Driving Health Care Efficiencies: Consolidate and Innovate, But Proceed with Caution

Physician Self-Referral Reform Still Pending, Health Care Antitrust Enforcement Aggressive

Despite the U.S. substantially outspending peer high-income nations with almost 18 percent of GDP dedicated to health care, on any number of statistical measurements from life expectancy to birth rates to chronic disease, the U.S. achieves inferior health outcomes. In short, Americans receive a very disappointing return on investment on their health care dollars, causing economic and social strain. Accordingly, the debates rage on: What is the top driver of health care spending? Among the culprits: Poor communication and coordination among disparate providers, paperwork required by payors and regulations, well-intentioned physicians overprescribing treatments, drugs and devices, outright fraud and abuse, and medical malpractice litigation.

Fundamentally, what is the best way to reduce U.S. health care spending, while improving the patient experience of care in terms of quality and satisfaction, and driving better patient health outcomes? Mergers, partnerships and consolidation in the health care industry, new care delivery models like accountable care organizations and integrated care systems, bundled payments, information technology, innovation through new drugs and/or new medical devices, or some combination of the foregoing?

While debate rages on Capitol Hill over “repeal and replace,” only limited attention has been directed toward reforming the current “fee for service” model pursuant to which providers are paid for volume of care rather than quality or outcomes. Indeed, both the Patient Protection and Affordable Care Act (ACA) and proposals for its replacement focus primarily on the reach and cost of providing coverage for health care, rather than specifics for the delivery of health care. With the U.S. expenditures on health care producing inferior results, experts see consolidation and alternatives to “fee for service” as fundamental to reducing costs. Integrating care coordination and delivery and increasing scale to drive efficiencies allows organizations to benefit from shared savings and relationships with payors and vendors. Deloitte forecasts that, by 2024, the current health system landscape—which includes roughly 80 national health systems, 275 regional systems, 130 academic medical centers, and 1,300 small community systems—will morph into just over 900 multi-hospital systems.

Even though health care market and payment reforms encourage organizations to consolidate and integrate, innovators must proceed with extreme caution. Health care organizations attempting to drive efficiencies and bring down costs through mergers may run afoul of numerous federal and state laws and regulations. Calls for updates or leniency in these laws are growing, including the possible recognition of an “Obamacare defense” to antitrust restrictions and speculation that laws like Stark that restrict physicians from having financial relationships will be repealed, ostensibly to allow sharing of the rewards reaped from coordinated care. In the meantime, however, absent specific waivers or exemptions, all the usual rules and regulations apply, including antitrust constraints, physician self-referral and anti-kickback laws and regulations, state fraud and abuse restrictions, and more. In short, a maelstrom of conflicting political prescriptions, health care regulations, and antitrust restrictions undermine the ability of innovators to achieve efficiencies through joint ventures, transactions, innovative models and other structures. Last fall, bipartisan legislation was introduced in the House and Senate to make significant reforms to the Stark Law, which bars a physician from referring patients to an entity with which the physician has a financial

relationship, subject to certain limited exceptions. These bills (H.R. 4206 and S. 2051) recognize that some aspects of the Stark Law interfere with the more recent federal policy that the development and widespread use of innovative alternative payment models (APMs) should be fostered.

Under the Stark Law, the entity receiving a prohibited referral cannot bill or collect for designated health services performed in connection with the referral. For this purpose, the term "financial relationship" includes direct and indirect ownership or investment interests and direct or indirect compensation arrangements between a referring physician and the entity providing a designated health service. The Stark Law, however, authorizes certain exceptions (i.e., waivers). For example, under the physician services exception, physicians may self-refer for services personally performed or supervised by the physician or a member of his or her group practice. The in-office ancillary services exception allows a physician to self-refer specified designated health services rendered or supervised by the physician, or a member of their group practice, in either the same building that contains the physician's office, or a specific centralized building that are billed for by their group practice, and not by a separate provider or entity.

H.R. 4206 and S. 2051 take important steps toward making Stark waivers available beyond the confines of these demonstration projects. In other words, the bills potentially would allow waivers for APMs that are not demonstration projects, although the APMs would have to meet criteria established by the Centers for Medicare and Medicaid Services (CMS).
The current-law waivers offer limited relief for a few specific delivery models, but the waivers do not offer sufficient latitude for providers to broadly integrate in an effort to rein in costs. Without greater latitude, providers face regulatory obstacles to collaboration and integration. The new legislation would open the door for providers to increase integration and innovation in the name of achieving greater efficiency.

For more information on the tension between health care efficiencies and antitrust and regulatory laws, please see "Health Care Efficiencies: Consolidation and Alternative Models vs. Health Care and Antitrust Regulation - Irreconcilable Differences?" by Michael W. King as published in the *American Journal of Law & Medicine* (November 2017, available upon request).

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