The coronavirus disease 2019 pandemic has brought into focus the limits on flexibility and innovation associated with market consolidation in care delivery. While anecdotes about the ossification in care delivery predominate, broader economic indicators point to the negative outcomes of consolidation. As hospital industry consolidation has increased over the past 20 years, labor productivity has remained flat or negative. Increasing costs from digitization of records and other regulatory mandates has resulted in a wave of physicians seeking corporate employment. This has left a minority in independent practice, a market structure associated with increased costs. With many US individuals residing in consolidated markets for both hospital and ambulatory care, policy makers are confronting the limits of antimonopoly law. Because antitrust law affects the entire economy, policymakers seek more targeted solutions to increase competition in health care delivery. Encouraging growth of physician-owned and physician-operated enterprises through Stark law reform represents a promising, untapped policy lever to increase competition between physician and corporate care delivery.

Physicians and corporations have long competed for patients. Both have experienced the tensions of volume-driven revenue in fee-for-service settings and economic incentives to limit care in early capitated, managed care programs. The dominance of fee-for-service medicine juxtaposed with rising Medicare program expenditures in the 1980s brought increased scrutiny to physician self-referral.

Policy makers responded with a series of reforms limiting self-referral by physicians, collectively known as Stark law. Passed as a series of legislative proposals and federal rule making, Stark law prohibited physician self-referral in the Medicare program for designated health care services that they own, including physical and occupational therapy, radiology services, home health services, and other services. While most policymakers saw no reason to think that corporations might have less self-interest than physicians, corporate self-referral remained incompletely addressed.

In the subsequent decades, markets responded to the challenges of self-referral. Managed care developed tools to address health care overutilization: utilization review, prior authorization, network tiering, and changes in benefit design (eg, bundling). Medical specialty societies created tools to address inappropriate use, such as the Choosing Wisely criteria. Increasingly, specialized care narrowed specialists’ scope of practice, fundamentally changing the nature of referral relationships.

Stark law itself created new challenges. Patients, who are frequently not informed consumers, depend on both health systems and physicians to participate in shared decision-making. Prohibiting self-referral for either corporations or physicians can reduce access for those with the greatest socioeconomic and health burdens, such as disabled individuals, elderly individuals, and those with multimorbidities, by transferring tasks, such as quality assessment of physical therapy centers, care coordination for home health, and follow-up, back onto the patient. Unsurprisingly, patients frequently struggle, resulting in avoidable declines in functional status, hospital readmission, and loss of independence. As we transition to value-based payment, Stark law presents a barrier to physicians who seek to seek to create value through integrated care and one-stop shopping for these beneficiaries. Creating a level playing field by applying Stark laws to institutional clinicians would serve to create the same barriers to access for patients.
At its core, Stark law conflates the need for a regulatory solution for the challenges of self-referral and ownership with a statutory ban, reducing competition by serving as a brake on physician-owned and physician-operated integrated care models. Red-line boundaries for self-referral are nonsensical: physicians can refer patients to other physicians, yet they are statutorily prohibited from referring them to services they own. For example, an orthopedist can refer a patient to a shoulder specialist physician partner, while they are simultaneously forbidden from referring to owned services, such as physical therapy or imaging centers, both critical for integrated orthopedic care. In contrast, corporations can engage in self-referral with fewer restrictions, because fraud, waste, and abuse regulations provide oversight of corporate self-referral in place of a blanket ban. In this setting, many corporate hospitals (nonprofit and for profit) even mandate self-referral and actively target leakage to competitors.

Centers for Medicare & Medicaid Services has long recognized these challenges, and in conjunction with the Office of the Inspector General, it has implemented recent reforms to Stark law and the Anti-Kickback Statute. These defined the term value-based enterprise and set specific, safe-harbor exceptions for such entities when they enter into value-based arrangements bearing full financial risk, considerable downside risk (10% or more), or general value-based arrangements. Operational execution remains challenging. Physicians and organizations will have to ensure that their organization and contract meet the definitions and prespecified criteria prior to the time of referral, a complication that clashes with the realities of time-pressured, resource-constrained clinical practice.

Simpler alternatives could be executed in the marketplace. A prohibition on payment for referrals within a fee-for-service context should be maintained for both physicians and corporations, encouraging markets to transition to value-based care. Self-referral for both physicians and corporations should be permitted within capitated, risk-adjusted payment programs, a universe including Medicare Advantage and Medicaid managed care. Allowing the benefits of self-referral within the confines of capitated payment better aligns financial incentives and ideally would promote both the growth of integrated care delivery and increased competition between corporate-owned and physician-owned models of care.

Concerns remain. Capitation can protect against overutilization through aligned incentives, a role dependent on health plans serving high-functioning intermediaries to control costs. As a model, capitation is effective only if rising costs and utilization are met by addressing volume, price, or intensity of care and not passed to taxpayers and employers in the form of higher capitation rates.

Operationally, tying self-referral exceptions to an easily identifiable measure, such as payer status, would facilitate automated execution in the now highly electronic clinical practice environment. Enhanced auditing and oversight by the Centers for Medicare & Medicaid Services, the Office of the Inspector General, and others, coupled with the tools of managed care, would help prevent fraud and abuse.

While future policy efforts should involve competition policy experts from the Federal Trade Commission and the Department of Justice Antitrust Division, Congress could modify Stark law to create a statutory exemption from self-referral for designated health services within the context of preexisting, capitated health benefit programs. Doing so could encourage the growth of clinician-owned and clinician-operated delivery systems, launching a new front in the war on consolidation in care delivery.
Hopkins Carey Business School, Baltimore, Maryland (Miller); Medical College of Wisconsin, Milwaukee (Ehrenfeld); The Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Wu).

**Conflict of Interest Disclosures:** Dr Miller formerly served as a Special Advisor at the Federal Trade Commission. He reports serving as a member of the Centers for Medicare & Medicaid Services' Medicare Evidence Development and Coverage Advisory Committee and receiving fees outside the submitted work from the Federal Trade Commission, the Health Resources and Services Administration, Rayus Research, Oxidien Pharmaceuticals, and the Heritage Foundation. Dr Ehrenfeld reports serving as a member of the American Medical Association Board of Trustees. Dr Wu reports grants from AIG and Gen Re and consulting fees from Osmotica, GlaxoSmithKline, ViIV, and Gore outside the submitted work.

**REFERENCES**
