

Special Commentary

CMS and the OIG Revise the Anti-Kickback, Stark and Self-Referral Regulations, Proclaiming: *"The rules provide greater flexibility for healthcare providers to participate in value-based arrangements and to provide coordinated care for patients."*

Now What??

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As recently as August of 2020, CMS was predicting that these recently proposed guidelines would be delayed by a year. Instead, on November 20th the final rules were published as part of a press release stating that they will be promulgated on December 2nd through the Federal Register. The effective date for most of the rules will be January 19th of 2021.

For those who have been anticipating these changes, the dates only matter to mark the end of a two-year process in which almost every healthcare constituency added their unique perspective to changing regulations which date back to 1989 with the original passage of the Stark Bill. This recent process was characterized as a “patients over paper” reform that could streamline regulations and release providers to allow, or promote, improved coordination of patient care by removing what many in the healthcare industry felt were confusing regulatory standards and draconian penalties that actually had the effect of impeding care coordination and value-based contracting.

Following the December 2nd publication of the new rules in the Federal Register, it is reasonable to expect that every major law “health law” firm in the U.S. will be issuing a synopsis based upon its team’s analysis of what these new regulations might mean. I would not pretend to be able to offer a useful synthesis of these changes since hundreds of law clerks are drafting CLIFF Notes™ on them to stream into people’s inboxes throughout the holidays. Many in the industry will be reading the advance publications and drawing their own conclusions.

For those readers who feel compelled to review the material in its original form, be warned that the CMS document runs over a thousand pages and, separately, the OIG published its update in over 600 pages. These are interesting in that they include many of the industry comments on the proposed rules, as well as the CMS or OIG responses. Most significant, of course, is that they contain the final rules.

Almost every healthcare constituency will be affected in some way. The important roles of healthcare financial planners and executives will become obvious as consultants, contractors, and middle-market actors restructure their offerings to address new financial models inclusive of revised risk parameters and new approaches to physician involvement in reimbursement opportunities that expand the provider revenue base beyond fee-for-service. With fundamental change, there are always unintended consequences and unappreciated opportunities.

Included in these regulations are new safe harbors for value-based arrangements and the recognition of new levels of accepted risk within contracts that depend upon remuneration between contract participants (read that as doctors and hospitals). This is to foster collaboration engineered to assure better coordination and improved patient care. The regulations address safe harbor standards for the levels of risk assumed and the form of payment, along with the nature of the arrangements and their impact on the improvement of health outcomes or efficiency. Patient engagement is recognized as an element in the improvement of quality care and many features of the regulations allow tools to be used that will foster coordinated efforts between hospitals and doctors to manage healthcare outcomes together. Electronic health record support for physician practices is referenced, as is cybersecurity. Safe harbors are defined for groups participating in CMS-sponsored models, both existing ones and those yet to be proposed.

A CMS fact sheet states that the exceptions will allow physicians and other healthcare providers “to design and enter into value-based arrangements without fear that legitimate activities to coordinate and improve the quality of care for patients and lower costs would violate

the Stark Law.” However, the reimbursement implications will cause physicians who have only experience with fee-for-service reimbursement to perceive renewed pressure to enter arrangements that they have traditionally resisted. The regulations will also benefit selective network strategies that will channel patients into organizations that are designed around “outcome-based payments.” Market change may not be incremental as providers rush to be first in line to form new managed care offerings structured around these new definitions and safe harbors.

This event is more about financial modeling and transaction management than it is about compliance. Of course, one must acknowledge that compliance restraints still overshadow transactions, but there are new rules to understand and new definitions of old rules. The CFO needs to be at the table with a solid understanding of what this redefinition of traditional regulatory standards will mean for the institutions they guide. While there are no universal truths, depending upon the market in which healthcare changes will be made, there are some obvious issues that healthcare systems should be considering:

- Organizations need to have a prepared response to queries, both public and private, regarding these regulations. One can expect that entrepreneurial segments within the medical community will fashion their own plans which will include new hospital joint ventures and shared initiatives. Individual members of the medical staff will approach with requests based upon some of the features now allowed and encouraged in the regulations: i.e., assistance with medical records, care coordination staff, and cybersecurity.
- Opportunities exist to reconsider and redefine relationships with provider groups and doctors. The risk parameters have been softened and these groups will be factoring in these changes and seeking partnerships with healthcare organizations which were once thought to be impractical.
- Physician contracts need to be revalued and re-evaluated with new reimbursement models addressed. This may not mean a wholesale abandonment of present income determination methodologies, but this is the time to assure that there is flexibility injected in the contracts to allow for change as local markets embrace quality and value standards. The option to wait for contracts to expire is simply no longer practical.
- Strategic plans must be refreshed to acknowledge that commercial insurance plans may move quickly to value-based contracting. This was already beginning in many markets with employer-based health clinics and direct contracting, but these trends will gain new energy as middle-market consolidators craft arrangements based upon guarantees that hospitals and doctors are not accustomed to providing.
- Hospital franchises with specialty groups which do not have the flexibility to respond quickly to market demand must be reconsidered and reformatted. This includes not only the standard pathology, radiology, ER, and hospitalist contracts but also the monopolistic controls that some specialists have on procedural units or product lines.
- Collaboration must be reconsidered with groups that are foreign, or historically adversarial, to traditional healthcare organizations. This might include national organizations and venture capital firms. It might also include Medicaid and Medicare managed care delivery systems.
- Planning and budget cycles need to be revamped to be responsive to these changes. Bondholders will be advised by consultants using new measures to define prospectus

profiles and assess the relative going-forward viability of borrower entities. Organizations that demonstrate that they have embraced new streams of revenue – and the new models of attaining such – will be rewarded by the capital markets.

These changes to regulatory oversight were triggered by political initiatives to reduce paperwork and minimize government oversight. Whatever the motivation as to the timing of their release, the pressures that galvanized these changes have been felt within the healthcare sector for decades. Healthcare organizations are, by nature, conservative and slow to react. However, those that recognize this event as a rare opportunity will certainly be rewarded by significant advances in market share. The challenge will then be to manage the efficiencies that these new regulations have been crafted to allow.

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