

# Supporting Value-Based Care: The Role of Compliance

Take Time to Make Sure Your Organization Is Ready

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**V**alue-based care and the associated acronyms and care models and strategies that have sprouted up around this concept over the past few years is changing the way we pay for, receive, and provide health care in this country. As a result, the health care system is being required to evaluate what it has always done, to shift away from an entrenched fee-for-service paradigm, and to innovate, all while controlling cost.

In order to respond to the changing environment, compliance programs will need to go on a similar journey. Just like providers and payors, compliance programs need to evolve in a way that supports this change. The most successful programs will grow to understand both the new operational and regulatory landscape, and encourage a culture of compliance that is at once both nimble enough to change and innovate, yet secure enough to not falter in the face of extreme pressure.

This article focuses on where to begin. Section 1 sets the stage and provides an overview of value-based care and the various care models.<sup>1</sup> Section 2 highlights some of the legal and regulatory considerations associated with these models. Section 3 covers where and what to look for when evaluating compliance obligations and identifies the structural components of a compliance program that will need to be reviewed and updated in order to reflect new legal and regulatory standards. Finally, Section 4 focuses on the importance of operational integration in the value-based environment, including strategies to ensure the compliance program is both aligned with operations and integrated into strategic planning and initiatives to support risk-based decision making.

## **SECTION I: OVERVIEW OF VALUE-BASED CARE AND ALTERNATIVE AND ADVANCED ALTERNATIVE PAYMENT MODELS**

### **Health Care Reform and the Affordable Care Act**

Value-based care (VBC) is a reimbursement system that rewards clinicians who deliver the highest-quality, most

efficient care. This focus on the *value* associated with the care provided is in stark contrast to the fee-for-service (FFS) model, which reimburses providers for the *volume* of care provided. In 2010, Congress passed sweeping health care reform legislation, what we now refer to simply as the Affordable Care Act or ACA.<sup>2</sup> The ACA established a framework and provided inertia, structure, and incentives for the health care industry as a whole to embrace VBC. It did so by (1) establishing new models of care delivery, including the Medicare Shared Savings Program (MSSP), (2) shifting reimbursement from volume to value through performance-based reimbursement models in the acute care setting (*e.g.*, value-based purchasing and hospital readmissions reduction programs), and (3) investing in resources to accelerate innovation in health care delivery (*e.g.*, Center for Medicare and Medicaid Innovation (CMMI)).

The new models of payment and care delivery authorized by the ACA were developed and quickly adopted — for example, over 400 MSSP accountable care organizations (ACOs) serving nearly 7.2 million Medicare beneficiaries by 2015.<sup>3</sup> Adoption of the available models, however, was not across-the-board, and financial incentives, particularly for physicians, had yet to materialize. Smaller hospitals and health systems also struggled with the up-front costs associated with the technology, human resources, and infrastructure required to be successful in the VBC models available. Notwithstanding the challenges, the shift away from FFS had begun and was gaining momentum.

### **MACRA and APMs**

Though the ACA was not without controversy, payment reform, with the goals of shifting provider payments and incentives from volume to value, has proved to be a health policy issue that has bipartisan support.<sup>4</sup> In January 2015, the Department of Health and Human Services (HHS) announced that it intended to link half

of all traditional Medicare payments to a value-based reimbursement model by the end of 2018. The announcement was quickly followed by the unveiling of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) framework that focuses on alternative payment models (APMs). MACRA created the Quality Payment Program (QPP) that: (1) repealed the Sustainable Growth Rate formula; (2) changed the way that Medicare rewards clinicians for value over volume; (3) streamlined multiple quality programs under the new Merit Based Incentive Payments System (MIPS);<sup>5</sup> and (4) gives bonus payments for participation in eligible APMs.<sup>6</sup>

An APM is a payment approach that gives added incentive payments to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. Advanced APMs are a subset of APMs and let physician practices earn more for taking on some risk related to their patients' outcomes.<sup>7</sup> Two of the most common APMs are bundled payments and ACOs and are described in more detail below. Other APMs include: Next Generation ACO model, Comprehensive ESRD Care (CEC), Comprehensive Primary Care Plus (CPC+), Oncology Care Model (OCM), and Comprehensive Care for Joint Replacement (CJR) Payment Model.

### **Bundled Payments**

Bundled payments can be an organization's first step into APMs; they are relatively focused, engage specialists, and do not upset a hospital's FFS business model. Under bundled payment models, health care providers are held accountable for the cost and quality of care beneficiaries receive during an episode of care, which usually begins with a triggering health care event (such as a hospitalization or chemotherapy administration) and extends for a limited period of time thereafter. The focus here is not on reducing overall hospitalizations but on reducing readmissions, transitioning patients to the most appropriate

site of care, and reducing length of stay, if appropriate.

The Bundled Payments for Care Improvement (BPCI) initiative was developed by CMMI and is comprised of four broadly defined models of care. Under the initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. The intent is to align incentives for hospitals, post-acute providers, physicians, and other practitioners, allowing them to work closely together across all specialties and settings. Those organizations that have been the most successful in the BPCI program are those that are able to invest in technology and data analytics and who have partnered with high-quality skilled nursing facilities and engaged physicians.<sup>8</sup>

The payment methodology varies between each of the four BPCI models, but each assumes a level of savings for the Medicare program. Participants keep any additional savings and are allowed to enter into gainsharing arrangements with physicians to improve care efficiency and lower costs.

### **Accountable Care Organizations**

ACOs are designed to incentivize health care providers to become accountable for a patient population and to invest in infrastructure and redesigned care processes that provide for coordinated care, and high quality and efficient service delivery. One of the first programs mandated by the ACA was the Medicare Shared Savings Programs or MSSP. Eligible providers, hospitals, and suppliers participate in the MSSP by creating or participating in an ACO.

Most MSSP ACOs participate in Track 1, under which they do not bear downside financial risk, meaning they are not responsible for repaying “shared losses” back to the Medicare program. MSSP ACOs participating in Tracks 2 or 3, while eligible for greater shared savings payments, also are responsible for repaying a portion of shared losses back to the Centers

for Medicare & Medicaid Services (CMS). In 2017, 486 MSSP ACOs participated in Track 1, six participated in Track 2, and 36 participated in Track 3.

In addition to the MSSP, in 2017 45 ACOs participated in the Next Generation (Next Gen) ACO model. The Next Gen model is an initiative for ACOs that are experienced in coordinating care for populations of patients. It allows these provider groups to assume higher levels of financial risk and reward than are available under the MSSP. The goal of Next Gen is to test whether strong financial incentives for ACOs, coupled with tools to support better patient engagement and care management, can improve health outcomes and lower expenditures for Medicare FFS beneficiaries.

The shared savings model has emerged as one of the most successful and widely used VBC initiatives with the most successful shared savings ACOs embracing the innovation that is necessary to fix the fundamental problems leading to poor quality and outcomes. Innovations include:

- investments in new integrated data systems and analytics platforms;
- care management protocols that span care settings to improve transitions of care between the hospital and ambulatory settings;
- investments in registries that allow physicians to track and better manage high-risk populations;
- the development and use of risk assessment risk stratification tools; and
- new ways to engage high-risk patient populations.

### **Population Health Management**

In addition to value-based care and alternative and advanced alternative payment models, one final concept critical to understanding where we are today is population health management (PHM). PHM, defined as the aggregation and analysis of patient data across multiple health information technology resources, is a method of using huge sets of data to improve clinical and

financial outcomes. It focuses partly on high-risk patients who generate the majority of health care costs, but it also systematically addresses the preventive and chronic care needs of every patient. PHM is the strategy that allows providers to be successful in VBC by integrating clinical services across providers, settings of care, conditions, and time.

## **SECTION II: LEGAL AND REGULATORY CONSIDERATIONS**

What all VBC payment and reimbursement models have in common is the need to think beyond the walls of the hospital, the confines of a single medical group, and outside traditional integrated health system models. To do this, many health care organizations are pursuing alliances, partnerships, or structural changes aimed at facilitating clinical integration. These partnerships and financial arrangements may not have been permissible under the FFS model because of the fraud and abuse or antitrust laws and regulations. Just as important, these new relationships require data sharing in ways that stretch the bounds of the Health Insurance Portability and Accountability Act (HIPAA) and in ways that a traditional electronic medical record (EMR) may not be equipped to support. What follows is a high-level overview of these areas.

### **Fraud and Abuse Laws and Waivers**

In the traditional FFS world, the presumption by the Stark, anti-kickback, and civil monetary penalty (CMP) laws (collectively the fraud and abuse laws) that any shared financial incentive is suspicious may have made sense. Keeping hospitals and physicians in silos was consistent with how providers were reimbursed by the FFS system. The fundamental need for integration, collaboration, care redesign, and engagement in the VBC environment, however, required Congress to authorize waivers of fraud and abuse laws specific to APMs.<sup>9</sup> The waivers are designed to allow otherwise unrelated providers the flexibility needed

to fund the development of any applicable legal entity, manage the distribution of savings, and engage with patients and providers without running afoul of fraud or abuse laws. Currently, there are waivers available for the Next Generation, and MSSP ACOs, the BPCI Models, and the Advanced APMs listed in Section 1 above.

Thus far there is no general waiver or exception to allow physicians and hospitals to participate in VBC programs without triggering liability under the fraud and abuse laws. Instead, waivers are program-specific and apply to such things as patient engagement incentives, shared savings distributions and gainsharing payments, and pre-participation and participation in a VBC program. Though the waivers for each program are slightly different, CMS has been clear that failure to fit in a waiver is not, in and of itself, a violation of the fraud and abuse laws. In addition, waivers are not needed to the extent the arrangement: (1) does not implicate the specific fraud and abuse law, or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law.

Arrangements that do not fit in a waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the various fraud and abuse laws.<sup>10</sup> Importantly, the fraud and abuse waivers do not waive applicable state law restrictions. Activities that would not be protected by a waiver include requiring physicians to pay for access to referrals (“pay to play” arrangements), sham medical director or personal service arrangements, payments to induce physicians to reduce medically necessary care, or providing gifts to referring physicians or suppliers.

### **Gainsharing**

“Gainsharing” typically refers to an arrangement in which a hospital agrees to share with a physician or group of physicians defined reductions in the hospital’s

costs that are attributable to the physician's or group's efforts. While beneficial to hospitals and physicians, gainsharing has long been a cause of concern for regulatory agencies tasked with protecting federally funded health care programs from fraud and abuse. The CMP law<sup>11</sup> is one of three key federal statutes that affect the structure of gainsharing arrangements.<sup>12</sup> The subsection of the CMP law applicable to gainsharing arrangements (the "Gainsharing CMP") authorizes a CMP of up to \$2,000 when a hospital or critical access hospital "knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services" provided to Medicare or Medicaid beneficiaries under the physician's direct care."

MACRA, however, modified the circumstances under which gainsharing would trigger a CMP by adding the word "medically necessary" to the statute so that now the Gainsharing CMP prohibits only inducements made to reduce or limit *medically necessary* services to Medicare or Medicaid beneficiaries. In MACRA, Congress also directed CMS to make a report recommending the removal of impediments and the inclusion of safeguards to make gainsharing programs available. And in November 2015, CMS issued new waivers for ACOs that eliminated an earlier gainsharing waiver from 2011 because the exception was no longer necessary. The BPCI waiver for gainsharing is still available.

### Antitrust

Collaboration is a constant theme in the VBC environment as outcomes can be contingent upon strategic partnerships in order to get the scale needed either in terms of number of physicians or number of covered lives. These partnerships, however, can lead to consolidation in the form of a merger or acquisition, development of a clinically integrated network (CIN) or ACO, or other purchasing agreements. Though there are clear opportunities to be

had, collaboration will also invite antitrust scrutiny and potential enforcement.

The antitrust regulatory authorities, the Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ), have issued statements expressing concern that such consolidation could reduce competition and harm consumers through higher prices or lower quality care. In October 2011, the DOJ and FTC issued a joint policy statement detailing how the agencies will enforce U.S. antitrust laws with respect to MSSP ACOs that may also serve commercially insured patients. Though the statement does provide a "safety zone" for certain ACOs, it also provides examples of conduct that, under certain circumstances, may raise competitive concerns. Importantly, the agencies noted that "all ACOs should refrain from, and implement safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside of the ACO."<sup>13</sup>

### Using and Sharing Data

Key to the ability of providers to make meaningful progress in clinical integration, accountable care, and population health is the data that supports and guides the collaboration and ultimately the care provided to patients. Without the data analytics necessary to inform decision making to help control costs, eliminate duplication of services, improve efficiencies, and make it easier for patients to get the care they need, the full potential of providers to actually manage the health of a population will never be realized. Unlike the fraud and abuse laws which were waived in recognition that new models of care required new collaborative capabilities, there is no HIPAA waiver for VBC. Covered entity and business associate obligations remain as critical to organizational compliance and patient care as ever before.

In addition to HIPAA obligations, to obtain patient data from CMS, organizations are required to sign a data use agreement (DUA). DUAs are similar to business associate

agreements but are more stringent than HIPAA in a number of ways. Importantly, the organization that receives the data may not disclose the data to anyone unless specifically approved by CMS. Typically, any subsequent disclosure comes as the result of needing a vendor to perform data analytics or care management. Unless the vendor signs a data use agreement addendum and that addendum is approved by CMS, any disclosure of data to that vendor would violate the terms of the DUA triggering the breach reporting provision which requires the organization to report to CMS “any breach of personally identifiable information from the CMS data file(s), loss of these data, or disclosure to an unauthorized person by telephone or email within one hour.”<sup>14</sup>

### SECTION III: COMPLIANCE PROGRAMS

In these final two sections the discussion will turn decidedly more tactical. I have two goals with these sections. The first is to help identify where to begin your evaluation of the compliance program requirements if your organization is already participating in VBC programs or will do so in the future. The second is to help take your compliance program beyond the core components and identify strategies and opportunities for operational integration. In these sections, most examples will relate to MSSP ACOs or the BPCI initiative, but the strategies will apply to all programs.

#### Step 1: Evaluate the Programmatic and Regulatory Requirements for Compliance Programs

##### (a) Regulatory Review

The first and probably most obvious place to start is with the regulations. With the exception of the MSSP, however, most VBC models have been established through the authority of the CMMI and do not have a distinct regulatory scheme. The MSSP is unique in that it fulfills a statutory obligation set forth by the ACA to establish a permanent program.

The MSSP regulations spell out specific compliance program requirements, which include five core components:<sup>15</sup>

1. a designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body;
2. mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;
3. a method for employee or contractors of the ACO, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer;
4. compliance training for the ACO, the ACO participants, and the ACO providers/suppliers; and
5. a requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

In addition to compliance program requirements, there are also specific shared governance requirements typically overseen by compliance, including the obligation to have a conflict of interest policy and process.<sup>16</sup>

##### (b) Review Program Documents

All VBC models will have some form of program documentation and/or participation agreements associated with the program itself. Evaluating these documents is important, especially for non-MSSP models with no regulatory framework, because they set the structure for the program and outline the governance, operational, clinical, and compliance requirements. As an example, the BPCI agreement with the BPCI awardee (*i.e.*, the entity that bears the financial risk) includes a section on the compliance program obligations that largely mirror the MSSP regulatory requirements. The main difference between the BPCI requirements and the MSSP, however, is that MSSP ACOs are legal entities distinct from the ACO participant providers

that typically implement a unique compliance program. For BPCI, though, there is no need to have a separate legal entity, so the existing compliance program and existing compliance officer of the awardee are generally used to comply with the contractual obligations.

### **(c) Review Participation Agreements**

In the MSSP, each ACO must have an ACO participant agreement with each of its ACO participant Tax Id Numbers (TINs). These agreements include the required regulatory language but also typically include any business associate agreement and related HIPAA obligations, and mandatory performance standards. If compliance was not involved in drafting the participant agreements, it is important to understand what is required of the ACO and what is required of each TIN.

### **(d) Review Application Materials**

Though maybe not an obvious place to look, in some cases application materials can provide insight into the type of compliance obligations most relevant to the particular VBC model. The MSSP application, for example, requires each ACO applicant to certify that its compliance program complies with the regulatory requirements. An organizational chart is also required in the application materials and must reflect the ACO compliance officer's reporting relationship that is consistent with the regulatory obligations. Organizational charts that do not reflect an accurate reporting relationship will not be accepted.

## **Step 2: Perform a Gap Assessment**

Once you've identified the compliance program obligations, your next step will be a gap assessment. This assessment typically involves the following:

1. identify what you already have in place that applies to the VBC model(s) you are evaluating;
2. determine whether what you have can be used either as-is or modified; and

3. identify what else you need to ensure your compliance program meets the applicable requirements.

In general, participation in non-MSSP ACO models does not require a new compliance program, but rather modifications to an entity's existing program will likely be sufficient. MSSP ACOs, however, are separate legal entities with operational and governance leadership that must be independent from the ACO participants.<sup>17</sup> The compliance officer, though allowed to also be a compliance officer for an existing entity, must not be legal counsel to the ACO and must report directly to the independent ACO board for purposes of the MSSP. Whether an existing compliance program is leveraged for purposes of the MSSP ACO or a new program is developed specifically for the ACO, the ACO board will want to make sure it adopts the program and it fully meets the regulatory requirements.

## **Step 3: Modify Existing or Develop New Compliance Program**

Whether starting from scratch or modifying an existing program, the following are things to keep in mind and questions to ask:

- *Scope:* How will your program reflect the relationships involved in the VBC model? Will all policies apply to all entities within the VBC arrangement? Will the VBC compliance program supersede or supplement the provider's current compliance program?
- *Disciplinary and Corrective Action:* Disciplinary and corrective action policies must take into account the authority of the organization to discipline or remove non-employees and non-employed providers. Will the policy apply to individuals employed by a physician group participating in the MSSP? Or will the physician group be responsible for taking disciplinary action? What authority does an ACO have to remove an individual or TIN for violation of the compliance program? What authority

does the organization or board have to ensure successful completion of corrective action?

- *Training:* How will training be dispersed and monitored across the collaboration? Who will maintain the records? Is additional training required, or will general compliance training satisfy the requirements?
- *Communication:* How will compliance issues be communicated across the collaboration? Are there ways to ensure that communication is effective?
- *Governance:* Who is monitoring the governance requirements for your MSSP ACO? Will the compliance officer have direct communication with the board or a board committee?
- *Policies:* With respect to HIPAA, is the organization a business associate or a covered entity, and do the policies accurately reflect that legal designation? ACOs, for example, are typically business associates. What processes and obligations will need to be implemented to ensure compliance with business associate obligations? Does your ACO maintain records in a designated record set? If so, how do the policies reflect the additional obligations?

#### **SECTION IV: THE IMPORTANCE OF OPERATIONAL INTEGRATION**

It has been generally accepted for quite some time that a compliance program that looks good on paper but is not effectively implemented is not sufficient. Just as integration, collaboration, and relationships are key drivers of VBC from an operational and clinical perspective, those concepts are also key in the context of effective compliance programs. Below are integration strategies to consider when developing or evaluating a compliance program responsive to VBC.

##### **Strategy #1: Get Involved in the Application Process**

What all of the VBC models have in common are rigorous application procedures,

including significant descriptions of how the applicant intends on complying with the various operational and clinical requirements of the initiative. By getting involved at the application stage you will gain critical knowledge of how the program works and how your organization intends to respond to the various requirements. This is also a great time to review legal documents, such as the participation agreements, as they are being drafted to include provisions that can help achieve the goals of the compliance program. For example, the MSSP participant agreement is a great document to include such responsibilities as:

1. *Exclusion checking:* Consider requiring each ACO TIN to conduct the necessary checks against the applicable federal and state exclusion databases and provide appropriate attestations versus the ACO taking on that responsibility.
2. *Training:* Consider including completion of training (including mandatory compliance training) as part of a TIN's performance standards necessary for distribution of shared savings.

##### **Strategy #2: Get Involved with Data Governance**

With VBC, it's not only data going in and out of organizations that puts organizations at risk; it can also be the type of data. For example, in some arrangements an organization may receive data for individuals that it does not yet have a treatment relationship with. How this data is treated in an EMR versus data resulting from a treatment relationship may not be something the EMR has been built to distinguish. Ensuring that compliance is represented on a data governance team or in a data governance process will help to ensure that issues like this are spotted quickly and addressed before a breach occurs.

##### **Strategy #3: Ensure Appropriate Oversight of Physician Disbursements**

Notwithstanding the various fraud and abuse waivers associated with many of the



VBC models, payments to providers must still be accurate and legitimate. Establishing a physician disbursement oversight process either before a payment is made or an audit process after the fact will help mitigate the ongoing fraud and abuse risk associated with provider relationships.

#### **Strategy #4: Get Involved in Vendor Selection and Contract Review**

Establishing a vendor selection and/or contract review process in which compliance has a role will help ensure that compliance has a voice early in the contracting process. Use this time to raise any concerns related to such things as data sharing and access so that the parties can address them before agreeing on final terms.

#### **Strategy #5: Regular Communication with Key Leadership and Departments**

For compliance, visibility is important, but it's not enough. Compliance also needs to bring value, and one of the best ways to do so is by regular communication with key leadership and departments. Internal and external auditors, legal counsel, population health administrative and clinical leaders, and governance leaders can all be critical allies for the compliance function. Ensuring that compliance is available and responsive will increase the likelihood that people know who to go to when an issue does come up.

#### **Strategy #6: Ongoing Involvement with the Industry**

It may seem counterintuitive to make a recommendation focused on looking outside of your organization when the goal is operational integration, but this particular strategy is really geared at ensuring compliance stays on top of not only what is going on with VBC but also how other compliance officers are addressing those issues in their own organizations. This recommendation is actually two-fold: first, seek out and maintain a network of other compliance officers working in your same

specialty and talk with them on a regular basis. Learning from others' experiences can be as beneficial as learning from your own. And second, keep up with the latest industry developments relevant to your organization. A compliance officer that not only understands the current operational and reimbursement landscape but also where it is headed is well equipped to become the strategic partner health care organizations need.

#### **CONCLUSION**

The core components of compliance programs have not changed in the VBC environment. What has changed is the application of those programs to new organizational structures and relationships, new clinical and care coordination practices, and new strategic partnerships. Evaluating your compliance program for its readiness for VBC or its responsiveness to the risks already in its path is not only wise but crucial to any organization committed to the goals of population health.

#### **Endnotes:**

1. Though this article focuses on government initiatives, value-based care is not exclusively driven by Medicare and Medicaid. Commercial payors are also establishing similar value-based care models and incentives.
2. Pub. L. No. 111-148 (March 23, 2010) the Patient Protection and Affordable Care Act, and Pub. L. No. 111-152 (March 23, 2010), the Health Care and Education Reconciliation Act of 2010 are collectively referred to as the Affordable Care Act or Obamacare.
3. [www.commonwealthfund.org/publications/issue-briefs/2015/may/aca-payment-and-delivery-system-reforms-at-5-years](http://www.commonwealthfund.org/publications/issue-briefs/2015/may/aca-payment-and-delivery-system-reforms-at-5-years)
4. HealthLeaders Media, Industry survey: Ready, Set, When? The Drawn-Out Shift to Value, January 2016, [www.healthleadersmedia.com/report/intel/industry-survey-ready-set-when-drawn-out-shift-value](http://www.healthleadersmedia.com/report/intel/industry-survey-ready-set-when-drawn-out-shift-value) (last accessed January 14, 2018)
5. The Merit-based Incentive Payment System (MIPS) is one of two new payment tracks established by MACRA that combines aspects of the Physician Quality Reporting System (PQRS), the Value Modifier (VM or Value-based Payment Modifier), and the Medicare Electronic Health Record (EHR) Incentive Program (Meaningful Use). MIPS consolidates these

- Medicare initiatives into a single program based on: quality, cost, advancing care information (meaningful use), and adds a new category called improvement activities, which is based on the medical home.
6. [www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html) (last accessed January 19, 2018)
  7. [qpp.cms.gov/apms/overview](http://qpp.cms.gov/apms/overview) (last accessed January 19, 2018)
  8. Deloitte, Navigating Bundled Payments: Key Strategies to Reduce Costs and Improve Health Care [www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/bundled-payments-and-alternative-payment-models.html](http://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/bundled-payments-and-alternative-payment-models.html) (last accessed January 19, 2018)
  9. Section 1115A(d)(1) of the Social Security Act (SSA) authorizes HHS to waive fraud and abuse laws as necessary for CMMI programs. The MSSP waivers were created separately under Section 1899(f) of the SSA.
  10. [www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-2-Waivers.pdf](http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-2-Waivers.pdf) (last accessed January 19, 2018)
  11. 42 U.S.C. § 1320a-7a
  12. The other two being the Stark law and the anti-kickback statute.
  13. [www.justice.gov/opa/pr/department-justice-federal-trade-commission-issue-final-statement-antitrust-policy-enforcement](http://www.justice.gov/opa/pr/department-justice-federal-trade-commission-issue-final-statement-antitrust-policy-enforcement) (last accessed January 19, 2018)
  14. [www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Data-Use-Agreement.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Data-Use-Agreement.pdf) (last accessed January 19, 2018)
  15. 42 CFR 425.300
  16. 42 CFR 425.106(d)
  17. 42 CFR 425.104(b)