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# Pandemic Lessons on Value-Based Care

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## What's Inside:



**It's hard to think about renovating a house that is on fire.** The pandemic has created significant opportunities and challenges for each one of us and much of what we have logically focused on is the immediate needs. However, we are reaching a point where it is time to think about renovations to the healthcare system. This article offers some ideas about how to do this from a value-based care perspective.

## Managing COVID and Other Healthcare Needs

COVID is not going away for years, if ever. In the history of man there is only one disease that we have eradicated globally—smallpox. The effort required to accomplish this took decades of coordination. Every other disease, including the bubonic plague, is still around. In fact, over 2,000 people a year still get it, although it is usually only a handful in the U.S. Thus, we should plan on a future that includes management of COVID in some form or fashion. Hopefully our ability to manage COVID through public health measures, vaccines, and therapeutics will continue to increase.

While the current attention on COVID has been necessary, it has come at the exclusion of other health needs. Everything from management of chronic disease to preventative services has become a lower priority. It will take time to determine the actual impacts of this as it is likely that we have been avoiding some necessary care. However, it is also likely that we are not focused enough on the known top causes of mortality including heart disease and cancer.

## Positive Changes Arising from the Pandemic

A benefit of COVID has been the ability to accelerate remote care and telemedicine. While the technology has been in place for years, payment was variable, and adoption slow. With in-person care no longer an option, telehealth services became covered and volumes went up like a rocket. This service has now been solidified as a viable form of care delivery. Ironically, MedPAC is considering ways to modify the payment for these services as they are now concerned about overuse.

Another benefit of COVID is that organizations that made investments in value-based care contracts have seen significant payouts. While the pandemic has decimated finances for almost all providers, payers have been having windfall profits. Although value-based care delivery has been called a fad and adoption has been very slow in most markets, COVID has established a clear and firm place for this strategy.

## Enhancing Value-Based Care Delivery

Value-based care delivery requires operations that are not contained in traditional healthcare delivery to identify who needs what, when, and how. There are several

### → Key Board Takeaways

As boards and senior leadership work to develop or enhance their value-based care delivery strategy, they should:

- Revisit and consider increasing the organization's investment in value-based care delivery efforts as both a hedge against fee-for-service and build out of a core capability.
- Make it a priority to have a functional segmentation and interventions process to better manage patients and improve outcomes. This includes having the data and analytical capabilities needed to implement the organization's value-based care strategy.
- Ensure that staff have the right workflow tools to operationalize the segmentation and reach out to the right patients with the right proactive care options. These tools should feed into dashboards to monitor the right metrics, and these dashboards can be used by management and boards to set goals and track progress towards those goals.

key elements that boards and senior leadership should consider as they think about leveraging the COVID context to develop or enhance their value-based care delivery operations.

### *Improve Segmentation and Intervention Efforts*

The core of value-based care delivery is mass customization of segmentation and interventions to help better manage outcomes for patients with disease; and to a lesser extent, reduce risk from future diseases. To bring this strategy to life requires data and analytical capabilities that are typically not a core competent of most hospitals or health systems. As healthcare organizations have recognized this need, it has received increased attention. However, most of the source data is historical claims, which is not a good predictor for the future on an individual basis. In addition to more sophisticated segmentation and interventions is the workflow tools to implement the new process and dashboards to monitor progress. These dashboards can be used by management and boards to set goals and track progress towards those goals.

### *Recognize the Challenges in a Clinical Setting*

In an acute care setting, every patient with the same clinical presentation requires the same care regardless of their payment status. However, in a clinic setting the strategies and operations to manage clinical care can be dramatically different. For example, if a patient presents with shortness of breath due to congestive heart failure, the protocols and pathways are going to be the same. However, if the same patient is managed in a clinic setting without any acute symptoms, the management of the patient could be dramatically different. The key intervention for this patient type may be behavior modification to impact diet and medication compliance. In a fee-for-service model, the incentive is to deliver more acute care and there are no systems and processes in place to prevent the breakdowns that result in admissions. Boards and management must understand how complex it is to break down the traditional silos while encouraging forward progress.

It is very challenging to deliver different types of care to patients in a clinic setting. The most notable difference is the process to manage patients before they have an acute crisis. Many physician offices today don't have the capacity to even see patients on the same day that they have an issue. In a value-based care environment, the clinic shifts focus from managing the problems to identifying potential problems and implementing interventions to avoid the breakdowns. This requires a completely

different operational setup than the fee-for-service environment. If a segment of the patients in the clinic is fee-for-service and another segment is value-based, it is operationally difficult, if not impossible, to deliver both models of care.

### *Ensure Value-Based Clinics Are Set Up for Success*

Current operations are typically focused on volume of patient visits, relative value units, and the resultant revenue from these activities. Value-based clinics require a completely different set of success metrics, as well as tools to achieve these goals. For example, a value-based clinic is more concerned with the total cost of care of the patients that are either enrolled or attributed to the clinic rather than the revenue from patient visits. Since the fundamental care model is different, the staff will need tools to operationalize the segmentation and reach out to the right patients with the right proactive care options. This requires workflow tools to support outreach to the right patients at the right time. Then these tools need to feed into dashboards to monitor the right metrics. These dashboards should be part of the standard management reports that the board monitors.

## Conclusion

The time to revisit and invest in value-based care delivery is now. Investing in value-based care delivery is a great financial hedge to the inconstant fee-for-service volumes due to COVID, and it also provides a pathway to improve the health of a community. Value-based care delivery really only applies in the clinic setting and thus you can leave your acute care operations unchanged. Hospital and health systems can certainly take advantage of this trend by creating a separate organization that manages the value-based population contracts, while simultaneously preparing for the cost and volume changes to the current business. Boards and senior leaders should highly consider increasing the organization's investment in value-based care delivery to both improve finances and the health of the communities they serve.

*The Governance Institute thanks Brian J. Silverstein, M.D., Managing Director, Health Care Wisdom, and Governance Institute Advisor, for contributing this article. He can be reached at briansilverstein@hcwisdom.com.*

# Balancing Oversight and Strategic Priorities When Everything Is Uncertain

*Last fall, Healthcare Financial Management Association (HFMA) Maryland Chapter held a panel discussion with Tori Bayless, CEO of Luminis Health; Sister Helen Amos, Executive Chair of Mercy Health; and Liz Sweeney, University of Maryland Medical System board member and President of Nutshell Associates, LLC, which was facilitated by The Governance Institute's Managing Editor, Kathryn Peisert. This article is a summary of the best practices presented in that session.*

**The rapid pace of change and complex industry environment in healthcare require decisive and swift action.** This was particularly true in 2020 and will continue through 2021 and beyond. For senior leaders, navigating approvals through the board of directors can be stressful and sometimes unpredictable. For board members, understanding and approving highly complex proposals, often with limited time, coupled with the large scope of the board's oversight responsibilities, can be overwhelming. During such times, board members are at higher risk of crossing the critical line between governance and management, which erodes trust and challenges the integrity of the board–management relationship.

This article discusses challenges of the board–management partnership and offers practical advice to senior leadership and board members for using this partnership as a foundation for enabling effective governance through uncertainty and beyond.

## Risks of Crossing the Board–Management Line

Healthcare boards are stewards of among the most complicated organizations in the world, at perhaps the most challenging time ever. The normal challenges of running a healthcare system, layered with COVID, have resulted in boards feeling overwhelmed, with strategic imperatives coming into question as boards and senior leaders try to determine how the future will be different.

Even under normal circumstances, it can be difficult for board members to understand, remember, and demonstrate the fine but distinctive line between governance and management. If boards fail to maintain focus on their role as stewards of the mission, vision, and strategy, their organizations will suffer.

Healthcare organizations require highly specialized and competent management teams to run. The board must rely primarily on the internal expertise and information provided by management. On the other hand, the board has core fiduciary responsibilities to its stakeholders and community. When you couple complexity with a fast pace of change, it can be hard to find the line between the board's setting strategy and policy and management's implementation. For example, while the board should set the strategic direction, it should not actually write the strategic plan. "The board is responsible to oversee dozens of activities from strategy to mission to risk management. Boards don't have the bandwidth to go down rabbit holes," said Liz Sweeney, President of Nutshell Associates, LLC and board member at the University of Maryland Medical System. "The board should ask reasonable questions, ask for

### → Key Board Takeaways

Even under normal circumstances, it can be difficult for board members to demonstrate the fine but distinctive line between governance and management. If boards fail to maintain focus on their role as stewards of the mission, vision, and strategy, their organizations will suffer. Best practices help uncover important issues and provide avenues for boards to conduct due diligence during periods of uncertainty:

- Build an effective board meeting agenda, relying on your strategic plan as a framework.
- Create an annual board calendar for agendas and education.
- Ensure board members are prepared with well-thought out board materials and include initial questions to help focus the meeting discussion.
- Ensure that meetings follow best practices including time management, time for Q&A, open forum, a "parking lot" for non-agenda items that come up, and regular executive sessions.
- Engage the board, management, and physicians in strategic planning and accountability.
- Establish a board–management compact outlining what each party needs and expects from each other to do their job well.
- Provide a strong orientation program that outlines, up front, the distinct roles between management and the board.
- Elevate board member education as a function of the board's responsibility.

outside opinions when they feel it's needed, and document their activities, but stop there."

Because board members are reliant on the information provided to them, management must present frank assessments of the organizations' strengths and gaps. They must be honest and open without becoming defensive when questions are asked. On the flip side, board members must ask perhaps more questions than might seem necessary, because "you don't know what you don't know." Best practices are in place for the express purpose of having processes for uncovering important issues and providing avenues for boards to conduct due diligence.

> "Culture matters more than anything. It behooves us all to attend to the culture of our organization and the level of trust that is required for responsible exercise of governance."
> *—Sister Helen Amos, Executive Chair, Mercy Health*

"You must bring bad news to the board," said Tori Bayless, CEO of Luminis Health. "You need to make time for lessons learned and contemplate carefully what happened, why, and how things should have been done differently, just like a root-cause analysis for a patient safety event." Bayless relies on her management team to bring different perspectives to the table. The chiefs who staff board committees have expertise and autonomy as well as strong working relationships with board members. Her team knows that questions and probing from the board means the board is seeking to understand and improve the organization. The board may have expertise that the management team lacks, and management needs to be open to that.

"A board member should support the organization and have an optimistic view about the organization's ability to succeed, but I think this idea gets conflated with supporting management," said Sweeney. "A board member should never vote 'yes' simply to show support for management. If I vote 'yes' on any proposal, that is an affirmative statement that I both agree *and* understand. If I don't understand, it's my job to ask questions until I do understand—I can't just rely on management."

## Key Ingredients of a Strong Board–Management Relationship

The following sections outline specific best practices with examples of how those practices can help boards and management teams perform at their highest capabilities, maintaining a strong relationship built on trust and transparency, even in times of extreme difficulty.

### *Build an Effective Board Meeting Agenda*

Leading boards rely on their organization's strategic plan to serve as a framework for topics of discussion at committee and board meetings. Many organizations moved to weekly board briefings during the COVID-19 pandemic, showing the ability to pivot quickly when needed. But keeping sight of the strategic framework at all times helps to guide and shape agendas and allow the board to maintain focus on the future while also prioritizing urgent issues.

Developing agendas should be an iterative process between management, the board chair, and committee chairs; management tees up the topics and then the chairs discuss (back and forth with management) and finalize. The governance development committee should be involved in the process to help identify where there is need for board education. Questions to ask include:

- What is happening in our organization?
- What is going on in our immediate region/environment?
- What are important trends at the national level?

And ultimately, the board agenda is the board's responsibility.

### *Create an Annual Board Calendar for Agendas and Education*

Prioritizing board agenda items can be challenging when there are so many issues for which the board is responsible. At times, urgent items take priority over others that might be more important but less urgent. Map out an annual calendar to set up foreseeable governance needs over the course of the coming year. Having a longer view of what will be on the agenda opens up opportunities to pair a board education activity with an upcoming decision. It improves the ability to redirect topics that more appropriately belong with management or a committee, and provides better visibility as to tradeoffs when urgent things come up in place of others that were planned.

### *Advance Preparation with Effective Board Packets*

Board materials should focus the board members' attention on the right areas for dialogue. For example, quality-related materials are often very detailed. A cover

page or executive summary that directs attention to areas where the organization is having the most trouble meeting targets, or a particular issue such as physicians overprescribing opioids, helps board members know where to focus their questions.

Each senior leader should be thinking about the audience as they prepare their report, about the specific board expertise needed for the decision making, and what kinds of questions to invite for discussion. Providing initial questions in the board materials takes it a step further. Then, ensure that materials are sent out at least a week in advance (Luminis sends packets out 10–14 days in advance) so that directors can prepare sufficiently and feel that their time is being respected.

"In our zeal to be thorough we include too much. Management must cull through a lot of information and present advanced materials that help keep the board at the right level," said Bayless. "The materials must be thorough but not overwhelming. How do we synthesize the information in a cover letter or executive summary? Then we pose some questions we want the board to be thinking about to keep them from homing in on a specific data point that might not be central to the action needed."

### *Effective Meetings and Decision-Making Processes*

Time management of the agenda is critical. Start the agenda with the most important issues. Allow time for Q&A and an open forum at the end to tee up a future topic or provide directors the opportunity to express any open concerns. The board chair must keep the discussion on point, using a formal "parking lot" process for lining up topics that may arise for future meetings. Setting expectations in advance helps board members understand that their voice is important but that there is a right time and place for each topic.

Hold an executive session after every meeting to provide regular opportunity for directors to discuss sensitive issues without staff present. "I sit on a board that holds two executive sessions at the end of every meeting, regardless of whether we know in advance if there will be an item for discussion," said Sister Helen Amos, Executive Chair of Mercy Health. "In the first session, the CEO is present and we do an instant analysis of whether the meeting was satisfying or where it fell short. Then the CEO leaves and anyone can bring up anything sensitive."

### *Engage Board, Management, and Physicians in Strategic Planning and Accountability*

The strategic planning process must allow board members, management, and physicians to enter into dialogue with a big-picture focus on the future (e.g., "What

is our mission calling us to do now in the circumstances that we are facing, in order to get us to our desired future?"). Then, the strategic plan becomes the spine of the accountability process. Annual corporate priorities come from the strategic plan, which become the outline of the accountability system. Achievement of these priorities for the year govern incentive compensation, for example. When concrete results come out of such a process, board members are much more willing to give their time and apply their perspective and expertise, and in turn the board becomes more valuable to the success of the organization.

### *Establish a Board–Management Compact*

Building personal rapport among board members and management helps to build the trust necessary for transparent and candid conversations. Everyone involved needs to feel that the boardroom is a place where they can share what they really think. A board–management compact outlines what each party needs and expects from the other to do their job effectively. Candor, trust, and respect should be central themes. It should be signed by all board members and senior management involved with the board, and revisited periodically to update as needed.

### *Provide a Strong Orientation Program*

New board member orientation is the best opportunity to outline, from the beginning, the distinct roles between management and the board, and why it is not a line that should be crossed. Introduce new board members to the subject matter experts who staff the board committees (CFO, CMO, CIO, etc.) to help them understand that there is a structure in place in which detailed questions can be asked and explored in committees, so that the questions asked during board meetings are at a higher level and the board can feel confident that those deeper level issues have already been hashed out during the committee meetings.

### *Ongoing and Robust Board Education*

Board members need confidence to engage in generative dialogue, and that is where education becomes key. Elevate education as a function of the board's responsibility, rather than relying on management to determine the board's education agenda.

In order to fit it into busy board members' schedules, the following are some practical suggestions:

- Include a short (15-minute) education session at each board meeting, with time for questions. Select the topics based on items planned for future meetings that

require decision making. Provide resources for board members who want to dig deeper into the topic on their own time.

- Find a topic that interests a smaller set of board members and offer it as a separate program for those who need it, at their convenience.
- Hold sessions that cover national perspectives and big environmental issues the industry faces, bringing in outside speakers. Board members can apply the larger perspective to the organization's specific strategies, operations, risk management, etc.
- Re-educate the board on committee responsibilities so that board members can feel more confident that the people on those committees have the necessary expertise to do strong due diligence. Then the board will feel less compelled to redo the work of committees in board meetings.

## Conclusion

In sum, governance best practices serve the purpose of laying a foundation that enables a strong and healthy board–management relationship, while also helping the board to ensure that it can maintain focus on the future, with effective oversight of operations in parallel. Rather than putting best practices aside in times of crises, having these practices in place, and reinforcing them through board and management behaviors, helps leaders lead more effectively through difficult times and bring their organizations through to the other side in a stronger position.

# Potential Impact of the Final Stark and Anti-Kickback Rules…If They Go into Effect

By **Anne M. Murphy,** Partner**,** *Arent Fox LLP*

## Overview

In late 2020, as part of a flurry of regulatory activity billed as the "Regulatory Sprint to Coordinated Care," the Trump Administration issued comprehensive final rules governing the physician self-referral law (Stark Law) and the Anti-Kickback Statute and related civil monetary penalty laws (AKS Laws) (collectively, the Final Rule).[1] The Final Rule, which is sweeping in scope, has been widely hailed as advancing value-based care and related innovations in healthcare delivery such as patient engagement and support arrangements and participation in government-sponsored models and ACO arrangements. Moreover, the Final Rule makes a number of modifications to existing regulatory provisions that would create greater flexibility for healthcare organizations in a variety of arrangements, including those between healthcare entities and physicians.

## Important Caveat

All of this, of course, is welcome news to healthcare providers and their governing boards. However, at least for the moment, it is important to appreciate that with the transition to the Biden Administration comes significant uncertainty as to whether the Final Rule will be implemented in its current form and, if so, its effective date.[2] In short, the General Accounting Office (GAO) has determined that procedural irregularities in the Final Rule's purported effective date (January 19, for the most part) violate federal law requiring Congressional review. This, in combination with a January 20 memorandum from the White House requiring review and delayed

1 CMS, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," *Federal Register*, December 2, 2020.

2 Tony Pugh, "Late Trump-Era Health Rules Raise Legal Questions Over Timing," *Bloomberg Law*, January 22, 2021.

implementation of certain late-stage rules issued by the Trump Administration,[3] raises a meaningful question as to whether the Biden Administration will undertake a re-review of the Final Rule.

This current uncertainty notwithstanding, the Final Rule reflects extensive efforts by the HHS Office of Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) to better align implementation of the Stark Law and the AKS Laws with value-based care, and to correct provisions that were deemed to unduly restrict business arrangements in healthcare delivery. Given this, there is a strong possibility that many, if not all, of the provisions in the Final Rule will stand. Accordingly, key provisions of the Final Rule are summarized below.

## Key Provisions of the Final Rule

As a preliminary matter, it is important to recognize that there are separate regulatory provisions in the Final Rule implementing the Stark Law, which is a civil statute with strict liability for non-compliance, and the AKS Laws, which are intent-based and include criminal provisions. In many cases in the Final Rule, including value-based care, both CMS and OIG issued rules. Overall, the provisions in the Final Rule governing the Stark Law create exceptions that are somewhat broader than the safe harbors governing the AKS Laws. According to CMS and OIG, this was

### → Key Board Takeaways:

- A recently issued Final Rule creates new clarity and flexibility regarding how value-based arrangements can be implemented under the Stark Law and Anti-Kickback Laws, and also addresses important longstanding impediments to other legitimate business arrangements.
- With the transition from the Trump Administration to the Biden Administration, however, the status of the Final Rule is not yet clear.
- Boards should dialogue with legal counsel and the executive team to understand the potential impact of the Final Rule on the organization's operations.

3 Memorandum for the Heads of Executive Departments and Agencies, "Regulatory Freeze Pending Review," January 20, 2021.

intentional, and was intended to allow the OIG provisions to serve as a "backstop" to abusive arrangements that might meet all the technical requirements of a Stark Law exception. The practical result is that, in most cases, both the CMS and OIG regulatory provisions need to be evaluated as part of any legal compliance review.

### *Value-Based Care*

Both CMS and OIG have adopted value-based exceptions and safe harbors. While there are significant differences between the two, both are tiered based on the degree of risk assumed by the value-based enterprise (VBE), through which VBE participants collaborate to put patients at the center of care. These tiers are:

1. Full financial risk
2. "Substantial" or "meaningful" downside financial risk
3. Other value-based arrangements

The greater the risk assumed by the VBE, the broader the latitude in terms of VBE arrangements between the VBE and the VBE participants.

Given the complexity of the value-based provisions, an example may be helpful in giving a glimpse into the way in which the Final Rule would work. Under the OIG provisions, a VBE assuming full financial risk is one that is at full risk for all healthcare items, supplies, devices, and services, on a prospective basis for at least a year with a payer for each patient in the target patient population, through a written value-based arrangement that specifies all material terms. If the VBE qualifies as full risk (which requires detailed evaluation of numerous definitions) and meets other requirements, then monetary or in-kind remuneration between the VBE and VBE participants that advances a VBE arrangement is generally protected under the safe harbor. Ownership or investment arrangements, however, are not protected. In addition, certain entities in the pharmaceutical, laboratory, and medical equipment and supply sectors are unable to avail themselves of this safe harbor protection.

### *Other Value-Based Care Provisions*

The Final Rule also contains several new or modified safe harbors for activities closely aligned with value-based care. The more significant of these include:

- **In-kind patient engagement tools or services** provided to patients in the target patient population of a value-based arrangement, which have a direct connection

to the coordination and management of care. This cannot exceed $500 in retail value annually, and can have no cash or cash equivalent benefit.
- Certain patient incentive payments and payment arrangements pursuant to **CMS-sponsored model arrangements and ACOs** participating in certain CMS-approved two-sided risk models.
- Donations of **cybersecurity technology** and related services, if certain conditions are met.
- Modification of the personal services and management contracts safe harbor to permit **outcomes-based payments**, if certain conditions are met, for the achievement of legitimate outcomes measures to improve quality, reduce costs, or both.

### *Modifications to Other AKS and Stark Provisions*

The Final Rule makes a great many other changes to existing safe harbors and exceptions, in an effort to provide greater flexibility and clarity to the healthcare sector. Certain of these modifications, if implemented, would have a significant positive impact on business arrangements that have long vexed healthcare organizations seeking certainty as to compliance with the Stark Law and the AKS Laws. Several of the more significant include:

- Modify the personal services and management contracts safe harbor to provide greater flexibility for **part-time arrangements** by eliminating the requirement that the written agreement detail the exact schedule, length, and charge for each service increment.
- In this same safe harbor, modify the requirement for **setting compensation in advance** to require only that the methodology be set in advance, rather than the aggregate compensation itself.
- Add to the Stark Law exceptions a definition of "commercial reasonableness" that makes clear an arrangement may be **commercially reasonable** even if it does not result in a profit for one or both parties. This is especially significant because recent False Claims Act cases have asserted that this lack of profit must mean that the compensation is impermissibly based on the volume or value of referrals.

## Conclusion

The Final Rule contains many welcome changes designed to advance value-based care and to eliminate impediments to legitimate business arrangements. Governing

boards may want to engage with legal counsel and others on the executive team to understand how the Final Rule would impact the organization's operations. One important aspect of this discussion should be to assure that any such modifications are not implemented until the Biden Administration's stance on the Final Rule is clear.

*The Governance Institute thanks Anne M. Murphy, Partner, Arent Fox LLP, for contributing this article. She can be reached at anne.murphy@arentfox.com.*