relinquishes, and discharges the Hospital and its officers, directors, employees, agents, and its and their successors and assigns, and each of them (“Released Parties”) from any and all claims, suits, damages, actions, or manner of actions that the Physician Group now has or may in the future have against Released Parties, or any of them, in any way relating to or arising out of any failure to pay compensation or reimbursement to the Physician Group for services provided under any Program or Program Description, except with respect to any Program Description which expressly
states that the Hospital is responsible for making payments to the Physician Group. The Physician Group agrees the foregoing release shall survive termination of this Agreement for any reason.

5.2 **Covered Person Hold Harmless.** For each Program approved by the Physician Group, unless the requirement is expressly waived in the applicable Program Description, the Physician Group hereby agrees that in no event, including, but not limited to, nonpayment, the applicable Payor’s insolvency, or breach of this Agreement, shall the Physician Group or any Physician Group Participating Physician bill, charge, collect a deposit from, seek compensation, remuneration, or reimbursement for Covered Services from, or have any recourse against, a Covered Person or any person who may be acting on a Covered Person’s behalf other than the applicable Payor. This provision shall not prohibit the Physician Group’s collection of deductibles, supplemental charges, or co-payments made in accordance with the terms of the Covered Person’s benefit plan. The Physician Group further agrees that (i) the hold harmless provision in this Section shall survive the termination of this Agreement regardless of the cause, if any, giving rise to the termination and shall be construed to be for the benefit of Covered Persons and that (ii) the hold harmless provision in this Section supersedes any oral or written contrary agreement now existing or hereafter entered into between the Physician Group and any Covered Person, or persons acting on his/her behalf under any Program approved by the Physician Group.

5.3 **Determination of Covered Services.** For each Program approved by the Physician Group, the Hospital will cause the Physician Group to be provided with a schedule of Covered Services for each applicable Program Description and will cause the Physician Group to be notified of any amendments or modifications to such schedules. The Hospital will also cause the Physician Group to be provided with telephone numbers to call to verify Covered Person’s eligibility under each such Program.

6. **RECORDS**

6.1 **Records Generally.** The Parties hereto shall maintain medical records in a current, detailed, organized comprehensive manner and in accordance with applicable state and federal laws, customary medical practice in the community where the Parties operate, and policies mutually determined by the Hospital and Physician Group. Medical records shall be legible, reflect all aspects of pertinent care, and contain a current and complete medical history and listing of allergies, medications, and diagnoses. For each patient encounter, there shall be completed, dated, and signed progress notes which, at a minimum, contain the chief complaint or purpose of the visit, diagnosis or findings, and therapeutic plan. Where appropriate, there shall be evidence of follow-up or previous encounters. The Parties agree that each of the Hospital, Physician Group, and Payors,
respectively, shall have the right, upon request and, with respect to medical records, upon presentation of a valid patient authorization that complies with all applicable laws and regulations, to inspect at all reasonable times and have copied, any accounting, administrative, and medical records maintained by a Party pertaining to the Covered Person’s enrollment or to a Party’s participation under this Agreement. The Hospital and Physician Group shall provide the other with copies of all medical records and other records relating to claims for provision of Covered Services to a Covered Person reasonably requested pursuant to this Section at no charge.

6.2 **Transfer and Confidentiality.** The Parties hereto agree to cooperate in the transfer of Covered Persons’ medical records to other providers, as necessary or reasonably requested, subject to all applicable federal and state laws and regulations. The Parties further agree to cooperate with each other and any state agency or federal agency in making available, and in arranging or allowing inspection of, such records as may be required under state or federal laws and regulations. The Parties each agree that each Covered Person’s medical records and identifiable health information shall be treated as confidential so as to comply with all state and federal laws and regulations regarding the confidentiality, privacy, and security of patient records and health information. Notwithstanding termination of this Agreement, the access to records granted hereunder shall survive the termination of this Agreement.

7. **TERM AND TERMINATION**

7.1 **Term and Renewal.** This Agreement will be effective on the Effective Date after execution and its initial term shall continue in effect thereafter for one (1) year, subject to the termination provisions of this Agreement. After the initial term, this Agreement, including all Program Descriptions then in effect, shall be automatically renewed for successive one (1) year terms unless either Party provides to the other at least sixty (60) days’ prior written notice of non-renewal. Termination or non-renewal of this Agreement shall terminate the participation in all Programs by the Physician Group and each Physician Group Participating Physician.

7.2 **Physician Group’s Termination of Participation.** The Physician Group may terminate this Agreement for any or no reason, without penalty, upon providing to the Hospital ninety (90) days’ prior written notice of such termination.

7.3 **Hospital’s Termination of Physician Group’s Participation.** The Hospital may terminate this Agreement and the Physician Group’s participation for any or no reason, without penalty, upon providing to Physician Group ninety (90) days’ prior written notice of such termination.
7.4 **Termination For Cause.** Either Party may terminate this Agreement for the material breach of any provision of this Agreement or any policy or procedure adopted by the Hospital and by the Physician Group upon 30 days’ prior written notice. Such notice must specify the exact nature of the breach. Termination shall not take effect if the cause specified in the notice is rectified within the thirty (30) day notice period, unless a longer time period is mutually agreed to by both Parties.

7.5 **Immediate Suspension from Participation.** Notwithstanding anything to the contrary herein, the Hospital may suspend immediately the Physician Group’s participation or any Physician Group Participating Physician’s participation in any and all Programs upon notice, either written or oral, to the Physician Group if the Hospital has a reasonable basis for concluding that any of the following has occurred: (i) a suspension or revocation of a Physician Group Participating Physician’s license, certificate, or other legal credential authorizing physician to practice medicine; (ii) a suspension or revocation of a Physician Group Participating Physician’s controlled substance certificate from the DEA or other right to prescribe medications or controlled substances; (iii) a Physician Group Participating Physician’s failure to maintain in good standing clinical privileges at the Hospital; (iv) an indictment, arrest, or conviction for any felony or for any criminal charge related to the practice of medicine or to the abuse or neglect of a patient; (v) the cancellation or termination of professional liability insurance as required by this Agreement, without replacement coverage having been obtained; (vi) the exclusion or suspension of the Physician Group or any a Physician Group Participating Physician from participation in the Medicare or state health care programs; (vii) a Physician Group Participating Physician is unable to perform his/her obligations pursuant to this Agreement; or (viii) the Hospital has determined that immediate suspension of the Physician Group or any Physician Group Participating Physician is in the best medical interest of the Covered Persons.

7.6 **Automatic Termination.** Notwithstanding anything to the contrary herein, this Agreement shall automatically terminate in the event of the Physician Group’s dissolution.

7.7 **Effect of Termination.** Any termination of this Agreement will not affect either Party’s obligations (including, without limitation any financial obligations) that arose prior to such termination.

7.8 **Continuation of Services.** Upon any termination of the Physician Group’s participation, the Physician Group, at the Hospital’s request, shall remain obligated to furnish Covered Services to any Covered Person under the Physician Group’s care pursuant to a Program approved by the Physician Group, who at the time of the termination is a registered inpatient at the Hospital or as otherwise
described in the Program Description. This Section shall survive the termination of this Agreement regardless of the cause giving rise to termination.

8. PROVIDER MANUAL, AMENDMENTS, AND NEW PRODUCTS

8.1 Provider Manual. The Parties hereto may collaborate on the preparation and approval of a Provider Manual to implement the terms of this Agreement and the terms of any Program Description(s). Subject to the provisions of Section 8.2, upon approval of the Provider Manual, or any amendments thereto, the Parties agree to comply with all provisions and procedures set forth therein.

8.2 Amendments. This Agreement or the Provider Manual may be amended at any time during the term of this Agreement by Hospital giving sixty (60) days prior written notice of such amendment. In the event an amendment is not acceptable to the Physician Group, then, notwithstanding any other provisions of this Agreement, the Physician Group may terminate this Agreement as of the date the amendment becomes effective by submitting written notice of termination to the Hospital at least thirty (30) days before the amendment’s effective date. However, during the sixty (60) day prior notice period, the Physician Group shall remain obligated under the terms of this Agreement and any Program Description(s) and the Provider Manual as those terms were in effect prior to the effective date of the amendment, unless the Hospital consents to such termination taking effect immediately. In the absence of written notice of termination by the Physician Group, the Physician Group shall be deemed to have accepted such amendment(s) as of the effective date thereof. Except as provided in this Article 8, no amendment shall be effective unless in writing and signed by the Physician Group and Hospital.

9. GENERAL PROVISIONS

9.1 Assignment. This Agreement shall not be, in any manner, assigned, delegated, or transferred by the Physician Group or Hospital. Any such assignment, delegation, or transfer shall be null and void without the consent of the other Party.

9.2 Waiver of Breach. The waiver by either Party of a breach or violation of any provision of this Agreement shall not be deemed a waiver of any other breach of the same or different provision.

9.3 Notices. Any notice required to be given pursuant to the terms and provisions hereof shall be in writing and shall be sent by certified mail, return receipt requested, to the Parties at the addresses set forth on the Execution Page of this Agreement. Such notice shall be effective upon mailing.

This exhibit is not a legal form, and is provided by the Integrated Healthcare Association for purposes of example only.
9.4 **Severability.** In the event any provision of this Agreement is rendered invalid or unenforceable by any Act of Congress or of the state legislature or by any regulation promulgated by officials of the United States or the applicable state agency, or declared null and void by any court of competent jurisdiction, the remainder of the provisions of this Agreement shall, subject to this Section, remain in full force and effect. In the event that a provision of this Agreement is rendered invalid or unenforceable or declared null and void as provided in this Section and its removal has the effect of materially altering the obligations of any Party in such manner as, in the judgment of the Party affected, (i) will cause serious financial hardship to such Party or (ii) will substantially disrupt and hamper the mutual efforts of the Parties to maintain a cost-efficient means of delivery of health care services, the Party so affected shall have the right to terminate this Agreement upon sixty (60) days prior written notice to the other Party.

9.5 **Headings.** The headings of the sections contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

9.6 **Governing Law.** This Agreement shall be construed and enforced in accordance with the laws of the State of California, without regard to such State’s statutes and cases concerning choice of laws.

9.7 **Physician Group Offices.** The Physician Group shall notify the Hospital at least sixty (60) days prior to making any addition or change in office locations.

9.8 **Construction.** Each Program Description approved by the Physician Group is enforceable under the terms and conditions therein and in the event of conflict between the language of this Agreement and any such Program Description, the language of the Program Description shall prevail with respect to the terms applicable to, and Covered Persons under, that Program.

9.9 **Confidential Information.** The Parties agree that all Confidential Information, except medical records of Covered Persons, is the exclusive property of the disclosing Party and that the other Party has no right, title, or interest in the same.

9.10 **Counterparts.** This Agreement may be executed in counterparts, all of which together shall constitute a single Agreement.

9.11 **Entire Agreement.** This Agreement and amendments thereto, including all Program Descriptions approved by the Physician Group and attachments as are now incorporated or as added from time-to-time pursuant to the terms of this Agreement, constitutes the entire understanding and agreement of the Parties and

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supersedes any prior written or oral agreement, negotiations, and understandings pertaining to the subject matter hereof.

9.12 Compliance with Law. The Hospital and Physician Group shall comply with all federal and state laws, whether or not such laws are specifically stated in this Agreement, which pertain to their respective rights, responsibilities, and actions under this Agreement. In furtherance of the above, the Parties shall specifically comply with all applicable provisions of the [State insurance law], as well as, without limitation, all applicable federal statutes and requirements as mandated by the Centers for Medicare and Medicaid Services and the Balanced Budget Act, as amended from time to time.
PHYSICIAN PARTICIPATION AGREEMENT

EXECUTION PAGE

In consideration of mutual covenants and promises stated herein and other good and valuable consideration, the undersigned have agreed to be bound by the ________________ Hospital Physician Participation Agreement, as of the Effective Date stated below.

[___________________________________] [HOSPITAL]

By: ________________________________
(Signature)

(Please Print Your Name)

Title: ________________________________

Date: ________________________________

EFFECTIVE DATE: _________________

Office Address(es):

__________________________________

__________________________________

__________________________________

(Primary Address for Notices and Payments)

__________________________________

__________________________________

__________________________________

Group Tax Identification Number: ____________

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Physician Participation Agreement
Program Description

Bundled Episode Payment:
Hospital-Physician Contract Parameters

A. Introduction

The intent of the participants is that the negotiated bundled episode payment should include all Covered Services provided to a Covered Person during the Episode Period for:

1. An Index Procedure of total knee or total hip replacement for a patient with degenerative osteoarthritis;

2. Routine Care appropriate to the Index Procedure; and

3. Patient Complications arising during the stay for Index Procedure or during the Epis

ode Warranty Period following the surgery, Included Readmissions, and Revision Procedures performed during the Episode Period because of complications associated with the original procedure or for mechanical failure.

The Hospital, Physician Group, and Payors may mutually agree to include an optional rehabilitation package for an additional negotiated fee.

B. Definitions

1. Covered Services. The following services are included in the episode definition and negotiated episode payment. They may not be separately billed by the Physician Group or Hospital when treating a Covered Person during the Episode Period.

   • During the Episode Period, and for any included Readmission, Covered Services include:

      o All physicians, anesthesiologists, other attending and consulting physicians, and all professional technical and ancillary services;

      o Preoperative visits after the decision is made to operate beginning with the day of surgery;

      o Intra-operative services that are normally a usual and necessary part of a surgical procedure;

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o All additional medical or surgical services required of the surgeon during the postoperative period of the surgery because of complications which do not require additional trips to the operating room;

o Follow-up visits during the postoperative period of the surgery that are related to recovery from the surgery;

o Postsurgical pain management by the surgeon;

o Supplies, except for those identified as exclusions;

o Miscellaneous Services (items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal tubes; and changes and removal of tracheostomy tubes);

o All other medically necessary services and supplies;

o All inpatient and outpatient professional services;

o Transfers during Episode Period to another surgeon, if authorized by the surgeon, unless the level of care or services required are not available at the originating hospital; and

o All services provided by originating providers.

- **During the Episode Warranty Period** (including Readmission), Covered Services include:

  o All Covered Services above: outpatient institutional and professional follow-up care, consultations, and related services, including but not limited to medical care, or similar services;

  o All other related episode covered services will be included unless they are clearly caused by injury or disease other than the underlying disease for which the Index Procedure is being undertaken. For example, injuries due to an automobile accident or disease unrelated to the diagnosis of degenerative osteoarthritis (for example, primary care or specialist visits for a dermatologic condition); and

  o Transfers during Episode Period to another surgeon, if authorized by the surgeon, unless the surgeon is unable to provide level of care or services required.

- **Covered Services do NOT include the following:**

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The initial consultation or evaluation of the problem by the surgeon to determine the need for surgery;

- Outpatient prescription drugs;

- Professional charges for treatment in a skilled nursing facility;

- Outpatient services clearly unrelated to the Index Procedure or underlying condition, for example, pregnancy or, for osteoarthritis treatment, surgical evaluation and planning for a procedure on a different joint than the one on which the Index Procedure was performed (knee replacement on the other leg); and

- Inpatient services not provided during the admission for the Index Procedure or an Included Readmission (for example, admission for an appendectomy).

2. **Episode Period:**

- The Episode Period begins on the date of admission for the Index Procedure and continues to the 90th day following the date of the original admission.

- Readmissions (as defined) that begin within the Episode Period are included in the episode price (may not be separately billed), even if the period of readmission extends beyond 90 days following the date of the original admission. For example, if a patient were readmitted for a surgical site infection on the 89th day of the Episode Period, the Episode Period would be extended until that patient is discharged.

- Patients who elect to have a second Index Procedure (i.e., total knee replacement on the other knee) during the first Episode Period, begin a new 90-day Episode Period on the date of admission for the second surgery.

- For purposes of determining Covered Services, the Episode Period is divided into:
  
- The *acute period*, which begins on the date of admission for the Index Procedure and continues to the date of discharge from the Hospital for the Index Procedure;

- The *warranty period*, which begins on the date of discharge from the Hospital for the Index Procedure and continues through the 90th day following date of admission for the Index Procedure; and

- The *rehabilitation period*, which applies only for participants contracting for the optional rehabilitation package and begins on the date of discharge for the Index Procedure and continues through the 21st day following discharge for the Index Procedure.
3. **Readmissions.** For purposes of this program, a Readmission is defined to mean any subsequent admission to an acute care facility that occurs within the Episode Period. However, whether a Readmission is included in the contracted episode rate (and thus may not be separately billed) depends on: a) the facility where the patient is readmitted, and b) whether the readmission is considered to have been caused by or related to the Index Procedure (according to rules below).

- The Hospital and Physician Group agree that patients will be readmitted to the Hospital except when: the patient requires emergency admission to a closer facility, the patient requires care that cannot be provided at the Hospital, or the patient refuses to be readmitted to the Hospital.

- A readmission at the Hospital is assumed to be related to the Index Procedure and is included in the episode price (may not be separately billed) if the readmission groups to one of the defined set of DRGs below.

**Defined DRGs for Index Procedure of Total Knee Replacement**
- 175, 176—Pulmonary embolism
- 294, 295—Deep vein thrombophlebitis
- 463, 464, 465—Wnd debrid & skin grft, exc hand, for musculo-conn tiss dis
- 466, 467, 468—Revision of hip or knee replacement
- 485, 486, 487, 488, 489—Knee Procedures with and without pdx of Infection
- 539, 540, 541—Osteomyelitis
- 553, 554—Bone diseases & arthropathies
- 555, 556—Signs & symptoms of musculoskeletal system & conn tissue
- 559, 560, 561—Aftercare, musculoskeletal system & connective tissue
- 564, 565, 566—Other musculoskeletal sys & connective tissues diagnoses
- 602, 603—Cellulitis
- 856, 857, 858, 862, 863—Post-operative or post-traumatic infections
- 870, 871, 872—Septicemia or severe sepsis (note: these DRGs are included only if septicemia is related to a septic joint or central line infection)
- 901, 902, 903—Wound debridements for injuries
- 919, 920, 921—Complications of treatment
- 939, 940, 941—O.R. procedure with diagnosis of other contact w health services

**Defined DRGs for Index Procedure of Total Hip Replacement**
- 175, 176—Pulmonary embolism
- 294, 295—Deep vein thrombophlebitis
- 463, 464, 465—Wnd debrid & skin grft, exc hand, for musculo-conn tiss dis
- 466, 467, 468—Revision of hip or knee replacement
- 480, 481, 482—Hip & Femur procedures except major joint
- 533, 534—Fractures of Femur

*This exhibit is not a legal form, and is provided by the Integrated Healthcare Association for purposes of example only.*
• 535, 536—Fractures hip and pelvis
• 537, 538—Sprains, strains, dislocation hip, pelvis, thigh
• 539, 540, 541—Osteomyelitis
• 553, 554—Bone diseases & arthropathies
• 555, 556—Signs & symptoms of musculoskeletal system & conn tissue
• 559, 560, 561—Aftercare, musculoskeletal system & connective tissue
• 564, 565, 566—Other musculoskeletal sys & connective tissues diagnoses
• 602, 603—Cellulitis
• 856, 857, 858, 862, 863—Post-operative or post-traumatic infections
• 870, 871, 872—Septicemia or severe sepsis (note: these DRGs are included only if septicemia is related to a septic joint or central line infection)
• 901, 902, 903—Wound debridements for injuries
• 919, 920, 921—Complications of treatment
• 939, 940, 941—O.R. procedure with diagnosis of other contact w health services

4. **Index procedures.** The tables below outlines the primary procedure codes (i.e. are in the primary position on the billing code) that will trigger the provisions of this Program Description. Revision procedures other than those occurring with 90-days of an Index Procedure for a patient participating in this Program are also excluded.

<table>
<thead>
<tr>
<th>Definition of Total Knee Replacement Index Procedure</th>
<th>Definition of Total Hip Replacement Index Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Index Procedure Code:</strong> This procedure must exist to trigger the episode.</td>
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</tr>
<tr>
<td><strong>CPT:</strong></td>
<td><strong>CPT:</strong></td>
</tr>
<tr>
<td>- 27447—Arthroplasty, knee condyle and plateau, medical and lateral compartments</td>
<td>- 27130—Arthroplasty,</td>
</tr>
<tr>
<td><strong>ICD-9 Px:</strong></td>
<td><strong>DRG:</strong> Episode must map to one of these DRGs.</td>
</tr>
<tr>
<td>- 81.54—Total Knee replacement</td>
<td><strong>DRG:</strong> Episode must map to one of these DRGs.</td>
</tr>
<tr>
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<td><strong>ICD-9 Px:</strong></td>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>714.0x—Rheumatoid Arthritis</td>
<td>714.0x—Rheumatoid Arthritis</td>
</tr>
<tr>
<td>736.89—Other acquired deformities, lower limb</td>
<td>736.89—Other acquired deformities, lower limb</td>
</tr>
<tr>
<td>170.7—Malignant neoplasm of long bones of lower limb</td>
<td>170.7—Malignant neoplasm of long bones of lower limb</td>
</tr>
<tr>
<td>171.3—Malignant neoplasm of soft tissue, lower limb, hip</td>
<td>171.3—Malignant neoplasm of soft tissue, lower limb, hip</td>
</tr>
<tr>
<td>198.5—Secondary malignant neoplasm of bone, marrow</td>
<td>198.5—Secondary malignant neoplasm of bone, marrow</td>
</tr>
<tr>
<td>822, 823, 827, 828, 836, 891—Fractures, dislocations and open wounds</td>
<td>822, 823, 827, 828, 836, 891—Fractures, dislocations and open wounds</td>
</tr>
<tr>
<td>928—Crushing injury</td>
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</tr>
</tbody>
</table>

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acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft, or
• 27125—Hemiarthroplasty, hip, partial (e.g., femoral stem prosthesis, bipolar arthroplasty) (when performed for reasons other than fracture)

ICD-9 Px:
• 81.51—Total hip replacement
• 81.52—Partial hip replacement (when performed for reasons other than fracture)
• 00.85—Resurfacing hip, total, acetabulum and femoral head
• 00.86—Resurfacing hip, partial, femoral head

Major Joint Replacement or Reattachment of Lower Extremity without MCC
AND
APR DRG SOI of 1 or 2

736.89—Other acquired deformities, lower limb
170.7—Malignant neoplasm of long bones of lower limb
171.3—Malignant neoplasm of soft tissue, lower limb, hip
198.5—Secondary malignant neoplasm of bone, marrow
822, 823, 827, 828, 836, 891—Fractures, dislocations and open wounds
928—Crushing injury

5. **Optional rehabilitation package.** If both parties to the contract agree, the episode may include an optional package of rehabilitation services that will be provided during the rehabilitation period (defined above under Episode Period). This package will include:

- Initial evaluation by a Physical Therapist, including development of a recommended physical therapy plan;
- All Physical Therapy visits in accordance with the recommended physical therapy plan;
- Evaluation by a Home Health Aide or Occupational Therapist of the patient’s physical environment and need for durable medical equipment; and
- Home health visits and/or blood draws to calculate the International Normalized Ratio (INR) for patients receiving anti-coagulant therapy.

6. **Covered Person.** For inclusion in the program, a patient must be:

- Undergoing surgery provided by an orthopedic surgeon contracting to provide services under the program for the specific health plan;

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• Being admitted to the Hospital to provide specified services under the Hospital’s Payor agreement;

• Presenting for the Index Procedure with an American Society of Anesthesiologists (ASA) rating of <3 (and post-discharge assignment to APR-DRG SOI level of 1 or 2);

• Presenting for the Index Procedure without:
  o Clinical history that demonstrates a clinical condition of active cancer, HIV/AIDS, or End Stage Renal Disease;
  o Body Mass Index (BMI) of 40 or greater;

• Over age 18 and under age 65 on the date of surgery; and

• Covered (as primary plan) by a participating employer and health plan on date of surgery.

7. **Patient complications.** All Covered Services provided to treat patient complications that arise during the Episode Period are included in the negotiated episode rate, and may not be separately billed through the end of the Episode Period. Examples of complications include patients with infections, wound issues, or cellulitis. Service examples include joint injection, pain management, X-Ray or MRI, dislocation, incision and drainage of hip joint, or removal of hip prosthesis. (All outpatient services after the end of the Episode Period will be excluded from Covered Services; e.g., treatment for infections that continues for 12 months. However, all costs of an included readmission that begins within the Episode Period even if the readmission extends beyond the 90-day window will be included as a Covered Service.)

8. **Revision Procedures.** Revision procedures are included in the episode payment only if performed within the 90-day Episode Period as a result of patient complications or device failure.

*This exhibit is not a legal form, and is provided by the Integrated Healthcare Association for purposes of example only.*
### Revision Procedures for Knee Replacement

#### Procedure Code
These procedure codes constitute a covered revision if performed within 90-days of Index Procedure

**CPT:**
- 27486—Revision joint total knee arthroplasty with or without allograft 1 component
- 27487—Revision joint total knee arthroplasty fem and entire tibl component

**ICD-9 Px:**
- 00.80—Revision of knee repl, total (all components)
- 00.81—Revision of knee repl, tibial component
- 00.82—Revision of knee repl, femoral component 00.83—Revision of knee replacement, patellar component
- 00.84—Revision of knee replacement, tibial insert (linear)
- 81.55—Revision of knee replacement, NOS

**DRG:** Admission must map to one of these DRGs.

**MS DRGs**
- 466—Revision of hip or knee replacement with MCC
- 467—Revision of hip or knee replacement with CC
- 468—Revision of hip or knee replacement without CC/MCC

**APR SOI limitation does not apply if patient was included in the program for the Index Procedure.**

**Included Diagnoses:**
- All

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### Revision Procedures for Hip Replacement

#### Procedure Code
These procedure codes constitute a covered revision if performed within 90-days of Index Procedure

**CPT:**
- 27134—Revision of total hip arthroplasty; both components, with or without autograft or allograft
- 27137—Revision total hip arthroplasty, acetabular component only, with or without autograft or allograft
- 27138—Revision total hip arthroplasty, femoral component only, with or without autograft or allograft

**ICD-9 Px:**
- 00.70—Revision of hip repl, both acetabular and femoral components
- 00.71—Revision of hip repl, acetabular

**DRG:** Admission must map to one of these DRGs.

**MS DRGs**
- 466—Revision of hip or knee replacement with MCC
- 467—Revision of hip or knee replacement with CC
- 468—Revision of hip or knee replacement without CC/MCC

**APR SOI limitation does not apply if patient was included in the program for the Index Procedure.**

**Included Diagnoses:**
- All
component
- 00.72—Revision of hip repl, femoral component
- 00.73—Revision of hip replacement, acetabular liner and/or femoral head only
- 00.87—Resurfacing hip, partial, acetabulum

9. **Routine care appropriate to the Index Procedure.** This includes:

- Preoperative Visits—Preoperative visits after the decision is made to operate beginning with the day before the day of surgery for major procedures and the day of surgery for minor procedures;

- Postoperative Visits—Follow-up visits during the postoperative period of the surgery that are related to recovery from the surgery;

- Postsurgical Pain Management—By the surgeon;

- Supplies—Except for those identified as exclusions; and Miscellaneous Services—Items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal tubes; and changes and removal of tracheostomy tubes; and

- Diagnostic tests and procedures, including diagnostic radiological procedures.

**C. Payment Terms**

d) Price: Knee (with or without optional rehab package);
e) Price: Hip (with or without optional rehab package);
f) Bonus based on cost savings or payment of quality incentives applicable to surgeons and other specialists such as anesthesiologists, hospitalists, etc.;
g) Stop loss or catastrophic claim provisions if any;
h) Collection of patient cost-sharing as required;
i) Special payment provisions for incomplete episodes (e.g., transfer or readmission to another facility);
j) General billing and payment terms—per respective Payor agreement or flow developed as part of the project (Could be in Policy Manual);
k) Special tracking or payment provisions regarding potential problem areas (e.g., evidence of bias toward selection of healthier or less complicated patients; Could be in Policy Manual); or
l) Episode breakers. Billing and payment terms revert to the master contract when:
   - Patient discharge status is “left against medical advice,”
• Patient is transferred to another facility (further discussion needed, see also covered services,) or
• Patient is readmitted to another facility

D. Miscellaneous Provisions

1. **Quality Improvement.** The Hospital and Physician Group agree to participate and cooperate with the Payors and others as desirable or appropriate for purposes of furthering quality improvement and reporting processes as developed for this program project (e.g., quality measure development and reporting, patient education, and/or shared-decision making processes). These processes will not include public reporting of quality information unless such reporting is mutually agreed upon in advance by the Hospital and Physician Group. The Physician Group shall participate with the Hospital in a best practices/quality improvement program which includes, at minimum, an annual meeting and examination of clinical data generated by the Program.

2. **Authorization Procedures.** In connection with the provision of Covered Services hereunder, both the Hospital and Physician Group shall comply with their respective Authorization procedures as set forth in their applicable Payor Agreements. For purposes of this Section, “Authorization” shall mean the documented approval by the Hospital and/or Physician Group respectively, prior to providing Covered Services for which approval is required by the applicable Payor.

3. **Grievance Procedure.** A grievance procedure has been established for the processing of any patient complaint regarding Covered Services furnished by the Hospital or Physician Group. Such procedure will be coordinated by the Hospital and its contracting Payors. The Physician Group shall comply with, and subject to its rights of appeal, shall be bound by such grievance procedure to the extent such procedure is provided in writing to the Physician Group.

4. **Coordination of Benefits.** The Hospital agrees to coordinate with the Physician Group for proper determination of the coordination of benefits and to bill and collect from other payors such charges for which the other payor is responsible. The Hospital agrees to promptly notify the Physician Group of any third-party entity which may be responsible for payment and collection of Coordination of Benefits, if such payment is not to be made pursuant to a Payor Agreement for Covered Services. Such coordination is intended to preclude the Hospital and Physician Group from receiving or a Covered Person from paying an aggregate of more than one hundred percent (100%) of the rates set forth in the Hospital’s and Physician Group’s applicable Payor Agreement for Covered Services hereunder.

5. **Continuation of Services.** Upon any termination of the Physician Group’s participation, the Physician Group, at the Hospital’s request, shall remain obligated to furnish Covered Services to any Covered Person under the Physician Group’s care pursuant to this

*This exhibit is not a legal form, and is provided by the Integrated Healthcare Association for purposes of example only.*
Program Description, who at the time of termination is a registered inpatient at the Hospital or is currently in the Warranty Period following an Index Procedure until the end of the Episode Period.

By ________________________________  By: ________________________________
(Signature)  (Signature)

(Please Print Your Name)

Title: __________ Date: __________

EFFECTIVE DATE: __________