Coordination of Care or Conflict of Interest? Exempting ACOs from the Stark Law

Genevieve P. Kanter, Ph.D., and Mark V. Pauly, Ph.D.

Suppose you are a Medicare-insured patient with coronary artery disease. You will visit, on average, 10 physicians at six practice sites in a given year.[1]

Such fragmentation of care has spurred efforts by health care systems and payers to coordinate the delivery of care by multiple providers in a range of settings. Hospitals and physician practices are merging at increasing rates to form integrated delivery systems with the goal of delivering harmonized services across the continuum of care — from initial primary care visit to hospital admission to nursing facility discharge. In addition, under the Affordable Care Act, hospitals and physician groups are encouraged to form accountable care organizations (ACOs) that jointly contract to deliver care to specified populations of Medicare beneficiaries. Care coordination has become a central theme of new payment and delivery systems and is believed to be an indispensable strategy for eliminating delivery inefficiencies, controlling costs, and improving outcomes.

There is, however, at least one downside to care coordination arrangements: they clash with existing regulations on financial conflicts of interest in medicine. This set of regulations, collectively known as the Stark law, prohibits physicians from referring patients to providers when a financial arrangement would allow the referring physician to benefit from such a referral. For example, physicians who have a profit-sharing agreement with a nursing home are prohibited from referring their Medicare and Medicaid patients to that facility. The concern is that if physicians earn more money when they refer patients for additional care, they have an incentive to recommend more services, regardless of medical necessity. Indeed, numerous studies have reported increased utilization of services and greater spending when physicians can, because of either exemptions to the Stark law or poor enforcement of it, refer their patients to facilities in which they have a financial stake.[2] ACO arrangements may violate self-referral prohibitions because of the shared-savings and referral relationships among providers within an ACO.

This tension between care coordination and conflicts of interest has come to the fore with a recent request for information issued by the Centers for Medicare and Medicaid Services (CMS) in the service of "addressing unnecessary obstacles to coordinated care . . . caused by the physician self-referral law."[3] CMS currently allows physicians and organizations participating in Medicare ACOs to receive temporary waivers from prosecution for violations of the Stark law. But legislation introduced in November would establish a permanent exemption for providers in ACO and other alternative payment and integrated care arrangements.

The easy way forward would be to add this exemption to the burgeoning number of permanent Stark law exemptions — but we are convinced that that is not the right way. The clash between ACO arrangements and conflict-of-interest laws tells researchers something important about potentially negative consequences of ACOs that could undermine not only physicians' obligations to their patients, but also broader efforts to improve care and control costs. As policymakers deliberate on how ACOs fit into the existing regulatory landscape, a key question should be: Do the care coordination benefits of ACOs outweigh the harms from unnecessary referrals?

It is important to note that coordinated care and integrated delivery systems are predicated on the idea that operating efficiencies can be gained from vertical integration, which is defined as the merging of two entities, one of which provides a flow of inputs to the other. Examples of vertical integration in medicine include mergers between physician practices and hospitals and between primary care practices and specialty practices. Coordinated care mechanisms such as ACOs are a loose form of vertical integration in that hospitals and physician practices don't formally merge but contractually agree to share profits and jointly provide services for a population of patients. Vertical integration, the theory goes, reduces health care costs by eliminating redundancies, lowering transaction costs, and aligning incentives across the continuum of care.

Despite this promising possibility, studies have shown scant evidence of cost reductions. Studies of integrated delivery systems in the 1990s revealed negligible reductions in cost and little quality improvement. Studies of more recent mergers between hospitals and physician practices have shown that vertical integration has resulted in price increases and has had mixed effects on care quality.[4] And evaluations of Medicare ACOs have shown minimal cost savings for Medicare.[5]

Why the underwhelming effect? There are three likely culprits. First, when physician practices and hospitals combine, both parties become more constrained. Physicians are less able to refer patients to an unaffiliated hospital, even if that facility may be best able to serve a particular patient. Similarly, hospitals may be exclusively tied, for better or worse, to the practices that are part of their network.

Second, when physicians and hospitals are part of the same integrated system, physicians benefit from their affiliated hospital's profitability. Thus, when ACOs are paid under fee-for-service systems, as most are, physicians have an incentive to refer patients to hospitals and for other services within the system — the classic conflict-of-interest problem that the Stark law was trying to address. Moving from a fee-for-service system to bundling or a capitation-based system, in which providers are paid fixed amounts, would not necessarily improve matters, however, since there is evidence that such systems could lead to stinting on care and reduced quality.

Finally, studies of the gains from coordinated care may be underwhelming because there may simply be no low-hanging fruit for eliminating inefficiencies, or because implementing the administrative systems required to coordinate care is more costly than anticipated.

These explanations suggest that ACOs and other care coordination programs have important fundamental limitations in their ability to improve care and reduce costs. Enacting a permanent Stark exemption for ACOs would therefore most likely lead to few gains and substantial losses. Instead, a careful reevaluation of ACOs is needed.

Moving forward, we think that studies of large-scale care coordination payment mechanisms should be conducted systematically, under conditions that enable rigorous evaluation of the positive and negative effects of integration. The existing waiver arrangements, which protect Medicare ACOs from prosecution under the Stark law for specified periods, could be continued and even expanded to include other alternative payment and delivery systems — but we believe that design elements ensuring valid comparisons between ACOs or integrated systems and non-ACO alternatives must be in place. Sustained cost savings and superior quality of care should be demonstrated under controlled conditions before policymakers enact ACO-related changes in the Stark regulation.

More generally, however, Stark law exemptions are second- or third-best solutions to the conflict between ACOs and the law. Despite the admirable intent of the Stark regulation, it is badly in need of critical reexamination. The existing 30-plus exemptions to the law render it ineffective in preventing waste and unnecessary referrals. Most important, concerns related to physician self-referrals and kickbacks derive from flaws in Medicare's payment systems, so continuing an ad hoc exemption approach to regulating conflicts of interest seems fundamentally misguided.

Although granting a Stark exemption for ACOs seems like a simple solution to the sticky problem of ACO arrangements clashing with the Stark law, it is a bit too simple. The tension between care coordination and conflicts of interest should not be used as a pretext for weakening an already impaired Stark regulation; instead, we think it should be used as strong motivation for reevaluating the way we approach both care coordination and regulation of conflicts of interest.

Disclosure forms provided by the authors are available at NEJM.org.

From the Division of General Internal Medicine, Department of Medicine, and the Department of Medical Ethics and Health Policy, Perelman School of Medicine (G.P.K.), and the Department of Health Care Management, Wharton School (M.V.P.), University of Pennsylvania, Philadelphia.

1. Elhauge E, ed. The fragmentation of U.S. health care: causes and solutions. New York: Oxford University Press, 2010.
2. Adashi EY, Kocher RP. Physician self-referral: regulation by exceptions. JAMA 2015;313:457-8.
3. Centers for Medicare & Medicaid Services. Medicare program; request for information regarding the physician self-referral law. June 25, 2018 (https://www.federalregister.gov/documents/2018/06/25/2018-13529/medicare-program-request-for-information-regarding-the-physician-self-referral-law).
4. Post B, Buchmueller T, Ryan AM. Vertical integration of hospitals and physicians: economic theory and empirical evidence on spending and quality. Med Care Res Rev 2018;75:399-433.
5. McWilliams JM, Hatfield LA, Chernew ME, Landon BE, Schwartz AL. Early performance of accountable care organizations in Medicare. N Engl J Med 2016;374:2357-66.

DOI: 10.1056/NEJMp1811304
Copyright © 2019 Massachusetts Medical Society.