Tips & Tricks in Evaluating & Implementing Value-Based Care Arrangements

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Five years have passed since the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) effectuated its "regulatory sprint to coordinated care" by publishing final rules to modernize regulations implementing the federal physician-self-referral law, commonly referred to as the "Stark Law" (Stark), the federal Anti-Kickback Statute (AKS), and the beneficiary inducement provisions of the Civil Monetary Penalties Law (CMP Law).[1] The final rules were part of the U.S. Department of Health and Human Services (HHS) initiative to support transitions to value-based care, promote improvements in technology infrastructure, and spur innovation.

Despite significant changes in the political climate and direction of the administration, the push toward value-based care continues to gain momentum. The shift to value-based care started slowly, waylaid by uncertainty and complexity but there has been a lot of movement in recent years. In 2021, CMS established a goal to have 100% of Medicare beneficiaries and the vast majority of Medicaid beneficiaries in some type of accountable or value-based care arrangement by 2030.[2] Although the administration has changed, the value-based care goals have not. In 2025, the Trump administration announced its "Make America Healthy Again," initiative which included a priority of "shifting the paradigm for healthcare from a system that focuses on sick care to one that fosters prevention, wellness, and chronic disease management" signaling the new administration's likely continuation of value-based care initiatives.[3] In May 2025, the CMS Innovation Center (CMMI) announced its intention to promote evidence-based prevention, empower people to achieve their health goals, and drive choice and competition, all while protecting federal taxpayers.[4] This strategy involves preventing the onset of disease through health lifestyle, improving function, reducing adverse events and acute care utilization, slowing or halting disease progression, and increasing time at home. To drive choice and competition, CMMI aims to reduce administrative burdens, customizing pathways for rural health providers, creating more predictability in models, and providing start-up funding. Each of these goals and the actions taken by CMMI in the last six months, including the announcement of several new models, point to the longevity of value-based care.

Similarly, commercial plans have continued to expand their value-based care initiatives. Although value-based care in commercial plans lag behind Medicare Advantage, as of 2023 commercial value-based care risk models exceeded those in Medicaid for the first time.[5] Large employers are interested in value-based care and commercial plans seem to be more willing to apply the lessons learned in entering and operating Medicare Advantage and managed Medicaid value-based care programs to their commercial plans. In addition to increasingly engaging others to take risk and coordinate care, large insurers like Humana, Aetna, Anthem (Elevance Health) and UnitedHealth Group (Optum) have invested in both providers and value-based

[1] CMS: Modernizing and Clarifying the Physician Self-Referral Regulations – 85 Fed. Reg. 77492 (Dec. 2, 2020) and OIG: Revisions to Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements – 85 Fed. Reg. 77684 (Dec. 2, 2020); *see also* CMS and OIG Proposed Rules 84 Fed. Reg. 55694 (Oct.17, 2019) and 84 Fed. Reg. 55766 (Oct. 17, 2020).

[2] CMS Press Release. The CMS Innovation Center's Strategy to Support Person-centered, Value-based Specialty Care (Nov. 7, 2022).

[3] CMS Press Release: Dr. Mehmet Oz Shares Vision for CMS (Apr. 10, 2025).

[4] CMS, Innovation Center Strategy Refresh (May 2025); CMS Webinar, CMS Innovation Center's 2025 Strategy to Make America Healthy Again (May 13, 2025).

[5] Health Care Transformation Task Force, Driving Commercial Value-Based Care Adoption (2025).

care.[6] In addition, large health systems have entered the value-based care market either by launching their own health plans or partnering with outside payors.[7]

In order to effectively transition to value-based care, providers must find ways to not only improve outcomes and reduce costs but establish and monitor value-based care agreements with applicable payors. For the most part, the quality and cost improvements come from incentivizing physicians to change the way they treat patients, stronger coordination of care across healthcare silos, the consideration and resolution of social determinates of health, and motivating patients to follow treatment plans and make healthy choices. Further, providers must find ways to manage the up-front investments needed to implement technology and the personnel necessary to compile, analyze and report the quality and claims data required for value-based care agreements.

All that said, today many payors, providers, and practitioners have gained quite a bit of familiarity and comfort with value-based care agreements. Whereas those who have waited on the sidelines to watch and learn are increasingly jumping into the fray, whether motivated by others' successes or by mandatory care models. Nonetheless, at this point, it is important for most industry players to be prepared to evaluate and negotiate value-based care arrangements.

I. Value-Based Care Means a Lot of Different Things – A Concepts Primer

At its heart, the concept of value-based care is paying for healthcare based on care quality and outcomes rather than paying for the quantity or volume of patients treated (i.e., fee for services). There are a variety of ways to try and achieve this general aim, which is why value-based care is such a broadly used term. Before diving into tips and tricks for negotiating and implementing value-based care, it is helpful to set a baseline understanding of the different types of value-based care payment concepts. Note, however, that value-based care arrangements have evolved to often contain more than one of these concepts (e.g., performance bonus and shared savings). Below is a high-level overview of the most commonly referenced value-based payment models and concepts, roughly from the least risky to the riskiest.

- **Performance Bonuses (or Penalties).** Performance bonuses are bonuses designed to reward (or penalize) a practitioner or provider for reporting and/or achieving certain performance objectives, often tied to tracking and hitting pre-selected quality metrics, financial benchmarks or achieving certain outcomes. At its heart, this is the concept upon which the Medicare Merit-Based Incentive Payment System (MIPS) program is based. Practitioners are required to track and report data on certain quality metrics and depending on performance can result in either a positive or negative adjustment to their Part B payment amounts. Many commercial payors have similarly included quality bonuses for meeting certain quality objectives in their participation agreements with physicians, practices, and other healthcare providers.

- **Bundled or Episodic Payments.** Bundled or episodic payment programs establish a single, fixed payment for a collection of services provided during an episode of care. The recipient of the payment is responsible for coordinating with and paying the entire care team involved in that

[6] *See e.g., Noha Tong,* Fierce Healthcare, "California insurers join forces on new primary care model" (Feb. 11, 2025); Nona Tepper and Alex Kacik, Modern Healthcare, Volume 52; Issue 6, "Building the 'Payvider': Looking at the Future of Healthcare Payment and Delivery" (Mar. 21, 2022); Bruce Japsen, Forbes, "UnitedHealth Group's Value-Based Care Spend Hits $69 Billion" (Oct. 17, 2018).
[7] *Id.*

episode of care. The goal is to promote collaboration and coordination to improve outcomes and reduce the total cost, for example by avoiding hospital re-admissions. Often the costs of the clinical episode are estimated based on historical claims data for the services bundled into the episode. The patients are typically attributed to the model based on a particular healthcare need, e.g., a knee or hips replacement. CMMI models that are premised on bundled payments include the Bundled Payments for Care Improvement (BPCI) Advanced (ended in 2025), the Oncology Care Model, and the new mandatory model Transforming Episode Accountability Model (TEAM).

- **Shared Savings.** In a shared savings model, the parties agree to share savings, which are usually any amounts below a given financial benchmark for the attributed patient population. At a high level, this is based on the parties' determination of the expected cost of care based on historical claims and other data for individuals in the attributed population (e.g., all patients in a certain geographic area with a substance use disorder diagnosis) and then the value-based care organization agrees to try and provide the care that is the same or higher quality for lower cost, and if they succeed they share the savings with the payor. Models that allow providers to receive a share of savings without also having to pay for any deficits if the cost of care goes above the benchmark is often referred to as "upside-only" meaning they get to share in the savings if they are successful but do not have to cover any losses if care ends up costing more than expected. Examples of models that involve shared savings include Medicare Shared Savings Program (MSSP) and the accountable care organization (ACO) Realizing Equity, Access and Commercial Health (REACH) Model, and a number of managed care arrangements have similarly used this model.

- **Shared Risk.** As you might suspect, this is the inverse of shared savings. An organization is at risk if they agree to be responsible for the cost of the population's care that exceeds the financial benchmark set out by the parties. They can be at full risk (i.e., be responsible for paying back, or covering the cost of, everything – 100% – of amounts above the financial benchmark) or at partial risk (i.e., be responsible for paying a pre-agreed proportion of the losses.) This is often referred to as taking on "downside" risk. This concept is also present in the MSSP and ACO REACH programs, as well as a number of managed care models.

- **Capitation.** Capitation is a means of paying a set amount up front intended to cover the predicted costs of all or some healthcare services for a specific patient over time. For example, some value-based care programs pay a per member per month fee for "care coordination" and a number of commercial payors pay per member per month (PMPM) fees for primary care services. If the cost of the services on average is below the capitated payments, the provider has profited and the capitated payments provide certainty of revenues each month. However, if the cost of care on average exceeds the capitated payment, the provider is responsible for covering all of those additional costs. As a result, this is considered a full-risk model for the agreed upon set of services.

- **Care Collaboration.** Although not a financial model per se, it is worthwhile to highlight care collaboration. Overall, there has been recognition that sometimes patients get lost in a system of healthcare providers and facilities operating in silos. For example, a patient may be discharged from a hospital with a recommendation to make an appointment with their physician and fill a prescription, but the patient has no way to get to a pharmacy or to their physician's office, so the treatment and follow up both fail and the patient winds up back in the hospital again. As a result, organizations at financial risk for the care of patients have recognized that care collaboration – ensuring a patient gets from point A to point B – is necessary to improve outcomes. Value-based care organizations at risk for patients (e.g., ACOs, IPAs, provider groups) are increasingly focused

on dedicating resources to coordinating and managing patient care with the aim of improving receipt of preventative care and addressing social determinants of health (e.g., inability to get prescriptions due to lack of transportation) all with the ultimate goal of improving outcomes. [8]

Value-based care models may involve one or several of the concepts outlined above. Understanding the terminology is only the starting point, because from the financial calculations and attribution methodologies the details of any one value-based care arrangement could be a chapter in and of itself.

II. Recent U.S. Value-Based Care Developments & Initiatives

The Trump administration and HHS, which includes CMS and CMMI, are promoting and testing new value-based care initiatives. In the second half of 2025, the Trump administration announced a number of new CMMI programs, both mandatory and voluntary, as well as tweaking and ending others. Below is an overview of some of the recent changes. In addition, the Rural Health Transformation Program initiated in 2025 aims to promote value-based care in rural areas.

1. CMMI: New & Updated Value-Based Care Models

a. Mandatory Models

In general, CMMI has rarely required participation in its models. Prior to 2025, there were only two mandatory models: the Comprehensive Care for Joint Replacement (CJR) Model ended in December 2024 and the ESRD Treatment Choices (ETC) Model was ended early by the Trump administration in December 2025. A mandatory model created by prior administration, the Transforming Episode Accountability Model (TEAM) just started in January 2026 despite industry requests to convert it to a voluntary model; although CMS did make several tweaks to the model in July 2025 to reduce some of the administrative burden and broaden patient choice. In addition, CMMI announced several new mandatory models in late 2025. The new models and changes to existing models all seem to focus on the "Make America Healthy Again" strategy of HHS.[9]

- ***IOTA.*** The Increasing Organ Transplant Access (IOTA) Model aims to increase end-stage renal disease patients' access to kidney transplants. The model launched July 1, 2025, and is mandatory for a group of around 100 randomly selected kidney transplant hospitals. The IOTA Model uses an upside and, after the first year, downside incentive payment for kidney transplants performed on Medicare patients. The incentive payment (or obligation) is determined by the participant's performance score, which is based on the number of transplants, organ offer acceptance rate ratio (efficiency-based), and post-transplant composite graft survival rate (quality-based). Participant's score determines an incentive payment of up to $15,000 per transplant upside or $2,000 per transplant downside payment. CMS has proposed changes that would take effect upon the beginning of the second performance year.[10]

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[8] See CMS Innovation Center, Key Concepts Website at www.cms.gov/innovation/key-concepts

[9] Modern Healthcare, CMS makes mark with flurry of value-based care, payment models (Jan. 13, 2026).

[10] Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model, 89 Fed. Reg. 96280, 96281 (Dec. 4, 2024); Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model 90 Fed. Reg. 57598, 57599 (Dec. 11, 2025). *See also* CMS IOTA website at https://www.cms.gov/priorities/innovation/innovation-models/iota.

- ***TEAM.*** TEAM, announced by CMMI in August 2024, is mandatory for hospitals in select geographic areas and will test whether episode-based pricing for select surgical procedures can reduce costs while maintaining or improving quality. TEAM will run from January 2026 until December 2030. The scope of this model is substantial compared to previous mandatory models. Almost a quarter of acute care hospitals paid under the inpatient prospective payment system (IPPS) will be mandatory TEAM participants.[11] CMS projects savings to Medicare to be about $481 million over five-years.[12]

  TEAM is intended to improve and expand upon prior bundled payment models, such as the prior CJR model. TEAM allows for up to 20% upside and downside risk on certain service "episodes." The episodes are: Coronary Artery Bypass Grafting, Lower Extremity Joint Replacement (LEJR), surgical Hip and Femur Fracture Treatment, Spinal Fusion, and Major Bowel Procedure. All items and services paid under Medicare Part A and Part B (except for specifically excluded Part B drugs) are included in an episode. An episode begins with an "anchor" hospital outpatient department procedure visit or acute care hospital stay and continues for 30 days after discharge. The hospital is fully financially responsible for the episode subject to the track chosen to limit risk. Certain hospitals, such as rural and safety net hospitals, may opt for a track that limits upside and downside risk.

- **ASM.** The Ambulatory Specialty Model[13] (ASM) is a mandatory model that begins January 2027 and will run through December 2031. The ASM will focus on, and be mandatory for, specialists who commonly (i.e., 20 or more patients a year) care for Medicare patients with heart failure or low back pain in certain geographic areas. Participating specialists will be required to report on targeted quality and care improvement metrics clinically relevant to their specialty type. Using these reports, CMS will assess quality, cost, interoperability, and care coordination. How a provider scores in these metrics compared to their peers will result in an increased or decreased payment for future Medicare Part B claims.

- **GLOBE and GUARD.** Last, and perhaps less value-based care oriented, are two newly proposed mandatory models related to Medicare Part B and D drug costs: Global Benchmark for Efficient Drug Pricing[14] (GLOBE) and Guarding U.S. Medicare Against Rising

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[11] The Value-Based Dream TEAM? How CMS's New Payment Model Could Spur Widespread Adoption of Value-Based Arrangements (Jan. 1, 2025).

[12] CMS, Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes, 89 Fed. Reg. 68986, 70026 (Aug. 28, 2024). See also www.cms.gov/priorities/innovation/innovation-models/asm.

[13] CMS, Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payments and Coverage Policies, 9 Fed. Reg 49266, 49562 (Nov. 5, 2025). See also www.cms.gov/priorities/innovation/innovation-models/asm.

[14] CMS, Global Benchmark for Efficient Drug Pricing (GLOBE) Model, Proposed Rule, 90 Fed. Reg. 60244 (Dec. 23, 2025). See also, www.cms.gov/priorities/innovation/innovation-models/globe and Modern Healthcare, CMS proposes 'most favored nation' Medicare drug price models (Dec. 19, 2025).

Drug Costs (GUARD). As proposed and if finalized, the GLOBE[15] Model will be a mandatory model intended to reduce the cost U.S. Medicare beneficiaries pay for certain Medicare Part B drugs compared to drug prices in other countries. GLOBE will run October 1, 2026 through 2031. This model will require manufacturers to pay rebates when the price of the drug exceeds an international benchmark, with the intention of keeping drug costs similar to what is paid by those in other countries for the same drug. The GUARD Model, as proposed, will also be mandatory and functions similarly to GLOBE, except that it applies to Medicare Part D drugs.[16] GUARD would run January 1, 2027 through 2031 and similarly would implement manufacturer rebates for Medicare Part D drugs based on an international cost benchmark to help keep drug prices more comparable to those in other countries.

b. Voluntary Models

In addition, a host of new voluntary models were announced in late 2025 which are worth noting.

- **LEAD.** The Long-term Enhanced ACO Design (LEAD) Model[17] is a new model building upon the lessons learned in the ACO REACH model (which ends in December 2026). LEAD is one of CMMI's most ambitious models, running for 10 years from January 1, 2027 through 2036. This model, like ACO REACH, is an ACO-focused model with changes aimed to promote broader provider participation through enhanced flexibility and tools to support providers, particularly smaller, more rural, and independent practices and those that serve high-needs patients. In addition, the model aims to encourage patient engagement through a variety of benefit enhancements and incentives (e.g., cost-sharing support and incentives to promote healthy eating, physical activity, and potential use of hemp products). Like the ACO REACH program, LEAD ACOs may select from "global" (100%) and "professional" (50%) upside and downside risk options, as well as involve some flexible population-based capitated payments. The model implements more accurate risk adjustment and benchmarking for patients with complex needs, allowing for organizations with more complex patient populations to care for those patients under an accountable care framework.

- **ACCESS**. The Advancing Chronic Care with Effective, Scalable Solutions[18] (ACCESS) Model will test outcome-aligned payments to enable clinicians to offer technology-supported care to help manage chronic disease for Medicare beneficiaries, including those with high blood pressure, diabetes, chronic musculoskeletal pain, and depression. The model will run for 10 years beginning July 5, 2026. ACCESS is designed to complement traditional care by providing payments for utilizing novel and technology-based methods of

[15] CMS, Global Benchmark for Efficient Drug Pricing (GLOBE) Model, Proposed Rule, 90 Fed. Reg. 60244 (Dec. 23, 2025). See also, www.cms.gov/priorities/innovation/innovation-models/globe and Modern Healthcare, CMS proposes 'most favored nation' Medicare drug price models (Dec. 19, 2025).
[16] CMS, Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, Proposed Rule, 90 Fed. Reg. 60338 (Dec. 23, 2025). See also, www.cms.gov/priorities/innovation/innovation-models/guard.
[17] CMS to end ACO REACH, launch LEAD model in 2027 - Modern Healthcare; CMS Website: www.cms.gov/priorities/innocation/innovation-models/lead.
[18] Modern Healthcare, CMMI introduces new ACCESS payment model. Here's what to know (Dec. 2, 2025); CMS Website: www.cms.gov/priorities/innovation/innovation-models/access.

treatment, such as telehealth, wearable devices, and coaching applications. The model will pay participating organizations recurring payments for managing patients' qualifying conditions, with full payment being tied to achieving measurable health outcomes determined based on each patient's starting point.

- ***WISeR.*** The Wasteful and Inappropriate Service Reduction (WISeR) Model is intended to test the use of technology and artificial intelligence (AI) to decrease waste. WISeR began January 1, 2026 in six states.[19] Through the model, technology companies will apply their technology to identify and review coverage determination for services that: (1) CMS views as posing patient safety concerns if delivered inappropriately; (2) have publicly available coverage criteria; or (3) have been identified in reports of fraud, waste, and abuse. However, it excludes inpatient, emergency, and other services for which delays would pose a risk to patients. Model participants (i.e., technology companies) will receive a percentage of savings attributed to averted wasteful and inappropriate care, with the percentage adjusted based on performance measures. Providers in certain regions may choose from utilizing a prior authorization process or being subject to a post-service/pre-payment review. In the future, providers and suppliers with a history of compliance may be exempt from the program. Providers have expressed concern that this program may result in inappropriate denials and harm access to care, plus add administrative complexity[20]

- ***MAHA ELEVATE.*** The "Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence" (MAHA ELEVATE) Model is designed to provide funding to evaluate how proactive, holistic, and functional or lifestyle medicine approaches that are not currently covered by Medicare can support conventional care. MAHA ELEVATE is expected to provide $100 million in funding for up to 30 proposals that promote health and prevention. The services tested under the model must not currently be covered by Medicare. The model is expected to launch September 1, 2026, with more details and a first Notice of Funding Opportunity expected in early 2026. [21]

- ***AHEAD.*** The Achieving Healthcare Efficiency through Accountable Design (AHEAD) Model is a revamped and renamed voluntary total cost of care model which aims to drive state and regional primary care and population health transformation, with alignment of all payers, to lower costs and improve outcomes. As of January 2026, six states are the primary participants[22], but primary care providers, hospitals, and "geo-entities" (which do not have to be provider-owned) can also be participants. As part of AHEAD, primary care providers can participate through one of four pathways, each offering different levels of financial risk and care transformation requirements. Hospitals may participate in a

[19] New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington.

[20] Medicare Program; Implementation of Prior Authorization for Select Services for the Wasteful and Inappropriate Services Reduction (WISeR) Model, 90 Fed. Reg. 28749, 28750 (July 1, 2025). *See also* CMS WISeR website at https://www.cms.gov/priorities/innovation/innovation-models/wiser and Modern Healthcare, AI Medicare prior authorizations look as providers fret (Oct. 31, 2025).

[21] CMS MAHA Elevate available at https://www.cms.gov/priorities/innovation/innovation-models/maha-elevate; see also Modern Healthcare, CMS targets chronic care, nutrition in "MAHA" Medicare Payment Model (Dec. 11, 2025).

[22] Cohort 1: Maryland; Cohort 2: Connecticut, Hawaii, and Vermont; Cohort 3: Rhode Island and New York. Additional states may be invited to participate.

Hospital Global Budget Program in which the hospital receives a prospective payment for a specific patient population, and geographic ACOs selected through competitive bidding which will be accountable for the total cost of care and quality outcomes for attributed beneficiaries, who may align through voluntary selection, claims-based attribution, or geographic assignment. The model will run through 2035 for all states. [23]

- ***BALANCE.*** The Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth (BALANCE) Model is a drug pricing-related model which intends to improve access to select glucagon-like peptide-1 (GLP-1) medications and healthy lifestyle interventions. CMS intends to negotiate drug pricing and coverage terms with GLP-1 manufacturers on behalf of state Medicaid and Medicare Part D plans with the aim of making GLP-1s more accessible. The BALANCE model will begin May 2026 for state Medicaid plans and January 2027 for Part D plans; both will run through 2031. [24]

- ***GENEROUS.*** The GENErating cost Reductions fOr U.S. Medicaid (GENEROUS) Model is another drug-pricing model which aims to ensure accessibility for patients and fair drug pricing for Medicaid plans. As part of the model, participating manufacturers will enter negotiated agreements with CMS to provide set pricing on their covered medications. Pricing to state Medicaid programs that choose to participate will be calculated based on select international pricing data and drugs from participating manufacturers will have standardized coverage criteria. [25]

2. Rural Health Transformation Program

The RHT Program was established as part of the budget reconciliation legislation, commonly known as the One Big Beautiful Bill Act (OBBBA) in 2025.[26] The RHT Program provides $50 billion over five years to strengthen rural communities and improve healthcare access, quality, and outcomes. CMS will implement the RHT Program in conjunction with the states. Half of the funds will be shared equally among all participating states, while the other half will be allocated by CMS based on various factors, including rural population, the proportion of rural health facilities in the state, the situation of certain hospitals in the state, and other factors.[27] On December 29, 2025, CMS announced the awards for 2026, which included all 50 states. The 2026 awards averaged $200 million and range from $147 million to $281 million.[28]

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[23] CMS AHEAD website at https://www.cms.gov/priorities/innovation/innovation-models/ahead.See also, Modern Healthcare, What to know about AHEAD, CMS' revamped all-payer model. (Sept. 25, 2025).

[24] CMS Press Release: CMS Launches Voluntary Model to Expand Access to Life-Changing Medicines, Promote Healthier Living (Dec. 23, 2025); CMS BALANCE Website at https://www.cms.gov/priorities/innovation/innovation-models/balance.

[25] CMS Press Release; CMS Announces New Drug Payment Model to Strenghten Medicaid and Better Serve Vulnerable Americans (Nov. 6, 2025); CMS GENEROUS website at https://www.cms.gov/priorities/innovation/innovation-models/generous.

[26] Public Law 119-21, § 71401 (July 4, 2025). available here.. See also www.cms.gov/priorities/rural-health-transformation-rht-program/overview.

[27] *See* Grants.gov. Rural Health Transformation Program, DHHS-CMS, CMS-RHT-26-001available here. See also, Rural Health Transformation Program – Innovation Opportunity for States and Rural Providers, Bass, Berry and Sims (Oct. 9, 2025).

[28] DHHS, Press Release: CMS Announces $50 Billion in Awards to Strengthen Rural Health in all 50 States (Dec. 29, 2025).

The strategic goals of the RHT Program include promoting value-based care and innovation aimed at improving disease prevention, chronic disease management, behavioral health, and prenatal care. Moreover, the funding is aimed in part at growing innovative care models to improve health outcomes, coordinate care, and promote flexible care arrangements, as well as developing and implementing payments that incentivize providers or ACOs to reduce costs, improve quality, and shift care to lower cost settings.

Although states were (and will be) the applicants for and recipients of the funds, providers will play a vital role in partnering with states to utilize the funds for the permitted purposes, which include: promoting evidence-based, measurable interventions to improve prevention and chronic disease management; payments to healthcare providers for the provision of healthcare items and services (subject to certain restrictions); supporting access to opioid use disorder treatment services and mental health services; promoting consumer-facing, technology-driven solutions for prevention and management of chronic diseases; developing and supporting innovative and value-based care models, training and recruiting; and more.

III. Deciding What Value-Based Care Arrangement is Right for Your Organization

The primary characteristics of a healthcare organization are going to go a long way to narrowing the types of value-based care arrangements for which it is well suited. For example, hospitals are not likely to participate in the same programs – or at least not at the same level – as a primary care practice. Here are some things to keep in mind as you think about what value-based care opportunities may be right for your organization:

- **Start By Defining Your Patient Population and Identifying Its Payor Mix.** This information will help you narrow your focus and direction relatively quickly. The answer may be easy for some organizations. For example, if the organization is focused on substance abuse and most of its patients struggle with opioid use disorder, then that is likely the right patient population on which to focus. The question may be a bit harder for a health system or hospital that treats patients with a variety of conditions. In that instance, the organization needs to evaluate where it thinks it can have the most significant impact and start there. The patient population could be determined based on one or more diagnosis (e.g., opioid use disorder, multiple chronic conditions), a particular procedure (e.g., joint replacement), or simply geography (e.g., all primary care patients seeing certain physicians in a certain geography). Once the population is defined, then it should be relatively easy to determine the major payors at hand. Returning to our substance abuse example, most adults with opioid use disorder are covered by either Medicaid managed care organizations (MCOs) or commercial payors. Whereas if your organization is focused on treating elderly patients with multiple chronic conditions, then the payors that will matter the most are Medicare and MCOs with Medicare Advantage plans so you should consider value-based care opportunities relevant to those payors and that population.

- **Recognize that MSSP and CMMI Models Are Mostly Not Negotiable.** MSSP is set out in regulation and CMMI models are structured by CMS in sub-regulatory guidance. All participants are committed to abide by the terms and conditions established by CMS in its guidance, regulations, and/or participation agreement. This may take flexibility out of the arrangement but also may add some certainty as to how it works. Comparatively, commercial and managed care arrangements are negotiable, but as discussed in the next section, not abundantly so.

- **Determine Your Ability/Desire to Take Risk and Do Your Financial Homework.** There is no way around the fact that value-based care is extremely data heavy and that it is important to understand historic claims data and financial projections. Before starting a value-based care arrangement, particularly one with downside risk, it is important to have thoughtfully evaluated the historical claims data, determine how your organizations plan to improve quality and bring down costs, and project financial results. Perhaps less important when simply setting up performance bonuses based on outcomes metrics, but when considering or undertaking risk – whether you have your own actuarial team or plan to rely on a third-party consultant – understanding how the payments will work and projecting a realistic financial picture is extremely important. Further, it is important to balance the financial investments needed to improve care against the fact that shared savings and other performance payments may not be received until nine months after the end of a given performance year. The organization should consider how it will finance those initial expenses and whether it needs some sort of up-front payments (e.g., monthly care coordination payments or advances on shared savings) to be able to achieve positive results.

IV. Negotiating Value-Based Care Arrangements with Managed Care Plans

Value-based contracts are some of the most challenging agreements to negotiate, and for once, it is not due to complex legal issues. The heart of the business arrangement lives in the risk-related exhibits or appendices, which are often overlooked by lawyers because of their financial complexities. The lawyers need to fully understand these exhibits and be able to translate the intent of the parties to ensure the business teams really understand the terms of the agreement and the risks. In addition, in negotiating with payors, there are many factors that are beyond the control of the provider that can make negotiating such arrangements extremely frustrating. There are, however, tactics and best practices that can help protect your company.

There is a saying in the industry: if you've negotiated one agreement with one health plan, you've negotiated exactly one agreement with one health plan. Every plan is different and even geographic divisions and lines of business (Medicare vs. Medicaid) of the same plan are different, so prior experience with a health plan rarely translates into useful strategies for future negotiations. Each plan also has different ideas on how value-based arrangements should be structured, and given that it is a developing area, those internal ideas may shift mid-negotiation. In addition, contracts are often negotiated by the plan's contract specialists who are not lawyers. In our experience, these contract specialists have an extreme aversion to getting plan counsel involved, often because the plan is trying to keep their contracts as uniform as possible. Therefore, even when you know a quick conversation between lawyers would likely resolve an issue relatively quickly, that is often not an available option. Therefore, it is extremely helpful to understand who the decision makers are (local vs. corporate) and to work to maintain those relationships despite turn-over and shifting roles.

Health plans move at a very slow pace given the need for multiple teams to review and authorize – turn-over, competing priorities, and other unknown issues can impact progress. Provider business teams, however, are anxious to get agreements inked as quickly as possible so they can start implementing their plans and realizing the quality and financial outcomes they hope to achieve. Providers may turn agreements around in a couple of business days just to wait multiple weeks to hear anything back from the health plan. This desire to sign the contract as soon as possible puts pressure on the provider's negotiating leverage to the point where business teams often end up negotiating against themselves just to get the deal done.

1. Provider vs. Vendor Templates

A value-based arrangement is typically created as an exhibit or addendum to a health plan's vendor agreement or provider agreement. In almost all cases, health plans will insist upon using their template agreement and many of the terms in those agreements are not negotiable. Providers should understand the differences between the two types of templates and consider whether they want to try and push for one or the other. Either way, but especially with vendor agreements, there are likely to be terms in the main agreement that simply are not applicable to a value-based arrangement.

Most value-based organizations and providers prefer to document value-based arrangements as part of a provider agreement. Framing the content as a provider agreement is a positive factor in a plan's analysis as to whether the spending under the arrangement is treated as part of medical expense rather than administrative expense under their MLR under 45 C.F.R Part 158. The use of a vendor agreement will almost always result in the health plan treating the expense as administrative rather than medical and, therefore, often results in the plan being less willing to negotiate rate increases under such contract. To the extent that an arrangement involves member outreach, data analytics, or other consulting type services, a plan may prefer to bifurcate the arrangement such that the non-clinical services fall under a vendor agreement together with a business associate agreement and only the pure clinical aspects fall under the provider agreement. In such cases, the plan will likely treat the expense under the vendor arrangement as administrative expense and the expense under the provider arrangement as medical expense.

From the provider standpoint, there are several drawbacks to splitting the arrangement into a vendor and provider arrangement. The first is the pure complication of negotiating and managing two different agreements with the health plan for the same program. On the health plan side, the negotiation of the arrangements will likely belong to two separate internal teams: one for the vendor agreement and one for the provider agreement. Thus, leaving the provider to negotiate with two separate teams (and negotiate renewals with two separate teams). It can put the provider in a tight spot when the provider agreement has been renewed but the vendor agreement renewal is still under review by a separate team at the health plan. In addition, providers that contract under a vendor agreement are subject to greater scrutiny from the health plan. Most health plans annually audit their vendors but do not do the same with providers. These audits can be extensive requiring review of policies and procedures, confirmation of training, and extensive questionnaires that may result in corrective actions plans for the provider.

2. Understanding & Negotiating the Addendums

The agreement addendums to value-based arrangements contain the substance of the business deal. As a result, they are typically the most important and most complex portion of the agreement. It is important for the finance, legal, and actuarial teams to work closely. This is not the time for the lawyers to take a step back and let the business folks do the drafting. If a dispute arises in the arrangement, it will likely stem from the calculation of savings and/or loss, or the components input into such calculations. In drafting and/or reviewing those addendums/exhibits, it is helpful to have the business teams create one or more examples of how the financial arrangement and the calculations are expected to work. These examples should be reviewed and confirmed by both sides and ideally attached as an illustrative example to the agreement. Including examples in the addendum not only makes sure the parties are in synch on how the financial calculations will work, but also helps the lawyers to confirm the language of the addendum matches the parties' intent.

In addition to understanding how performance metrics will be measured and how savings and losses will be calculated in the addendum, the provider needs to clearly understand the components that go into the calculations within the addendum. This requires knowledge of: (1) how plan members are assigned or attributed to the arrangement and how and when a member is removed (i.e., no longer attributed); and (2) what is included in, and excluded from, medical expense. Again, this area is ripe for dispute if not clearly defined. As a result, it is best practice to have a clearly articulated process by which the parties can raise and resolve discrepancies in the calculation and inputs. In addition, as a preventative measure, it is best practice for the parties to communicate frequently throughout the measurement period to make sure that the parties are in agreement regarding how the calculations are trending. The earlier the parties can identify and raise differences in how their calculations are tracking, the easier it is to figure out why there are differences and come to some resolution.

3. Tips to Protect Provider Organizations

There are several things that providers can do when negotiating these arrangements to protect themselves and their investments to effectuate value-based care.

- **Term & Termination.** The first is to push for a multi-year initial term. Value-based arrangements typically take time and require investment on behalf of the provider to achieve savings. A one-year term will often not be enough for the provider to recoup its investment. The longer the term the better, though most arrangements do not extend beyond three to five years. In addition, pay particular attention to termination for convenience provisions or other provisions that would allow the health plan to unilaterally alter the economics of the relationship. In some cases, the termination for convenience provision is not negotiable. If that is the case, consider negotiating a penalty for the plan terminating prior to a designated date to allow the provider to recoup its investment or provide that the plan may not terminate for convenience prior to a certain date.

- **Limit Downside Risk Initially.** If a provider plans to take downside risk, the provider should consider limiting their downside risk in an arrangement, especially in the early years. Again, these programs often need time to ramp up. There are multiple ways to limit downside risk. One option is for the provider to take a lower percentage of the downside risk in the first year or two and gradually increase that risk over time. The provider might also want to consider limiting its risk to the fees, if any, the provider receives from the health plan during the course of a year such that the provider would not have to pay back more than what it received from the plan in that year. Another option could be to start with a case rate arrangement (e.g., X$ per member per month for managing the members' care) before moving to risk in order to give the provider time to understand the network and population in the market. In addition, providers should consider excluding from its cost of care risk those portions of a population that it cannot impact. For example, a kidney care value-based entity might exclude patients in hospice given that its model would not likely be able to impact that patient's cost of care. We have often seen value-based care programs, particularly those taking on mostly full risk, exclude things like members in hospice, members receiving transplants, and member pharmaceutical expenses.

- **Adverse Events.** A provider should also consider negotiating protections for adverse changes outside of its control. What happens if a state or federal healthcare program (FHCP) changes pricing and it negatively impacts your target population more than other populations, what if new drugs are introduced that were not included in the baseline, or what if there are changes in laws

or regulations? These issues can be addressed in a more general or prescriptive manner. It is in the provider's best interest to have more general language that covers a broad range of adverse events and allows the parties to negotiate an adjustment to the baseline, as issues arise. Health plans, however, are going to want to narrow such flexibility in order to provide more certainty on the outcome and reduce having to negotiate multiple adjustments to the baseline. For example, a health plan may want to utilize Milliman's actuarial trend assumptions to guide retroactive base line adjustments. Milliman Health Trend Guidelines is a resource that provides "insurers, healthcare providers, and employers monthly information on healthcare expenditures and utilization for individuals enrolled in commercial insurance plans in the United States."[29] While Milliman is a useful reference point for trend and utilization, these calculations may have limited applicability to certain population subsets and do not take into account considerations like population acuity. As a result, provider organizations should confirm that their actuary team is comfortable with applying the Milliman trend assumptions. In addition, a health plan may want to limit the applicability of any adjustments by negotiating a materiality threshold that must be hit before an adjustment may be considered.

- **Quality Measures.** Quality measures are becoming increasingly important in value-based arrangements and may have a material impact on the financial results. Quality measures are also a factor that health plans consider when determining whether the plan's payments under the arrangement will be counted as administrative or medical expense. In addition, in Medicaid contracts, certain quality measures are often required by the state to be included in the provider agreement. When it comes to financial impact, quality measures may serve as a gate to a provider earning any savings in an arrangement. Said another way, if the provider does not meet certain minimum quality measures (i.e., the gate), it will not be eligible to receive a portion of any shared shavings. In addition, quality measures may be a trigger for receiving a bonus for achievement. In some cases, quality measures serve as both a gate and a bonus metric, meaning minimum quality measures must be achieved to be eligible for savings and better performance on the same or different quality measures may make the provider eligible for a bonus. Quality, however, is often difficult for a provider to manage. For example, the data from which quality is calculated requires several months' run out resulting in a delay before the results of any needed changes or course corrections to the program start to show. In addition, the parties can run into issues regarding being in sync on how quality is being measured given differences in data sets and processing, often making it difficult for the provider to know where they stand on such metrics at any point in time. Some of this can be addressed in negotiations, but as data and metrics change it can easily evolve. As a result, establishing a good working relationship to enable the parties to sort out these nuances as early as possible in the relationship is valuable on both sides.

- **Member Engagement**. In addition to quality, health plans are also increasingly focused on engagement of their membership. Like quality, plans may require outreach to and/or enrollment of a certain percentage of their membership prior to sharing any savings with the provider. Prior to agreeing to such arrangement, a provider should have a strategy for engaging with the population and whether the proposed gate is reasonable for its model. In addition, providers should try to get the plan to commit to some initial and ongoing outreach to applicable members to inform them of the availability of the provider's services. Without the plan's help, it can be significantly harder for providers to get the members to engage with them because it is hard for

[29] Milliman Health Trend Guidelines available at www.milliman.com/en/Products/Milliman-Health-Trend-Guidelines.

the members to distinguish between value-based care providers their plan has engaged to help them and providers simply undertaking general marketing. Moreover, value-based care providers that contract with Medicaid managed care plans or Medicare Advantage plans should be attuned to rules and regulations surrounding marketing.

- **Data.** Another pressing issue in value-based arrangements is access to and use of data. Any value-based care provider will benefit from data analytics. Data analytics allows providers to better understand their population and how to manage it. For example, it may tell the provider where their attributed members are accessing care, which members are high costs, etc. To the extent that data is a required element of a provider's arrangement, it is important to obligate the health plan to provide the needed data in the requisite time frame and in the needed format. In addition, the value-based care agreement, and any accompanying business associate agreement, should recognize and grant the provider's rights to obtain, maintain, and use the data, as needed.

Value-based arrangements can be complicated and often take longer than anticipated to negotiate. Negotiating them requires a strong partnership among the company's legal, finance, and actuarial teams. A provider can put itself in a stronger position by having a clear understanding of the facets of the deal that it is striking with the health plan. Ultimately, a provider is more successful when they run their program as a partnership with their health plan client rather than as a standard vendor or provider relationship.

V. Negotiating Downstream Relationships with Physicians & Practices

Frequently, the value-based organization that has elected to take on risk is neither a payor nor a provider, rather it is an organization that plans to partner with providers to improve or maintain quality and reduce costs. These types of organizations can include health systems, ACOs, independent physician associations (IPAs), physician networks, and other risk-bearing organizations, or as sometimes referred to by CMS, conveners. In addition to contracts with the payor (whether that be CMS or a health plan), these organizations must also establish and implement agreements with downstream providers, often physician practices or other healthcare providers (e.g., home health, skilled nursing facilities, and more) to collaborate and implement quality improvements. Negotiating and effectuating these downstream participation relationships are important to the success of the organization.

With respect to Medicare ACOs (i.e., Medicare Shared Savings Program, REACH, and soon LEAD), the ACOs typically prefer to enter into the same agreement with each participating provider. Most ACOs design their agreements to incorporate terms required by the CMS participation agreement. As a result and because they want consistent agreements across their participants, once again they are often not willing to negotiate a lot of the terms beyond the financial terms, which are often in exhibits. It often takes some explanation to educate participants on CMS requirements in the agreement that cannot be changed. In addition, sometimes the ACO's business teams are in a hurry to confirm their participation roster ahead of CMS deadlines, which in the rush can lead to the agreement exhibits not being entirely completed prior to signing. As a result, it may be wise to go back and periodically audit participation agreements for completeness. Moreover, sometimes ACOs will have a master agreement with a health system to incorporate all or most of their affiliated physician practices, with additional individual agreements between the practice and the ACO to meet CMS requirements. In some ways this can be easier, after all health systems have sophisticated internal counsel and they will help negotiation on behalf of all their affiliated practices; however, health systems do not typically move quickly so it may take some cajoling to get the agreements across the finish line in time to participate in the next performance year.

Often backed by private equity or other investors, these value-based care organizations can bring actuarial expertise and financing to support investments in care collaboration and technology to promote and effectuate innovation. In addition, these organizations tend to be more willing to take on risk than physician practices and other providers. As a result, it is not unusual to see value-based organizations take full risk, but for their downstream providers to only share in upside savings.

There are unique nuances to these downstream arrangements because in order to achieve the goals of improving quality and reducing costs, the value-based organization needs to motivate the practitioners to devote time and resources to utilizing new technology and undertaking activities that may go beyond their usual clinical services. Moreover, practitioners may not appreciate the delayed gratification of waiting almost two years to reap savings. In addition, the value-based organization needs to balance both recouping its initial investments over the life of the arrangement and sharing savings to keep the practitioners engaged.

Last, but certainly not least, wherever there are physicians (and other practitioners) and the exchange of money, items or services. (i.e., any financial relationship), it is very important to ensure the arrangement complies with applicable federal and state fraud and abuse laws, including Stark and AKS, and their state law equivalents. In addition, substance abuse providers need to take into consideration the Eliminating Kickbacks and Recovery Act (EKRA), which is an all-payor federal kickback law.[30] Among other things, this involves careful analysis of all current and proposed financial relationships to ensure that they can be and are structured to comply with a Stark exception, if necessary, and either meet a safe harbor to the AKS or is otherwise sufficiently low risk. For an overview of these exceptions and safe harbors, see D. Sloane, Regulatory Sprint to Coordinated Care: Final Rules Modernize the Federal Stark and Anti-kickback Laws, Health Law Handbook, Volume 21, pg 62-115. In addition, participants in some older CMMI models (or their successors) or the Medicare Shared Savings Program may still be able to rely upon fraud and abuse waivers. In order to conduct the analysis, however, it is vitally important to understand the flow of money, the payment calculations, and likely practitioner referral relationships.

VI. Addressing Social Determinants of Health

Once the value-based care arrangement has been negotiated, everyone quickly moves on to effectuating change. As value-based care has taken hold, the industry has come to recognize that one of the most effective ways to improve quality and reduce healthcare costs for a given patient population is to evaluate and address social determinants of health (SDOH). Recent literature consistently demonstrates that identifying and mitigating SDOH—including housing instability, food insecurity, transportation barriers, education, and socioeconomic status—leads to measurable improvements in patient outcomes, reductions in preventable complications, and enhanced continuity of care.[31] In addition, states are requiring Medicaid MCOs to address SDOH needs. Those MCOs are in turn requiring their value-based providers to help fulfill those obligations through quality measures. Traditional Medicare does not obligate providers to address SDOH needs. Medicare does, however, encourage providers to address such needs by, for example, paying for SDOH risk assessments[32] and requiring hospitals and some provider organizations to screen for and report data on addressing SDOH needs to CMS. Moreover, some CMMI

[30] 8 U.S.C. § 220.

[31] See e.g., Vrtikapa K, Hoque Urmy F, Hoque F. Social Determinants of Health: The Impact of This Overlooked Vital Sign. *Brown Hospital Medicine*. Vol. 4, Issue 3 (July 2025).

[32] CMS MLN Matters, Annual Wellness Visit: Social Determines of Health Risk Assessment, MM13486 (Oct. 2024).

models, such as REACH ACOs and the LEAD program, include beneficiary enhancements and beneficiary incentives designed to promote care improvement and access to overcome SDOH, like expanded use of telemedicine for those that are homebound.

Despite the evidence, the requirements, and the encouragement around addressing SDOH needs, there are legal implications that providers must evaluate prior to funding such SDOH programs under the federal fraud and abuse laws applicable to patient incentive programs, namely the AKS, EKRA, and the CMP Law's beneficiary inducement provision. Fraud and abuse laws traditionally are aimed at reducing overutilization of healthcare services, protecting patient choice, and avoiding unnecessary costs to FHCPs. Ideally, providers should design their programs to fulfill SDOH needs to satisfy an AKS safe harbor and/or a CMP Law exception and thereby protect themselves from any federal False Claims Act (FCA)-related claims based on failure to comply with those laws. Outside of a safe harbor or exception, the government will review a proposed arrangement based on the surrounding facts and circumstances. In that situation, providing items or services to address SDOHs should be designed thoughtfully and carefully to incorporate safeguards that help to ensure that the program is initially set up, and over time is operationalized, in a way that continues to keep the risk relatively low. It is important also to recognize that a government regulator will not look at an SDOH program in isolation in evaluating if there is an impermissible intent present to influence patient choice; rather, under a "stacking" concept, all incentives and offerings to FHCP beneficiaries are likely to be viewed in the totality (i.e., adding together all incentives, discounts, gifts, and promotional items/services).

Providers need to pay particular attention to this analysis given that there is active enforcement in this area. For example, in August 2025, a Department of Justice (DOJ) settlement was announced relative to the provision of housing and food to patients. In summary, NUWAY Alliance, a nonprofit substance use disorder treatment clinic, entered into an $18.5 million settlement with the DOJ. In the complaint, among other allegations of wrongdoing, NUWAY was accused of providing free housing and free food to patients as a condition of participation in NUWAY's IOP treatment services.[33] As this case demonstrates, there can be a fine line between providing items and services to patients as a means to promote the program and increase patient volume versus aiming to address patient SDOH challenges.

Given the legal constraints, providers often turn first to resources in the community to address SDOH needs. If there is an unaffiliated community resource providing, and most importantly funding, the support, then the healthcare provider solves the issue and can avoid fraud and abuse risk. These resources may range from the patient's health plan, religious organizations, nonprofit organizations, or federal or state programs. Of note, increasingly health plans, including Medicaid MCOs and Medicare Advantage plans, have programs to address SDOH, such as transportation, medication delivery, utility support, and more. These resources are very valuable and are able to address many needs, but there are circumstances where such resources are not reasonably available. The program might not be geographically suitable for the patient, the patient may not meet certain criteria of the program, or the program may not have capacity at the time needed. For example, a provider had a patient that needed housing. He met all of the criteria for a nonprofit housing program. The patient, however, was handicapped and the housing was not handicap accessible. As another example, a patient may qualify and have transportation available through its Medicaid MCO; however, to use that program the patient needs to schedule a ride two weeks in advance and for some reason that is not feasible.

[33] Complaint, U.S. ex rel. John Marston vs. Nuway Alliance et al. U.S.D.C. Minn, Case 0:21-cv-00171-SRN-DLM (June 2025). DOJ Press Release, NUWAY Alliance Agrees to Pay $18,500,000 Settlement in Medicaid Kickback Scheme, False Claims Violations.

If a provider is not able to address SDOH needs with a community resource and it wants to fulfill the need itself, it will want to design its program to comply with the fraud and abuse laws mentioned above. When undertaking that analysis, here are a few things to keep in mind:

- **Evaluate Whether the CMP Law Beneficiary Inducement Prohibition Applies; and, if so, Whether the Program Can Meet an Exception.** Under the CMP Law beneficiary inducement prohibition, providers may not offer or provide "remuneration" to FHCP beneficiaries that the person knows or should know is likely to influence their choice of a particular provider, practitioner, or supplier for any covered item or service.[34] To provide an example, if the patients have a choice of primary care practitioners through its Medicaid or Medicare managed care plan, then there is a possibility that the provision of patient supports could influence the patient's choice to select or remain with one primary care practice. Comparatively, however, if the patient is assigned to a primary care practice by the managed care plan and the provider is paid a PMPM fee regardless of whether the patient utilizes its services, there may be a good argument that the CMP prohibition is not implicated. If the provision of SDOH supports falls within the CMP Law, then exceptions to consider include: (1) the nominal value exception[35]; (2) the promotes access to care exception[36]; and (3) the financial need exception[37]. In addition to the CMP exceptions, meeting an AKS safe harbor qualifies as an exception to this CMP prohibition. As a result, meeting an AKS safe harbor does double duty, protecting the SDOH program participants from regulatory risk under both the AKS and CMP Law.

- **Evaluate the SDOH Program Under the AKS.** The AKS prohibits anyone from knowingly offering, paying, soliciting, or receiving any remuneration in exchange for a referral of patients for items or services payable under a FHCP[38]. This can include providing remuneration to a patient and, in that way, it targets the same behavior as the CMP. Unlike the CMP beneficiary prohibition, the AKS prohibition applies to influencing choice of Medicare or Medicaid MCOs as well as choice of providers and suppliers. The AKS has certain statutory exceptions and the OIG has promulgated safe harbors, both of which protect remuneration if all elements of the exception or safe harbor are met. Some safe harbors to consider include the discount safe harbor, local transportation safe harbor[39], and the patient engagement and supports (Patient Engagement) safe harbor.[40] Created in 2020, the Patient Engagement safe harbor requires establishment of a value-based enterprise (VBE) and protects up to $623 (CPI adjusted annually) of "in kind" tools and supports provided to patients to help coordinate and manage care that are recommended by their practitioner and not advertised.

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[34] 42 U.S.C. § 1320a-7a.

[35] OIG, Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), *available at* https://oig.hhs.gov/documents/special-advisory-bulletins/887/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf. *See also* Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (Aug. 2002), *available at* https://oig.hhs.gov/documents/special-advisory-bulletins/886/SABGiftsandInducements.pdf.

[36] 42 U.S.C. § 1320a-7a(i)(6)(F); 42 C.F.R. § 1003.110; 81 Fed. Reg. 88,368, 88,393-88,396 (Dec. 7, 2016) and OIG Advisory Opinion 20-08.

[37] 42 U.S.C. § 1320a-7a(i)(6)(H); 42 C.F.R. § 1003.110; and 81 Fed. Reg. 88,368 at 88,401-05. Note also that there are additional CMP exceptions not mentioned, such as one addressing copay and cost-sharing waivers.

[38] 42 U.S.C. § 1320a-7b(b).

[39] 42 C.F.R. § 1001.952(bb).

[40] 42 C.F.R. § 1001.952(hh); 85 Fed. Reg. 77,684, 77,789 (Dec. 2, 2020).

Failure to meet an AKS safe harbor is not a per se violation of the AKS. Instead, the OIG would review the individual facts and circumstances of an arrangement. Notably, although meeting one of the CMP exceptions would be a positive factor in a facts and circumstances review, technically meeting a CMP exception does not qualify as an AKS safe harbor.

- **Don't Forget to Consider EKRA If Your Organization Is Involved in Substance Abuse Treatment or Laboratory Services.** EKRA is a criminal law that prohibits, among other things, knowingly providing remuneration in exchange for referrals similar to the AKS, but it applies to services covered by commercial payors and only applies to substance abuse treatment programs, clinical laboratories, and sober living facilities. [41]

- **Track Annual Limits.** To the extent your SDOH program relies on a CMP exception or an AKS safe harbor that has a monetary value limit, it is important to track and audit the provision of such items to ensure the annual limit is not exceeded. It is easy to provide a patient with a lot of SDOH needs a number of benefits. Because remuneration is generally anything of value, it is easy to overlook that the multitude of supports provided to a patient or their caregivers is approaching or may exceed the monetary limit. In tracking, be sure to capture items provided to patients, their family members, and their care givers because the OIG does not seem to distinguish between supports provided to the caregivers of patients rather than the individual patient.

- **Don't Advertise or Promote SDOH Assistance.** Because fraud and abuse laws are focused on undue influence, one way to protect the provision of SDOH assistance where financially supported by a healthcare provider is to not advertise generally the availability of such services. While word-of-mouth cannot be avoided, any marketing or promotion of the provision of housing, food, or other supports will substantially increase risk under state and federal fraud and abuse laws.

VII. Engaging & Motivating Patients

In order to be successful (regardless of SDOH needs), all value-based organization and their participating providers should aim to motivate their patients to engage in their own healthcare. What that engagement looks like may differ by patient population. Some avenues value-based organizations and providers have taken to motivate patients to be more engaged in their treatment and care include incorporating digital tools (e.g., apps that remind patients to take their medications or complete their exercises) and rewards for attending counseling or preventative care screenings.

While clearly better engagement leads to better outcomes and reduced costs, what actually motivates patients to engage in their own healthcare does not appear to be a one size fits all solution. To the extent that a provider uses motivational incentives that qualify as providing anything of value to patients (i.e., gift cards or gifts) in order to keep them motivated to meet their treatment plans and goals, providers must walk through a similar fraud and abuse analysis to the one discussed in the previous section, including review of their patient engagement program under the AKS, CMP Law beneficiary inducement prohibition, EKRA, and similar state laws.

1. Rewarding Patients with Gift Cards

[41] 8 U.S.C. § 220.

One of the issues that often arises with respect to motivation incentives is rewarding patients with gift cards for treatment adherence or meeting treatment goals. Generally, to meet the AKS Patient Engagement safe harbor and several of the CMP exceptions, the items provided to patients are required to be either "in-kind" and/or not qualify as "cash or cash equivalents." While the OIG may consider a gift card that can only be redeemed for certain categories of services or items, such as a meal delivery service or a gasoline card to be "in kind," the OIG generally considers gift cards to "big-box" retailers (i.e. Target, Walmart, Amazon) to be "cash equivalents" and thus utilizing such gift cards or other cash equivalents, like a visa card, is likely to take a motivational incentive arrangement outside of an CMP exception or AKS safe harbor.[42]

The OIG has issued several favorable advisory opinions relating to thoughtfully using "big box" store gift cards to incentivize patients to engage in their healthcare. For example, in December 2020, the OIG issued a favorable opinion in Advisory Opinion 20-08 regarding a nonprofit federally qualified health center's proposal to offer $20 "big box" gift cards to incentivize certain pediatric patients who had missed two or more previously scheduled preventative and early intervention care appointments to attend rescheduled appointments.[43] Similarly, in August 2022, the OIG issued a favorable advisory opinion in favor of an entity that contracts with Medicare Advantage plans on a PMPM basis regarding a proposal to provide gift cards to certain Medicare Advantage enrollees who completed specific steps in an online education program.[44] Despite not meeting a CMP exception or AKS safe harbor, the OIG pointed to specific various safe guards that made the arrangements low risk, including: (1) the proposals were unlikely to increase the costs to FHCPs or the patient through overutilization or inappropriate utilization; (2) the proposals were not advertised to the public; and (3) the incentives were narrowly tailored to accomplish the purpose of the program.

Gift cards have also been in the enforcement news recently. In the fall of 2025, the compliance director and office manager of a substance use company were criminally convicted for giving gift cards to Medicaid patients for attending appointments. There is no indication in the court documents that any of the safeguards previously discussed were instituted. Instead, the two individuals were giving patients gift cards under the table based on the number of visits they attended each week. ($45 for three visits, $50 for four visits, and $60 for five visits). Some patients even received an extra gift card if they brought a friend along. These gift cards were also to a big box store, so the OIG would have categorized them as cash equivalents.[45]

2. Substance Abuse Contingency Management Programs

With respect to patients with substance use disorder, one of the clinically proven interventions to increase engagement and improve outcomes is clinical contingency management (CM).[46] CM programs aim to: (1) identify and specifically define target therapeutic behaviors such as drug abstinence; (2) carefully monitor the target behavior(s) objectively on a pre-specified schedule; and (3) deliver reinforcing or punishing

[42] 85 Fed. Reg. 77,684, 77,789 (Dec. 2, 2020); OIG General Questions Regarding Certain Fraud and Abuse Authorities (May 31, 2024) available at https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/.
[43] OIG Advisory Opinion 20-08 (Dec. 2020).
[44] OIG Advisory Opinion 22-16 (Aug. 2022).
[45] IRS, Press Release. Compliance director and office manager of substance abuse company convicted in scheme to pay Medicaid kickbacks to patients (Aug. 25, 2025).
[46] See e.g., Traci Sweet Psy.D., MBA, Contingency Management: What it is and Why it Works, Psychology Today Blog Post (May 2025).

events (e.g., tangible rewards or incentives, loss of privileges) when the target behavior is or is not achieved.

Even though CM has been clinical proven to be effective for substance use disorder patients, it has relatively low adoption among the industry due to concerns over regulatory risk from fraud and abuse laws. For a number of years, there was confusion in the industry that CM programs had to fit within the nominal value exception to the CMP which has an annual cap of $75, as reinforced based on the Substance Abuse and Mental Health Services Administration's (SAMHSA) limitation of its grant programs to $75 per patient per year (PPPY) due to its prior interpretation of certain OIG guidance. The industry generally did not believe that $75 PPPY was enough to properly incentivize a patient. The OIG, however, has never said that CM was limited to $75 annually. In fact, the OIG has issued a couple of favorable advisory opinions relative to CM programs with the first issued back in 2008.[47] These advisory opinions acknowledge the utility of using motivational incentives in the substance abuse treatment space and supported up to $600 per year in CM. Moreover, when establishing the Patient Engagement safe harbor in 2020, the OIG noted the effectiveness of CM and referenced CM as an example of a support that could be structured to fit within the Patient Engagement safe harbor, which has a cap of $623 for 2026 (CPI adjusted annually).[48]

Most recently, the Biden administration published guidance that allows SAMHSA grant programs that authorize CM interventions to provide incentive values of up to $750 PPPY, which previously was $75 PPPY.[49] SAMHSA acknowledged that the new cap exceeds the AKS Patient Engagement safe harbor cap (currently $623), but states that amounts that exceed this cap are not necessarily violative of AKS or the CMP. In combination, SAMHSA's guidance and the OIG's advisory opinions and other statements suggest that the government is supportive of CM when appropriate safeguards are in place. Although the government has given a nod toward CM, it is easy for these programs to become problematic, so it is important to design and implement them thoughtfully, including tracking the effectiveness on patient outcomes over time.

3. Carefully Design, Implement, & Monitor

Overall, whether CM is used in substance abuse or as a general motivational incentive to keep patients on track with their treatment plans, prior to implementing any patient engagement program that a provider plans to financially support, the provider should carefully review the relevant CMP exceptions, AKS safe harbors, and related OIG advisory opinions and guidance. The development of patient engagement programs can and should be crafted with as many safeguards as possible to help reduce the overall fraud and abuse risk, including not advertising, narrowly tailoring the program to be focused on the goal, ensuring it doesn't lead to overutilization, limiting cash equivalents where possible, and more. In addition, patient engagement programs that include incentives and rewards and the applicable safeguards should be set forth in a formal policy and should be tracked and audited for compliance with the policy and for effectiveness toward meeting the program goals.

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[47] OIG Advisory Opinion 08-14 (Sept. 2008); OIG Advisory Opinion 22-04 (Mar. 2022).

[48] 85 Fed. Reg. 77,684, 77,791-792 (Dec. 2, 2020); see also HHS, Contingency Management for the Treatment of Substance Use Disorders: Enhancing Access, Quality and Program Integrity for an Evidence-Based Intervention (Nov 7. 2023).

[49] SAMHSA Advisory: Using SAMHSA Funds To Implement Evidence-Based Contingency Management Services (Jan. 2025).

VIII. Conclusion

Value-based care is here to stay and negotiating and implementing these arrangements come with a host of legal considerations that differ from the fee for service environment in which the healthcare industry has historically operated. We hope our tips and tricks help you on your journey toward value-based care.

Authors

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