December 9, 2020

The Robinson+Cole Health Law Group is committed to examining and reporting on issues important to the health care and life sciences industries. Below are excerpts from our *Health Law Diagnosis* blog, where we post on fraud and abuse, government enforcement, Medicare and Medicaid, reimbursement, hospitals and health systems, pharmaceuticals, medical devices, and other areas of interest.

HHS Publishes Significant Updates to Anti-Kickback Statute Safe-Harbors and Beneficiary Inducement CMP Regulations

On November 30 and December 2, 2020, the Department of Health and Human Services Office of Inspector General (OIG) published two final rules (available here: November 30 Final Rule and December 2 Final Rule) which modify the safe harbor regulations to the federal Anti-Kickback Statute (AKS) and codify a new exception to the Civil Monetary Penalty (CMP) Rules related to beneficiary inducements. Most of the changes are effective January 19, 2021.

Together with the new physician self-referral law (also known as Stark) regulations published by the Centers for Medicare & Medicaid Services on December 2, 2020, these updates represent long-awaited changes to the federal fraud and abuse laws, and are part of the federal administration's Regulatory Sprint to Coordinated Care (see our analysis of that final rule here).

Please click on a heading below to jump to a specific topic or keep scrolling to read the full article.

New Safe Harbors:

- Point of Sale Reductions in Price for Prescription Pharmaceutical Products
- Pharmacy Benefit Manager (PBM) Service Fees
- Value-Based Arrangements
    - Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency
    - Value-Based Arrangements With Substantial Downside Financial Risk
    - Value-Based Arrangements With Full Financial Risk
- Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency
- CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives
- Cybersecurity Technology and Related Services
- ACO Beneficiary Incentive Program

Revised Safe Harbors:

- Personal Services and Management Contracts and Outcomes-Based Payments
- Warranties
- Discounts
- Electronic Health Records Items and Services
- Local Transportation

New CMP Exception:

- CMP Exception for Telehealth for In-Home Dialysis

New Safe Harbors

Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products (42 C.F.R. § 1001.952(cc)).
Effective January 29, 2021, the Point of Sale Safe Harbor provides safe harbor protection for certain point-of-sale reductions in price offered by manufacturers on prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations (MCOs), if the following 3 elements are met:

1. The manufacturer and the plan sponsor under Medicare Part D, a Medicaid MCO, or the PBM acting under contract with either, set the reduction in price in advance, in writing, by the time of the first purchase of the product at that reduced price by the plan sponsor or Medicaid MCO on behalf of an enrollee.
2. The reduction in price does not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy by the manufacturer, directly or indirectly, through a point-of-sale chargeback or series of point-of-sale chargebacks, or is required by law.
3. The reduction in price must be completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary.

OIG clarifies that reductions in price negotiated between manufacturers and plan sponsors under Part D (or through PBMs under contract with the plan sponsors) in the form of upfront discounts, rather than after-sale rebates, are eligible for protection under this safe harbor, rather than the discount safe harbor as modified.

PBM Service Fees (42 C.F.R. § § 1001.952(dd)).
Effective January 29, 2021, the PBM Service Fees Safe Harbor provides safe harbor protection for fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers if the following 4 elements are met:

1. The PBM has a written agreement with the pharmaceutical manufacturer, signed by the parties, that covers all of the services the PBM provides to the manufacturer in connection with the PBM's arrangements with health plans for the term of the agreement and specifies each of the services to be provided by the PBM and the compensation associated with such services.
2. The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
3. The compensation paid to the PBM is: consistent with fair market value in an arm's-length transaction; a fixed payment, not based on a percentage of sales; and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans, for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.
4. The PBM discloses in writing to each health plan with which it contracts at least annually the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan, and to the Secretary upon request, the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan and the fees paid for such services.

Value-Based Enterprise Safe Harbors

The OIG establishes three new safe harbors (VBE Safe Harbors) protecting certain types of remuneration exchanged in connection with a "value-based enterprise" (VBE):

(1) In-kind exchanges of remuneration used predominantly for value-based activities supporting care coordination and care management of a target patient population among a VBE and VBE participants under a value-based arrangement (Care Coordination VBE Safe Harbor);
(2) Exchanges of payment or other items of value between a VBE and VBE participant under a value-based arrangement where the VBE has agreed to assume "substantial downside financial risk" (as defined below) from a payor for a period of at least 1 year (Substantial Risk VBE Safe Harbor); and
(3) Exchanges of payment or other items of value between a VBE and VBE participant under a value-based arrangement where the VBE has agreed to assume "full financial risk" (as defined below) from a payor (Full Financial Risk VBE Safe Harbor).

The new VBE Safe Harbors each contain a significant number of specific requirements that must be met in order to obtain safe harbor protection under the AKS, with a number of new definitions specific to each VBE Safe Harbor. Notably, the VBE Safe Harbors are not available for remuneration exchanged by pharmaceutical companies (manufacturers, distributors or wholesalers), pharmacy benefit managers, laboratory companies, compounding pharmacies, medical device or supply manufacturers, durable medical equipment (DMEPOS) suppliers (other than entities who primarily furnish services such as physicians, pharmacies or other providers), or medical device distributors or wholesalers. However, the Care Coordination VBE Safe Harbor can protect certain arrangements

involving digital technology that include manufacturers of devices, medical supplies, or DMEPOS suppliers, as "limited technology participants."

The specific requirements for the VBE Safe Harbors are summarized below, followed by a review of a separate, but related, safe harbor for patient engagement arrangements (Patient Engagement Safe Harbor). In finalizing the VBE Safe Harbors, the OIG noted "concerns that the [AKS and beneficiary inducements CMP] have a chilling effect on innovation and value-based care" and determined that the safe harbors could "help providers and others develop sustainable value-based care delivery models for the future."

The three separate VBE Safe Harbors are distinguishable based on the amount of risk accepted by the VBE participants, with more risk allowing for more flexibility under the safe harbor. For example, the Care Coordination VBE Safe Harbor does not require assumption of risk but only protects in-kind remuneration, whereas the Substantial Risk VBE Safe Harbor and Full Financial Risk VBE Safe Harbor each require assumption of risk but also protect monetary and in-kind remuneration where safeguards are in place. However, OIG also notes in preamble commentary that parties to an arrangement involving monetary payments – e.g., shared savings or performance bonus arrangements – may also be able to obtain safe harbor protection under the new outcomes-based payment protection created by the OIG and discussed below. Interestingly, the OIG also reminds stakeholders in preamble commentary that because the AKS is a criminal intent-based statute – and not a strict liability law – the VBE Safe Harbors "need not capture the full universe of value-based arrangements that are legal under [the AKS] in order to accomplish the goals of removing barriers to more effective coordination and management of patient care."

Care Coordination VBE Safe Harbor (42 C.F.R. § 1001.952(ee))

The Care Coordination VBE Safe Harbor provides safe harbor protection for in-kind remuneration exchanged between a VBE and VBE participant or between VBE participants under a value-based arrangement if the following 13 standards are met:

1. The remuneration must be in-kind and used predominantly for value-based activities directly related to coordination and management of care for a target patient population (with no more than incidental benefit to individuals outside of such population), and not be exchanged or used more than incidentally for billing/financial management or for marketing purposes;
2. The value-based arrangement must be commercially reasonable;
3. The terms of the arrangement must be in writing and signed by the parties, with the written document specifying certain details about the arrangement (including the value-based purpose(s) of activities to be undertaken, the term, the target patient population, the remuneration and its cost/value, the recipient's percentage and amount of contribution and frequency of payments (if any), and the outcome or process measures by which the recipient will be measured);
4. The parties to the arrangement establish one or more legitimate outcome or process measures that (i) advance coordination and management of care to a target patient population, (ii) include one or more benchmarks for improvement, (iii) are subject to ongoing monitoring, assessment and update(s) as necessary, (iv) relate to the remuneration exchanged, and (v) are not based solely on patient convenience or satisfaction;
5. The offeror of the remuneration does not take into account volume or value of, or condition remuneration on, (i) referrals of patients who are not part of the target patient population or (ii) other business between the parties;
6. The recipient must pay at least 15% of the offeror's cost of the remuneration (or its fair market value), and if it is a one-time cost such payment must be made in advance of receiving the remuneration, whereas if it is an ongoing cost the recipient must make payments at reasonable regular intervals;
7. The value based arrangement cannot (i) limit any VBE participant's ability to make decisions in the best interest of patients, (ii) direct or restrict referrals to a particular provider, practitioner or supplier if the patient expresses an alternative preference, a payor determines the practitioner, or any such direction or restriction is contrary to Medicare or Medicaid law, or (iii) induce parties to reduce or limit medically necessary items or services or furnish medically unnecessary items or services to a patient;
8. Exchange of remuneration by a "limited technology participant" (as defined below) and the VBE or another VBE participant is not conditioned on exclusive use or a minimum purchase of items or services from the limited technology participant;
9. The VBE (directly or via an accountable body or participant acting on its behalf) monitors and assesses the following not less than annually (or at least once where the term of an arrangement is less than one year): (i) coordination and management of care for the target patient population, (ii) deficiencies in quality care delivery, and (iii) progress towards achieving outcome and process measures;
10. Where the VBE determines there are material deficiencies in care or the value-based arrangement is not advancing coordination and management of care for the target patient population, the parties must do one of the following within 60 days: (i) terminate the arrangement or (ii) develop and implement a corrective action plan designed to remedy the shortcomings within 120 days (provided that the arrangement must be terminated if the shortcomings are not remedied within 120 days);

11. The remuneration cannot be provided if the offeror knows it is likely to be diverted, resold, or used for an unlawful purpose by the recipient;
12. The VBE (or VBE participant(s)) must retain and make available to the Secretary of HHS for a period of 6 years all materials and records sufficient to demonstrate compliance with this safe harbor; and
13. The remuneration cannot be exchanged by one of the entities prohibited from eligibility for this safe harbor (listed above, including pharmaceutical companies, pharmacy benefit managers, laboratory companies, compounding pharmacies, DME suppliers, and certain medical device and supply companies), aside from a medical device or supply manufacturer acting as a limited technology participant or a DME supplier (other than a physician, pharmacy or other entity that primarily furnishes services) acting as a limited technology participant.

The OIG states that limited technology participants – i.e., certain manufacturers of medical devices and supplies, and certain DME suppliers – "are only eligible to rely on the care coordination arrangements safe harbor for arrangements involving digital health technology." The OIG's intention is to allow those participants to be included in certain value-based arrangements related to the provision of digital health technology, but also to prevent the participants from "locking-in use of their digital health technology" by other VBE participants in order to foster competition.

The Care Coordination VBE Safe Harbor contains a number of specific definitions that also apply to the other VBE Safe Harbors, and thus warrant review prior to implementing a value-based arrangement designed to be protected under any of the VBE Safe Harbors. Below please find definitions of certain relevant terms:

- Coordination and management of care refers to the deliberate organization of patient care activities and sharing of information between and among VBE participants, the VBE, and patients, that is "designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population."
- Digital health technology is "hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care."
- Limited technology participant is a VBE participant that exchanges digital health technology with another VBE participant or a VBE that is either a DME supplier (other than a physician, pharmacy or other entity that primarily furnishes services) or medical device or supply manufacturer other than one obligated to disclose physician ownership or investment under federal regulations.
- Target patient population refers to an identified patient population selected by the VBE and its participants "using legitimate and verifiable criteria" set out in writing at the commencement of the arrangement that further the VBE's value-based purpose(s).
- Value-based activities are any of the following that are reasonably designed to achieve at least one value-based purpose of the VBE: (i) provision of items or services, (ii) taking of an action, or (iii) refraining from taking of an action, provided that making a referral is <u>not</u> a value-based activity.
- Value-based arrangement is an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are the VBE and one or more VBE participants, or VBE participants in the same VBE;
- VBE refers to two or more VBE participants that collaborate to achieve at least one value-based purpose, each of whom is a party to a value-based arrangement with the other or at least one VBE participant, that have an accountable body or person overseeing financial and operational matters for the VBE, and that have a governing document describing the VBE and how it will achieve the value-based purpose(s).
- VBE participant is any individual or entity that engages in at least one value-based activity as part of a VBE, other than a patient.
- Value-based purpose means:
    A. Coordinating and managing the care of a target patient population;
    B. Improving the quality of care for a target patient population;
    C. Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
    D. Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

<u>Substantial Risk VBE Safe Harbor</u> (42 C.F.R. § 1001.952(ff))

The Substantial Risk VBE Safe Harbor provides safe harbor protection for the exchange of payments or anything of value between a VBE and VBE participant under a value-based arrangement if the following 8 standards are met:

1. The VBE (directly or through a VBE participant that is not a payor) has assumed (or entered into a written contract or value-based arrangement to assume in the next 6 months) substantial downside financial risk from a payor for a period of at least 1 year;

2. The VBE participant (other than the payor from whom the VBE is assuming risk, if applicable) is at risk for a meaningful share of the VBE's substantial downside financial risk for providing or arranging for the provision of items/services to the target patient population;
3. The remuneration is (i) directly connected to one or more of the VBE's value-based purposes (at least one of which must be (A), (B), or (C) under the definition of value-based purpose in the Care Coordination VBE Safe Harbor above), (ii) used predominantly to engage in value-based activities directly connected to the items or services for which the VBE has assumed substantial downside financial risk unless exchanged pursuant to a risk methodology meeting certain criteria, (iii) does not include the offer of any ownership or investment interest or any distributions related to any such ownership or investment interest, and (iv) is not exchanged or used for marketing purposes or patient recruitment by the VBE or a VBE participant;
4. The value-based arrangement is in a written document signed by the parties that sets forth its terms, including terms evidencing that the VBE is subject to substantial downside financial risk, a description of the VBE participant's meaningful share of such risk, the value-based activities, the target patient population, and the type of remuneration exchanged;
5. The VBE or VBE participant offering the remuneration does not take into account volume or value of, or condition remuneration on, (i) referrals of patients who are not part of the target patient population or (ii) other business between the parties;
6. The value based arrangement cannot (i) limit the VBE participant's ability to make decisions in the best interest of patients, (ii) direct or restrict referrals to a particular provider, practitioner or supplier if the patient expresses an alternative preference, the patient's payor determines the provider, practitioner or supplier, or any such direction or restriction is contrary to Medicare or Medicaid law, or (iii) induce parties to reduce or limit medically necessary items or services to a patient;
7. The VBE (or a VBE participant) must retain and make available to the Secretary of HHS for a period of 6 years all materials and records sufficient to demonstrate compliance with this safe harbor; and
8. The remuneration cannot be exchanged by one of the entities prohibited from eligibility for this safe harbor (listed above, including pharmaceutical companies, pharmacy benefit managers, laboratory companies, compounding pharmacies, a DME supplier (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services), and medical device and supply manufacturers, distributors and wholesalers).

In addition to terms defined under the Care Coordination VBE Safe Harbor, the Substantial Risk VBE Safe Harbor utilizes additional key terms that are specifically defined thereunder, including:

- Substantial downside financial risk: (i) financial risk equal to at least 30% of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care; (ii) financial risk equal to at least 20% of any loss, where losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care, and the parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; or (iii) the VBE receives a prospective per-patient payment from the payor that is designed to produce material savings, and paid on a monthly, quarterly or annual basis or a predefined set of items and services provided to the target patient population, designed to approximate the total cost of such items and services for the patient population.
- A "meaningful share" refers to the VBE participant: (i) assuming two-sided risk for at least 5% of losses and savings realized by the VBE, or (ii) receiving a prospective per-patient payment from the VBE that is designed to approximate the expected total cost of providing a set of predefined items and services for a target patient population, where the VBE participant does not also submit claims to a payor for such items or services.

Full Financial Risk VBE Safe Harbor (42 C.F.R. § 1001.952(gg))

The Full Financial Risk VBE Safe Harbor provides safe harbor protection for the exchange of payments or anything of value between a VBE and VBE participant if the following nine standards are met (to the extent applicable):

1. The VBE (directly or through a VBE participant that is not a payor) has assumed (or entered into a written contract or value-based arrangement to assume in the next year) full financial risk from a payor;
2. The value-based arrangement is in a written document signed by the parties that sets forth all material terms, including value-based activities and the term of the arrangement;
3. The VBE participant (unless the VBE participant is a payor) does not claim payment in any form from the payor for items or services covered under the arrangement;
4. The remuneration is (i) directly connected to one or more of the VBE's value-based purposes, (ii) does not include the offer of any ownership or investment interest or any distributions related to any such ownership or investment interest, and (iii) is not exchanged or used for marketing purposes or patient recruitment by the VBE or a VBE participant;

5. The value based arrangement does not induce parties to reduce or limit medically necessary items or services to a patient;
6. The remuneration offered does not take into account volume or value of, and is not conditioned on, referrals of patients who are not part of the target patient population or other business between the parties not covered by the value-based arrangement;
7. The VBE establishes a quality assurance program for services provided to the target patient population that protects against underutilization and assesses the quality of care provided to such population;
8. The VBE (or a VBE participant) must retain and make available to the Secretary of HHS for a period of 6 years all materials and records sufficient to demonstrate compliance with this safe harbor; and
9. The remuneration cannot be exchanged by one of the entities prohibited from eligibility for this safe harbor (listed above, including pharmaceutical companies, pharmacy benefit managers, laboratory companies, compounding pharmacies, a DME supplier (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services), and medical device and supply manufacturers, distributors and wholesalers).

In addition to terms defined under the other VBE Safe Harbors, for purposes of the Full Financial Risk VBE Safe Harbor the term "full financial risk" means that the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year.

Patient Engagement Safe Harbor (42 C.F.R. § 1001.952(hh))

The OIG also establishes safe harbor protection for patient engagement tools or supports furnished by VBE participants to patients in a targeted patient population in connection with a value-based arrangement, as long as the following 9 standards are met:

1. The patient engagement tool or support is furnished directly to the patient (or individual acting on the patient's behalf) by a VBE participant that is a party to a value-based arrangement (or is its agent);
2. The patient engagement tool or support (i) is an in-kind item, good or service (and is not cash or a cash equivalent) that has a direct connection to the coordination and management of care of the target patient population, (ii) does not result in medically unnecessary or inappropriate items or services, (iii) is recommended by the patient's licensed health care professional, and (iv) advances one or more of the following goals: (a) adherence to a treatment or drug regimen, or follow-up care plan, determined by the patient's licensed health care professional, (b) prevention or management of a disease or condition as directed by the patient's licensed health care professional, or (c) patient safety;
3. The patient engagement tool or support is not funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement, or an entity prohibited from participating in this safe harbor (as listed below);
4. The aggregate retail value of the patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis does not exceed $500 (as adjusted annually);
5. The VBE participant (or any eligible agent) does not exchange or use the patient engagement tools or supports to market other reimbursable items or services, or for patient recruitment purposes;
6. The VBE participant must retain and make available to the Secretary of HHS for a period of 6 years all materials and records sufficient to establish that the patient engagement tool or support was distributed in accordance with the safe harbor requirements;
7. The availability of the patient engagement tool or support is not determined in a manner that takes into account the patient's insurance coverage type; and
8. The VBE participant cannot be one of the entities prohibited from eligibility for the VBE Safe Harbors (listed above, including pharmaceutical companies, pharmacy benefit managers, laboratory companies, compounding pharmacies, a DME supplier (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services), and medical device and supply manufacturers, distributors and wholesalers), provided that the VBE participant can be a device or medical supply manufacturer if the patient engagement tool is digital health technology, unless the manufacturer was obligated under federal regulations to report one or more ownership or investment interests by a physician (or physician's family member) in the preceding calendar year or anticipates doing so in the current calendar year.

In its final rule preamble, OIG explains that "entities seeking safe harbor protection for remuneration provided to patients should look to" this Patient Engagement Safe Harbor, and not to the VBE Safe Harbors. Interestingly, the OIG declined in the final rule to provide specific examples of in-kind items, goods, or services that could qualify as patient engagement tools and supports (as it had done in the proposed rule), determining that it was not necessary to do so and could inadvertently omit certain tools from safe harbor protection. The safe harbor is available to protect a "broad range" of patient engagement tools and supports, including without limitation "health-related technology, patient health-related monitoring tools and services, and supports and services designed to identify and address a patient's social determinants of health."

CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives (42 C.F.R. § 1001.952(ii)).
The CMS-Sponsored Model Safe Harbor provides safe harbor protection for parties exchanging remuneration in connection with a CMS-sponsored model, as well as CMS-sponsored model patient incentives. OIG states that this safe harbor is intended to provide greater predictability to model participants as well as uniformity across models.

The safe harbor introduces a few defined terms, a few of which may be helpful to state up-front. "*CMS Sponsored Model*" means a model being tested by the Center for Medicare and Medicaid Innovation, or the Medicare shared savings program. "*CMS-Sponsored Model Arrangement*" means a financial arrangement between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model that is consistent with, and is not prohibited by, the participation documentation. "*CMS-Sponsored Model Participant*" means an individual or entity that is subject to and is operating under participation documentation with CMS to participate in a CMS sponsored model. "*CMS-Sponsored Model Party*" means a CMS-sponsored model participant or another individual or entity whom the participation documentation specifies may enter into a CMS-sponsored model arrangement.

- Model Arrangements: The safe harbor protects arrangements between CMS-sponsored model parties if the following 6 conditions are met:
    1. The CMS-sponsored model parties reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model;
    2. The exchange of value does not induce CMS-sponsored model parties or other providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient;
    3. The CMS-sponsored model parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the CMS-sponsored model;
    4. The CMS-sponsored model parties in advance of or contemporaneous with the commencement of the CMS-sponsored model arrangement set forth the terms of the CMS-sponsored model arrangement in a signed writing. The writing must specify at a minimum the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged under the CMS-sponsored model arrangement;
    5. The parties to the CMS-sponsored model arrangement make available to the Secretary, upon request, all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the conditions of this safe harbor; and
    6. The CMS-sponsored model parties satisfy such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

- Patient Incentives: The safe harbor protects CMS-sponsored patient incentives if the following 5 conditions are met:

    1. The CMS-sponsored model participant reasonably determines that the CMS-sponsored model patient incentive will advance one or more goals of the CMS-sponsored model;
    2. The CMS-sponsored model patient incentive has a direct connection to the patient's health care unless the participation documentation expressly specifies a different standard;
    3. The CMS-sponsored model patient incentive is furnished by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant's direction and control), unless otherwise specified by the participation documentation;
    4. The CMS-sponsored model participant makes available to the Secretary, upon request, all materials and records sufficient to establish whether the CMS-sponsored model patient incentive was distributed in a manner that meets the conditions of this safe harbor; and
    5. The CMS-sponsored model patient incentive is furnished consistent with the CMS-sponsored model and satisfies such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

Cybersecurity Technology and Services (42 C.F.R. § 1001.952(jj)).
The Cybersecurity Technology and Services Safe Harbor provides safe harbor protection for the provision of cybersecurity technology and services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity as long as the following 4 elements are met:

1. The donor does not (i) directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated; or (ii) condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals.

2. Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.
3. A general description of the technology and services being provided and the amount of the recipient's contribution, if any, are set forth in writing and signed by the parties.
4. The donor does not shift the costs of the technology or services to any Federal health care program.

Per OIG, this safe harbor is intended to facilitate improved cybersecurity in healthcare, and is available to all types of individuals and entities.

ACO Beneficiary Incentive Program (42 C.F.R. § 1001.952(kk)).
The ACO Beneficiary Incentive Program Safe Harbor provides protection for incentive payments made by an ACO to an assigned beneficiary under a beneficiary incentive program established under the Medicare Shared Savings Program, if the incentive payments are made in accordance with the requirements under Section 1899(m) of the Social Security Act. This safe harbor codifies the statutory exception to "remuneration" for such payments.

Revised Safe Harbors

Personal Services and Management Contracts and Outcomes-Based Payment Arrangements (42 C.F.R. § 1001.952(d)).
The existing safe harbor for Personal Services and Management Contracts is revised to create more flexibility for part-time or sporadic arrangements and arrangements where aggregate compensation is not known in advance, and to provide safe harbor protection for certain outcomes-based payments that are tied to achieving measurable outcomes that improve patient or population health or appropriately reduce payor costs.

- Part-time arrangements: The safe harbor is revised and no longer requires agreements for part-time or sporadic services to exactly specify the schedule of intervals, their precise length and the exact charge for those intervals. Further the safe harbor no longer requires that aggregate compensation be set in advance, but instead requires that "the methodology for determining the compensation paid" over the term of the agreement to be set in advance.

- Outcomes-Based Payments: Under the modified safe harbor, outcomes-based payments are eligible for protection as long the following 8 elements are met:

    1. To receive an outcomes-based payment, the agent achieves one or more legitimate outcome measures that are selected based on clinical evidence or credible medical support; and have benchmarks that are used to quantify either (a) improvements in, or the maintenance of improvements in, the quality of patient care; (b) a material reduction in costs to or growth in expenditures of payors while maintaining or improving quality of care for patients; or (c) both of the above.
    2. The methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement is set in advance; commercially reasonable; consistent with fair market value; and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties.
    3. The agreement between the parties is set out in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement. The writing states at a minimum: a general description of the services to be performed by the parties for the term of the agreement; the outcome measure(s) the agent must achieve to receive an outcomes-based payment; the clinical evidence or credible medical support relied upon by the parties to select the outcome measure(s); and the schedule for the parties to regularly monitor and assess the outcome measure(s).
    4. The agreement neither limits any party's ability to make decisions in their patients' best interest nor induces any party to reduce or limit medically necessary items or services.
    5. The term of the agreement is not less than 1 year.
    6. The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
    7. For each outcome measure under the agreement, the parties regularly monitor and assess the agent's performance, including the impact of the outcomes-based payment arrangement on patient quality of care, and periodically assess, and as necessary revise, benchmarks and remuneration under the arrangement to ensure that the remuneration is consistent with fair market value.

8. The principal must have policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.

Outcomes-based payments are limited to payments between a principal and an agent that reward the agent for successfully achieving an outcome measure, or recoup from or reduce payment to an agent for failure to achieve an outcome measure.

The safe harbor does not cover payments related solely to the achievement of internal cost savings, or based solely on patient satisfaction or patient convenience measures, which are not considered outcomes-based payments covered by the safe harbor. Similarly excluded from the covered outcomes-based payments are any payments made directly or indirectly by the following entities: (1) a pharmaceutical manufacturer, distributor, or wholesaler; (2) a pharmacy benefit manager; (3) a laboratory company; (4) a pharmacy that primarily compounds drugs or primarily dispenses compounded drugs; (5) a manufacturer of a device or medical supply; (6) a medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply; or (7) an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services).

Warranties (42 C.F.R. § 1001.952(g)).
The existing safe harbor for warranties is modified in several respects. The safe harbor includes an expanded definition of "*warranty*," provides protection for bundled warranties for one or more items and related services, and also adds two additional elements that manufacturers and suppliers must meet in order to be eligible for the safe harbor's protection. The OIG also clarifies that this safe harbor is available to any type of entity.

The definition of "*warranty*" eligible for protection under the safe harbor is expanded and now includes any of the following:

1. Any written affirmation of fact or written promise made in connection with the sale of an item or bundle of items, or services in combination with one or more related items, by a manufacturer or supplier to a buyer, which affirmation of fact or written promise relates to the nature of the quality of workmanship and affirms or promises that such quality or workmanship is defect free or will meet a specified level of performance over a specified period of time;

2. Any undertaking in writing in connection with the sale by a manufacturer or supplier of an item or bundle of items, or services in combination with one or more related items, to refund, repair, replace, or take other remedial action with respect to such item or bundle of items in the event that such item or bundle of items, or services in combination with one or more related items, fails to meet the specifications set forth in the undertaking which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a seller and a buyer for purposes other than resell of such item or bundle of items; or

3. A manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item or bundle of items (which is covered by an agreement made in accordance with the warranty safe harbor), on terms equal to the agreement that it replaces.

The revised safe harbor also includes two new elements that manufacturers and suppliers must comply with in order to be eligible for protection under the safe harbor. Under the revised safe harbor, a manufacturer or supplier must comply with all of the following 4 standards:

1. Either of the following:
    a. The manufacturer or supplier must fully and accurately report any price reduction of an item or service (including free items and services) that the buyer obtained as part of the warranty on the invoice or statement submitted to the buyer and inform the buyer of its reporting and disclosure obligations under the safe harbor; or
    b. When the amount of any price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its reporting and disclosure obligations under the safe harbor, and when any price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.
2. The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.

3. If a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same Federal health care program payment.
4. The manufacturer or supplier must not condition a warranty on a buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's or supplier's items or services.

Discounts (42 C.F.R. § 1001.952(h)).
Effective January 1, 2022, the changes to the existing safe harbor for discounts remove safe harbor protection for reductions in price in connection with the sale or purchase of prescription pharmaceutical products from manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers acting under contract with them, unless the reduction in price is required by law. Under the modified safe harbor, eligible discounts do not include the following:

1. Cash payment or cash equivalents (except that rebates may be in the form of a check)
2. Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology
3. A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs
4. A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary
5. Warranties
6. Services provided in accordance with a personal or management services contract
7. Other remuneration, in cash or in kind, not explicitly described
8. A reduction in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law.

The revised safe harbor also includes new definitions for "*manufacturer*," "*wholesaler*," "*distributor*," "*pharmacy benefit manager or PBM,*" and "*prescription pharmaceutical product*." These definitions are also applicable to the new safe harbors at (§ 1001.952(cc) and (dd)) and are effective January 29, 2021. OIG clarifies that reductions in price negotiated between manufacturers and plan sponsors under Part D (or through PBMs under contract with the plan sponsors) in the form of upfront discounts, rather than after-sale rebates, are eligible for protection under the safe harbor for Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products (42 C.F.R. § 1001.952(cc)) rather than this safe harbor.

Electronic Health Records (42 C.F.R. § 1001.952(y)).
The existing safe harbor for donation of electronic health records items and services is modified and clarified in several respects. Significantly, the safe harbor sunset date (previously, December 31, 2021) has been removed. The safe harbor is also clarified to provide protection for donations of cybersecurity software and services or other software and services that are necessary and used to protect electronic health records. Further, the donor of the software or services need not be an individual or entity that itself engages in delivering and submitting claims for health care services, but may be an entity comprised of such individuals or entities, such as an accountable health care organization or a health system. The safe harbor is further modified to remove the requirement that the recipient may not already possess an equivalent of the item or service. The safe harbor also clarifies that the recipient must still contribute 15% of the cost of the items and services, but in the case of updates to existing EHR systems the contribution need not be paid in advance.

The modified safe harbor also includes a revised definition of "*interoperable*" which means "able to securely exchange data with and use data from other health information technology; and allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law."

Local Transportation (42 C.F.R. § 1001.952(bb)).
The existing safe harbor for local transportation is revised to allow for transportation within 75 miles if the patient resides in a rural area. Prior to this expansion, local transportation under the safe harbor was limited to 25 miles or 50 miles for rural areas; the 25-mile limit for non-rural areas remains in place. In addition, under the expanded safe harbor, no mileage limits will apply if a patient is discharged from an inpatient facility following inpatient admission or released from a hospital after being placed in observation status for at least 24 hours and transported to the patient's residence, or another residence of the patient's choice. The revised safe harbor also provides that for shuttle services, the eligible distance to any stop in a rural area is also extended to 75 miles.

New Exception under the Beneficiary Inducement CMP Regulations:

Telehealth for In-Home Dialysis (42 C.F.R. § 1003.110 (10)).
OIG added a new exception to the definition of remuneration under the CMP regulations for telehealth technologies furnished to certain in-home dialysis patients. Under the new exception, prohibited remuneration to a beneficiary does not include the provision of telehealth technologies by a provider of services, physician, or a renal dialysis facility to an individual with end-stage renal disease who is receiving home dialysis, if the following 3 conditions are met:

1. The telehealth technologies are furnished to the individual by the provider of services, physician, or the renal dialysis facility that is currently providing the in-home dialysis, telehealth services, or other end-stage renal disease care to the individual, or has been selected or contacted by the individual to schedule an appointment or provide services;
2. The telehealth technologies are not offered as part of any advertisement or solicitation; and
3. The telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease.

For purposes of this exception, "*telehealth technologies*" are defined as "hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention, or ongoing care management."

If you have any questions, please contact a member of Robinson+Cole's Health Law Group

Lisa M. Boyle | Melissa (Lisa) Thompson | Brian D. Nichols

Leslie J. Levinson | Michael G. Lisitano | Theodore J. Tucci | Nathaniel T. Arden

Conor O. Duffy | Anna R. Gurevich | Peter Struzzi

For more updates on news and developments for the health care and life sciences industries, we invite you to subscribe to the Robinson+Cole Health Law Diagnosis blog.

Robinson+Cole 175 A History of Embracing Change

Boston | Hartford | New York | Providence | Miami | Stamford | Los Angeles | Wilmington | Philadelphia | Albany | New London