Bundled Payment Top Ten List

Part II

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This is the second of a two-part article on the subject of bundled payment reimbursement arrangements, which are becoming more widely implemented in health-care settings. (Part I was published in the prior issue of the *New Jersey Law Journal*.)

As noted in Part I, bundled payment arrangements show promise for controlling costs and maintaining quality. Indeed, the federal government has launched a $10 billion Bundled Payment Care Improvement (BPCI) initiative involving approximately 1,400 organizations. (Fischer, E.S., "Medicare's Bundled Payment Program for Joint Replacement Promise or Peril?" Journal of the American Medical Association, Editorial, Sept. 27, 2016, Vol. 316, No. 12.) These arrangements implicate a range of legal constraints, however. This top-ten list is intended to highlight key components of bundled payment arrangements that must be kept in mind when structuring them.

Items 1 through 5 have been discussed in Part I: (1) Temporal Boundaries; (2) Exclusions; (3) Early Termination; (4) Participating Providers; and (5) Financial Operations. Below is a discussion of items 6 through 10.

6. Allocation of the Bundled Payment

Bundled payment models typically involve the creation of a pool (or pools) of funds that are held for distribution to providers who meet certain quality and utilization targets. One common method for allocation is to have providers agree to a fixed floor, which may be lower than their standard rates. An incentive pool would be created by holding back amounts that would be needed to: (1) pay providers the difference between the low floor guarantee and their standard rates; and (2) pay providers a bonus in excess of standard rates. Under this model, the amounts withheld would be at risk if quality and utilization standards are not achieved. On the other hand, if those standards were achieved, the withheld amounts would be released and, depending on performance, the provider could receive bonus payments. Accordingly, the provider would have a financial incentive to achieve quality and utilization standards to not only maintain current rates, but to receive more.

Determining whether utilization standards are met may include comparing patients treated under the bundled payment model to a comparison group of similar patients (age and risk adjusted); alternatively, the comparison can be made with respect to a benchmark. A typical threshold for distribution of the withheld amounts is that there has been no diminution of quality. Criteria for the release of the bonus payment after the provider has demonstrated that quality has not been compromised could be that the bundled payment group is less expensive to treat than the comparison group (or the benchmark). The difference between the lower cost of treating the bundled payment group and the higher cost of treating the comparison group (or benchmark) can be viewed as actual cost savings, and that amount is shared among the payor and providers pursuant to a previously agreed upon formula. (Note that distributions of shared savings with respect to a self-funded health plan may require an analysis of ERISA laws pertaining to the treatment of "plan assets" if those funds are indeed "plan assets" as that term is defined in ERISA.)

7. Clinical Integration and Antitrust

When bundled payment arrangements involve pricing agreements among horizontal competitors, such as competing physician practices, antitrust issues arise. Generally, antitrust laws prohibit horizontal competitors to enter into price fixing agreements. However, the federal antitrust enforcement agencies, the Department of Justice and the Federal Trade Commission, recognize exceptions to this general rule if the providers are either "clinically" or "financially" integrated and, accordingly, would subject the arrangement to a "rule of reason" analysis. (See, "Statements of Antitrust Enforcement Policy in Health Care Issued by the U.S. Department of Justice and the Federal Trade Commission," Washington: U.S. Department of Justice, August 1996.) Typically, a bundled payment arrangement would require some degree of clinical integration among providers and could include some degree of financial integration. Careful analysis of regulatory guidance from governmental enforcement actions, advisory opinions and the like is therefore required to properly structure the arrangement.

8. Fraud and Abuse / CMP Law

Health-care executives, providers, and their attorneys are (or should be) well versed in fraud and abuse laws that govern the industry. These laws include, among others, the Civil Monetary Penalty (CMP) law, which prohibits hospitals from paying physicians to reduce or limit medical services. If a bundled payment model is designed so physicians are rewarded for limiting care,

there could be a CMP violation. Accordingly, all relevant CMP enforcement actions, advisory opinions, and similar governmental guidance pertaining to gainsharing arrangements should be analyzed to understand how those laws have been interpreted by the relevant enforcement agencies.

Bundled payment arrangements can also trigger federal laws that prohibit certain physician self-referrals (commonly known as the Stark Law), because the bundled payment establishes a "financial relationship" involving providers (such as physicians) for the purpose of rendering "designated health services." (42 U.S.C. 1395nn). The arrangement must therefore meet the criteria of an existing Stark exception. (42 CFR 411.357). Additionally, violations of Stark can constitute violations of the False Claims Act (which can lead to criminal liability and significant financial penalties), and prosecution under the False Claims Act can be triggered under the whistleblower provision of that act, thus increasing the probability of prosecution. State self-referral prohibition laws would also apply and are often broader in scope than Stark. That is, a bundled payment arrangement involving a commercial payor may not implicate Stark but could violate state law (such as the "Codey" law in New Jersey).

Federal anti-kickback laws must also be taken into account. The Federal Anti-Kickback Statute is violated if one purpose of the exchange (or offer to exchange) is intended to induce referrals of federal health-care program business. (*United States v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985)).In other words, an arrangement that espouses the virtues of, and perhaps even achieves the laudatory goals of quality, cost savings, efficiency and improved health status would be illegal if one purpose of it is to induce such referrals. There are, however, exceptions, or "safe harbors," which expressly permit activities that might otherwise be suspect. (42 CFR 1001.952). Accordingly, the arrangement should be structured to fit within all applicable safe harbors if possible (e.g., safe harbors with respect to employer-employee relationships, personal services and management agreements, and agreements regarding the rental of space). If the arrangement cannot meet all elements of a safe harbor, it should incorporate as many elements as possible.

9. Corporate Practice of Medicine

Many states prohibit, or strictly limit, the provision of professional medical services to only licensed health-care providers, disallowing lay ownership of professional practices. This

prohibition of the "corporate practice of medicine" (CPM) has a two-fold implication for bundled payment arrangements. First, if a physician cedes his or her professional medical judgment to a lay business investor, the CPM prohibition could be violated. Second, the economic structure of the bundled payment model must conform to applicable CPM restrictions. That is, in some states, a hospital, non-licensed or lay business entity may not be permitted to accept a bundled payment, a portion of which includes reimbursement for the provision of professional physician services. Accordingly, the model must be structured so services are billed and reimbursed in a manner that does not offend the CPM prohibition of the state in which the model operates.

10. Local Analysis

Bundled payment arrangements may implicate local laws, such as state laws that govern the ability of providers or other entities to assume financial risk, statutory requirements of commercial health insurance products, state self-referral prohibitions, state anti-kickback laws, provider geo-access requirements for commercial and government sponsored health plans, and reimbursement rules regarding state health programs. Therefore, careful analysis of and compliance with local regulatory requirements regarding the regulation of insurance, professional licensing, hospital licensing, insurance regulation, self-referral prohibitions and state anti-kickback laws is required in order to lawfully structure a bundled payment arrangement.

Conclusion

Whether one views bundled payment arrangements as a desperate attempt to reverse the unsustainable growth in health-care expenditures or a welcome and long overdue paradigm shift in how to pay for health-care expenses, or both, leaders of health insurance companies, hospital systems, physician groups, and ancillary providers such as rehabilitation facilities and home health agencies, are now weighing the pros and cons of these types of reimbursement models. Indeed, CMS has mandated bundled payments regarding its comprehensive joint replacement model for approximately 800 hospitals as of November 2015. Commercial insurance and self-funded health plans have also participated in bundled payment demonstrations and have instituted ongoing bundled payment arrangements. These reimbursement models have arrived and may be here to stay, and, therefore, familiarity with these central and fundamental components is baseline knowledge for today's health-care executives and attorneys who represent them.