

Bundled Payment for Physician Group Practices and Organized Delivery Systems

By Barry Liss, Esq.



The U.S. healthcare industry, spurred by 1) actions taken by the federal government and 2) widespread opinion that the current rate of increase in healthcare expenditures is unsustainable,¹ has turned towards value-based purchasing as an aid to control costs and retain quality of care. One type of value-based purchasing, bundled payment reimbursement, involves having the payor of healthcare services pay a fixed amount to be distributed among all providers involved in the treatment of an individual (e.g., hospital, physician, rehabilitation facility, physical therapist, home health agency, laboratory, etc.) for a specified episode of care (e.g., joint replacement, cancer treatment, coronary artery bypass graft). Bundled payment models

typically include the potential for bonus payments to providers, i.e., distributions of shared savings. Theoretically, bundled payment programs lead to enhanced clinical integration, oversight and conformity with best clinical practices among participating providers, which in turn, theoretically, lead to: 1) as good or better quality of care² and 2) better cost control.

Indeed, bundled payment models have, in fact, been shown to be effective in controlling costs without diminishing quality.³ Therefore, the adoption of bundled payment arrangements by commercial carriers, self-funded health plans and government-sponsored health plans is accelerating.

Posted with the permission of MDAAdvisor, A Journal for the Healthcare Community.

KEY STRUCTURAL COMPONENTS OF BUNDLED PAYMENT ARRANGEMENTS

Bundled payment arrangements must include certain fundamental components and must navigate a complex web of legal issues⁴ including the following five factors.

Temporal

Defining the time period to which the bundled payment applies is one of several fundamental components. Determining when it begins (e.g., at the time of hospital admission? on the date a lab test is confirmed?) and when it ends (e.g., three months after hospital discharge? six months?) requires a sophisticated actuarial assessment that providers and payors must agree upon.

Inclusion and Exclusion of Bundled Cases

Precise and clear operational definitions of which cases will be included and excluded are essential. Inclusion criteria can be based upon diagnostic and/or procedure codes and the case must be tied to the payor involved in the arrangement. Circumstances that could trigger exclusion might be those in which unintended high utilization costs would result, e.g., from co-morbidities, trauma, acute conditions, or chronic conditions unrelated to the bundle. Inclusion of prescription drugs should also be carefully weighed.

Early Termination

Situations will arise that require a case to be terminated before the completion of the bundled payment period, for example, loss of coverage, patient expires or admission to a hospital that is not included in the bundled payment arrangement.

Financial Operations

Although the term suggests that a lump sum is paid prospectively when a case is identified, in fact, the payment can be made either prospectively or retrospectively. If the latter, the payor and provider entity perform a reconciliation of actual expenditures that occurred during the bundle period and make an adjustment depending on whether the actual expenditures were above or below a target amount.

The target amount could be established by a comparison group of patients or an agreed upon benchmark.

Another aspect of bundled payment arrangements involves distributions of shared savings (if any) among providers and the payor involved. The potential for these distributions typically arises if the bundled cases are managed less expensively than they were previously managed by a matched comparison group or if the total cost of managing the bundled cases is lower than a previously agreed upon benchmark, provided quality of care has not been compromised.

Legal Compliance

There is a veritable laundry list of legal issues that can arise in bundled payment arrangements. So much so, that the federal government has issued waivers to many of them with respect to federal alternative payment models such as bundled payment.⁵ In the words of a joint statement on these waivers from the Office of Inspector General (OIG) and the Centers for Medicare and Medicare Services (CMS): “The Secretary has determined that the arrangements covered under these waivers are necessary to carry out the testing of the CJR model”⁶ [emphasis added by author]. (The CJR Model is a bundled payment model that was launched by CMS and applies bundled payments reimbursement methodologies to major joint replacement surgery such as hip and knee replacements.)

So, the question arises: What to do about commercial bundled payment models? Indeed, the jointly issued federal waivers apply only to the specific federal program for which they are designed. Bundled payment arrangements involving commercial and self-funded payors are not protected by these waivers and must, therefore, take into account numerous legal issues.

Antitrust. Pricing agreements between and among physician practices that compete in the same “relevant geographic area” are generally illegal per se under antitrust laws. Therefore, when competing physician practices agree to accept a certain rate under a bundled payment program, antitrust laws are implicated. However, if those practices are “clinically integrated” or “financially integrated,” the pricing agreements may be permissible. Bundled payment models typically require adherence to some degree of clinical uniformity, which can help establish the fact that the practices meet the test for clinical integration. Fortunately, the U.S. Justice

Department and Federal Trade Commission, which jointly enforce federal antitrust laws, have published numerous materials that can be used to guide the structure of a bundled payment arrangement.

Stark. The Stark Law generally prohibits referrals for federally funded healthcare services (e.g., payable by Medicare) by physicians to entities in which they have a “financial interest.”⁷ Since bundled payment models may involve physicians who have financial relationships with entities to which they may refer within the bundled model (e.g., employment agreements with a hospital, interests in an ambulatory care facility, interests in an imaging center, etc.) the legal structure must be carefully designed to comply with Stark. That is, all referrals generally prohibited by Stark must be structured to fit within an available Stark exception.⁸ (As noted earlier in this article, federal waivers pertaining to the Stark Law may apply to certain federal bundled payment arrangements.)

Anti-Kickback. The Anti-Kickback Statute prohibits any person, whether a physician or not, from offering or receiving anything of value for the purpose of inducing a referral that results in the submission of a claim for payment by the federal government.⁹ Unlike the Stark Law, which is a “strict liability” statute, the Anti-Kickback Statute is triggered only if the individual *intended* to induce the referral with his or her action. As noted above, certain waivers of the anti-kickback law may apply with respect to federally sponsored bundled payment arrangements, such as CJR. Prudence dictates that commercial and self-funded bundled payment arrangements should be structured to fit with all applicable “safe harbors” that pertain to the Anti-Kickback Statute, to the extent possible.¹⁰

Civil Monetary Penalty. The Civil Monetary Penalty law, which applies to federally funded healthcare programs, prohibits, among other things, hospitals from paying physicians to reduce medically necessary services.¹¹ As noted above, waivers to these laws may be available for certain federally sponsored bundled payment programs.

Professional Regulation: The Board of Medical Examiners. Bundled payment programs must also comply with local laws governing professional practices (e.g., physicians, physical therapists, etc.). These laws, which vary from state-to-state, may prohibit the “corporate

practice of medicine” and, therefore, would not permit a lay person or an entity owned by lay persons to provide professional services or bill for them on its own behalf. In both New Jersey and New York, the corporate practice of medicine is prohibited. Unless a rather narrow exception applies, professional practices must be owned by licensees, and physicians cannot cede their professional judgment to non-licensed individuals. That is, pursuant to the prohibition of the corporation practice of medicine, a lay business entity cannot direct physicians to make, or not make, treatment decisions (e.g., intended to reduce actual expenditures and, thus, increase the entity’s and/or a participating provider’s share of revenue derived from the bundled payment). Bundled payment models—which can blur the lines that otherwise distinguish the discrete roles of physicians, hospitals, payors, and other healthcare providers—must, therefore, be carefully structured to comply with these types of local laws.

Insurance Laws. Bundled payment models could involve risk assumption or otherwise be structured in a way that requires compliance with state insurance laws. For example, if an entity involved in the arrangement meets the definition of an organized delivery system (as discussed in the “Large Group Practices and Bundled Payments” section of this article) but fails to become certified or licensed (whichever applies) by the New Jersey Department of Banking and Insurance (DOBI), the arrangement could be in legal jeopardy.

The Employee Retirement Income Security Act (ERISA). Bundled payment models involving employer-sponsored health plans and which also provide for distributions of shared savings can trigger legal issues under ERISA. ERISA imposes strict rules governing the use of employee “plan assets.”¹² Having the ability to exercise discretion with respect to the use of plan assets (which must be held for the exclusive benefit of plan beneficiaries) triggers fiduciary obligations. Depending upon how a bundled payment program is structured, the source of funds from which shared savings are based, and the way in which shared savings payments may be characterized, ERISA’s fiduciary requirements may be implicated. Therefore, architects of bundled payment arrangements that involve employee-sponsored health plans must pay close attention to ERISA laws and related guidance issued by the U.S. Department of Labor (i.e., the federal agency that enforces ERISA).



PHYSICIAN GROUP PRACTICES AND BUNDLED PAYMENTS

Physician group practices can participate in bundled payment arrangements provided the arrangement does not violate or conflict with the legal structure of the group. Partnership agreements, stockholder agreements, employee contracts, bylaws, operating agreements and the like must be carefully examined to determine whether the bundled payment arrangement, which could impose treatment guidelines and incorporate specific compensation terms, would be permitted under the group's existing legal instruments.

Employment agreements typically set forth detailed compensation provisions, often based upon formulas that have been subject to exhaustive internal discussion and negotiation within the group. Bundled payment models may require a different approach to compensation. Accordingly, existing employment contracts (and any other legal instrument that governs compensation) must be carefully reviewed and amended if necessary to avoid a challenge from a member of the physician group that the bundled payment arrangement is unenforceable. For example, if a patient's medical expenses exceed the bundled payment, future physician payments might be used to offset the deficit. If physicians have not agreed to that type of offset, they could argue that the offset provision is unenforceable because the underlying employment agreement was not lawfully amended. Accordingly, the offset could be void and the bundled payment model could be in jeopardy.

Bundled payment models may incorporate treatment guidelines or best practices requirements that may not be addressed in the group's existing legal instruments. Indeed, such instruments may affirmatively reject the ability of the group to impose specific treatment guidelines on any of its members. An inventory of the group's legal instruments (e.g., bylaws, operating agreement, stock holder agreement, formally adopted policies and procedures, employment agreement, etc.) should be taken to ensure that the bundled payment arrangement does not violate any of them. It may be advisable to amend existing legal instruments to express an affirmative recognition and permission by the members of the group to have the group enter into the bundled payment arrangement.

ORGANIZED DELIVERY SYSTEMS (ODS) AND BUNDLED PAYMENTS

When contemplating the organizational structure of a bundled payment program in New Jersey, a fundamental question is whether any entity involved is an organized delivery system.¹³ For example, a corporation or limited liability company that contracts on behalf of a network of healthcare providers could be an organized delivery system, depending upon the purpose and scope of its contracts and the manner in which it is organized.¹⁴

Today, if the ODS assumes "financial risk" it may require a license.¹⁵ (Organized delivery systems that do not assume financial risk obtain "certification" rather than "licensure."¹⁶)

What is Financial Risk?

"Financial risk" means exposure to financial loss that is attributable to the liability of an organized delivery system for the payment of claims or other losses arising from covered benefits for treatment or healthcare services other than those performed directly by the person or organized delivery system liable for payment, including a loss-sharing arrangement. A payment method wherein a provider accepts reimbursement in the form of a capitation payment for which it undertakes to provide healthcare services on a prepayment basis shall not per se be considered financial risk. A financial risk shall exist if, under an agreement between the organized delivery system and the carrier, the financial obligations of the organized delivery system for payment of benefits or for providing treatment or healthcare services does or potentially may exceed any payments that may be received from the carrier. Financial obligation shall include the attendant administrative costs related to providing the treatment or services. (N.J.A.C. 11:22-4.2.)



Indeed, the New Jersey ODS statute and regulations specify when, for example, an entity that may appear to meet the definition of an ODS (e.g., a traditional IPA) is not required to obtain ODS certification.¹⁷

If a new ODS must be formed, New Jersey regulations set forth the application requirements that vary depending upon the functions the entity will perform, e.g., network management, utilization review design, appeals, credentialing, etc.¹⁸ Operating an ODS, whether licensed or certified, involves the creation and adoption of numerous internal policies and the submission of numerous documents and reports to the DOBI. The types of policies required by the DOBI depends upon the ODS's activities. If the ODS will accept risk, it must comply with financial deposit and reserve requirements.¹⁹ Licensed ODSs are also subject to inspection and examinations by the DOBI.²⁰ ODS applications for certification and licensure can be found on the New Jersey Department of Banking and Insurance website www.state.nj.us/dobi/division_insurance/managedcare/mcods.htm.

RISK ASSUMPTION AND RISK MITIGATION

The assumption of financial risk—to some degree—is inherent in bundled payment arrangements. Arguably, that is the point, and that is why it can be an effective cost control strategy. In some instances, a physician's risk may be limited to "upside risk" only, whereby the only financial risk would be the loss of a bonus payment. In other instances, the physician could be exposed to limited downside risk, such as having to accept a discount on rates in the event performance targets are not met. But in other instances, a physician or group may be at risk for high-cost episodes of care incurred by patients included in the model.

Understanding the degree to which financial risk is transferred to individual physicians and physician groups is critical and can vary widely under different bundled payment models. If the arrangement could potentially shift financial risk to the physician for expenses arising from extremely high-cost cases, that risk could be mitigated by stop-loss insurance, in which case, the stop-loss coverage could be triggered if costs exceed a certain fixed dollar or other appropriate threshold (e.g., upon exceeding "X" standard deviations from the average cost per patient).

CONCLUSION

The ripple effects of federal and local efforts to transform the U.S. healthcare delivery system from a volume-based to a value-based system include, among them, the proliferation of bundled payment arrangements, the consolidation of similarly situated stakeholders in the healthcare system and the convergence of historically antithetical healthcare enterprises. These effects are further complicated by state laws, such as the ODS laws in New Jersey, which arose in the wake of the failure of a large New Jersey HMO.

Survival strategies for many physicians and physician groups require extremely close attention to trends set by the federal and local government and the agility to effectively respond to those trends. Bundled payment is one such trend, and it has been wholly embraced by the federal government, i.e., CMS, which arguably shapes the healthcare delivery system more than any other single stakeholder.

These trends create additional ripple effects such as blurring historical boundaries among providers, insurers, professional licensees and lay businesses—boundaries that have been reinforced by a complex array of existing laws. Successful navigation of these laws and an understanding of how these historic boundaries are shifting have become more complicated but are, nevertheless, an imperative for those practitioners wishing to embrace these trends.



CMS Bundled Payment Initiatives

The Affordable Care Act, colloquially referred to as Obamacare, created, within the Centers for Medicare and Medicare Services (CMS), another center referred to as the Center for Medicare & Medicaid Innovation (CMMI or the Innovation Center). CMS, through the Innovation Center, has launched numerous, far-reaching bundled payment initiatives that involve hundreds of hospital, hundreds of physician groups and tens of thousands of patients. A few examples include the following:

Bundled Payments for Care Improvement Initiative (BPCI) was evaluated by the Lewin Group, which based its results on more than 58,000 episodes of care.¹ These 58,000 patient episodes involved a national group of providers who voluntarily participated in the BPCI, including 385 acute care hospitals, 283 physician group practices, 681 skilled nursing facilities and others.²

Oncology Care Model is a national bundled payment model involving 195 physician practices and 16 participating payors.³

Comprehensive Joint Replacement Care (CJR) is a mandatory bundled payment model imposed upon approximately 800 hospitals in 67 metropolitan statistical areas (MSAs).⁴

Bundled Payment Model for Cardiology Care has recently been proposed by the Innovation Center, applying payment rules to hospitals located in 98 randomly selected metropolitan statistical areas.⁵

¹ The Lewin Group. (2016, August). *CMS bundled payments for care improvement initiative models: 2-4, year 2 evaluation & monitoring annual report*. <https://downloads.cms.gov/files/cmimi/bpci-models2-4-yr2rpt-appendices.pdf>.

² Centers for Medicare & Medicaid Services. (2016, April 18). *Bundled payment for care improvement initiative (BPCI)*. www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-18.html.

³ Centers for Medicare & Medicaid Services. (2016, Oct. 11). *Oncology care model*. <https://innovation.cms.gov/initiatives/oncology-care/>.

⁴ Centers for Medicare & Medicaid Services. (2016, Oct. 5). *Comprehensive care for joint replacement model*. <https://innovation.cms.gov/initiatives/CJR>.

⁵ Centers for Medicare & Medicaid Services. (2016, July 25). *Notice of proposed rulemaking for bundled payment models for high-quality, coordinated cardiac and hip fracture care*. www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-25.html.

Barry Liss is a Director and Healthcare Team Leader at Gibbons P.C. in Newark, New Jersey. 

¹ See, e.g., Chustecka, Z. (2015, June 1). *New immunotherapy costing \$1 million a year*. www.medscape.com/viewarticle/845707.

² See, e.g., American Hospital Association. (2014, March). *The value of provider integration*. *Trendwatch*. www.aha.org/content/14/14mar-provintegration.pdf; Claffey, T. F., Agostini, J. V., Collet, E. N., Reisman, L., & Krakaur, R. (2012). *Payer-provider collaboration in accountable care reduced use and improved quality in Maine Medicare Advantage Plan*. *Health Affairs*, 31(9), 2074–2083.

³ The JAMA Network. (2016, September 19). *Hospital participation in Medicare bundled payment initiative results in reduction in payments for joint replacement*. <http://media.jamanetwork.com/news-item/hospital-participation-in-medicare-bundled-payment-initiative-results-in-reduction-in-payments-for-joint-replacement/>; RAND Corporation. (2010). *Analysis of bundled payment, technical report (TF-562/20)*. www.rand.org/pubs/technical_reports/TR562z20/analysis-of-bundled-payment.html.

⁴ See, e.g., Liss, B. (2016, December 19). *Bundled payments gain traction in health care top ten list - Part I*. *New Jersey Law Journal*, 222(50), 50; Liss, B. (2016, December 26). *Bundled payments, Part II*. *New Jersey Law Journal*, 222(51), 50.

⁵ See, Slavitt, A. M., & Levinson, D. R. (2015, November 16). *Notice of waivers of certain fraud and abuse laws in connection with the comprehensive care for joint replacement model*. www.cms.gov/Medicare/Fraud-and-Abuse/Physician-SelfReferral/Downloads/2015-CJR-Model-Waivers.pdf.

⁶ *Id.*, at 4.

⁷ 42 U.S.C. 1395nn.

⁸ 42 CFR 411.357.

⁹ 42 U.S.C. § 1320a-7b.

¹⁰ 42 CFR 1001.952.

¹¹ 42 U.S.C. § 1320a-7a(b).

¹² 29 USC 1103.

¹³ See N.J.S.A. 17:48H-1 et seq.

¹⁴ N.J.S.A. 17:48H-1.

¹⁵ N.J.S.A. 17:48H-11.

¹⁶ N.J.S.A. 17:48H-3.

¹⁷ N.J.A.C. 11:24B-2.1(c).

¹⁸ See, Liss, B. (2015, September 1). *An idea whose time has come: Organized delivery systems in N.J.* *New Jersey Law Journal* [Health Care Supplement].

¹⁹ See N.J.S.A. 17:48H-19 [minimum net worth]; N.J.S.A. 17:48H-20 [deposits of cash, securities]; N.J.S.A. 17:48H-21 [maintenance of fidelity bond]; N.J.S.A. 17:48H-22.2 [increase in amount of capital and surplus required of licensed organized delivery system]; N.J.S.A. 17:48H-22.3 [determination of increase, revision or redetermination; factors].

²⁰ N.J.S.A. 17:48H-17.