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Purpose:

The Care Compass Entities require compliance with applicable federal and state Anti-Kickback statutes and Civil Monetary Penalties ("CMP") by officers, directors, staff, Participants, and other entities participating in the Care Compass Entities' Networks. The Care Compass Entities' operations and Network-related activities will be conducted in accordance with the federal Anti-Kickback statutes and CMP Law, including, but not limited to, Anti-Kickback statues and CMP Law applicable to Medicaid, Medicare, and commercial healthcare markets. A summary of the legal background of the major Anti-Kickback statutes and CMP Law principles is attached as Appendix A.

Definitions:

Affected Individual(s): All persons who are affected by Care Compass Entities' risk areas including Care Compass Entities' employees, officers, Directors, managers, contractors, agents, subcontractors, independent contractors, governing bodies, or third-parties, who or that, in acting on behalf of the Care Compass Entities: (i) delivers, furnishes, directs, orders, authorizes, or otherwise provides health or social care items and services under State, Federal, or Care Compass programs; and (ii) contributes to the Care Compass Entities' entitlement to payment under Federal health or social care programs, or from other payor sources.

Care Compass Entities: Organizations that are directly, or indirectly through one or more intermediaries, owned or controlled by, or are under common ownership or control of, Care Compass Network, including Care Compass Collaborative, Inc. and Care Compass Supporting IPA, LLC.

Care Compass Entities Network: Healthcare and community-based organizations that are contracted with the Care Compass Entities to strengthen and integrate social care and clinical services.

Participant: Any organization that has signed an agreement related to a funded program with the Care Compass Entities.

Staff: Employees, contractors, agents, consultants, volunteers, and others who act on the Care Compass Entities' behalf.

Policy:

The Care Compass Entities will comply with federal and state prohibitions on remuneration provided to Federal healthcare programs, including Medicare or Medicaid, as improper inducements in relation to care, services and supplies payable under Medicare or Medicaid.

I. Exceptions and Safe Harbors Applicable to Care Compass Entities.

a. The Care Compass Entities may provide incentives and related items for no charge that fall under either "safe harbors" or "exceptions" to the general rule prohibiting most forms of inducements.

i. **Exceptions.** Section 1128A(i)(6) of the CMP Act (42 U.S.C. 1320a-7a(i)(6)) defines "remuneration", for purposes of the Beneficiary Inducements CMP, as "including transfers of items or services for free or for other than fair market value". Section 1128A(i)(6) of the CMP Act also includes a number of exceptions to the definition of "remuneration". There are statutory and regulatory exceptions described in this Policy.

ii. **Safe Harbors.** Safe harbors are set forth in the Anti-Kickback regulations which allow certain very specific arrangements to fall outside of the prohibited definition of "remuneration" defined in Section 1128B(f) of the CMP Act (42 U.S.C. 1320a-7b(f)). Importantly, the Anti-Kickback prohibitions and reach of "remuneration" are much broader than the area regulated under "beneficiary inducements".

b. The following statutory and regulatory exceptions may be applicable and reviewed by the Care Compass Entities in relation to potential programs authorized by the Care Compass Entities' Board of Directors. These are not exhaustive and certain programs may be reviewed on a case-by-case basis as allowed under the standards and advisory opinions published by the Health and Human Services Office of Inspector General ("OIG").

i. **Preventative Care.** Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied, directly or indirectly, to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may **not** include:

1. Cash or instruments convertible to cash; or
2. An incentive the value of which is disproportionally large in relationship to the value of the preventive care service (i.e., either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).

ii. **Promoting Access to Care.** Other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in 42 U.S. Code Section 1320a–7b(f) and designated by the Secretary of Health and Human Services under regulations);

1. Low Risk – Access. Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by:
    a. Being unlikely to interfere with, or skew, clinical decision making;
    b. Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
    c. Not raising patient safety or quality-of-care concerns.

iii. **Financial Need.** The offer or transfer of items or services for free or less than fair market value by a person, if:

1. The items or services are not offered as part of any advertisement or solicitation;
2. The items or services are not tied to the provision of other services reimbursed in whole or in part by the program under 42 U.S. Code Subchapter XVIII – Health Insurance for Aged and Disabled or a State health care program (as so defined);
3. There is a reasonable connection between the items or services and the medical or social care needs of the individual; and
4. The person provides the items or services after determining, in good faith, that the individual is in financial need.

iv. **Nominal "In-Kind" Gifts.** OIG has interpreted inexpensive gifts of nominal value to mean "in-kind items and services with a retail value of no more than $15 per item, or $75 in the aggregate, per beneficiary on an annual basis". (See 81 Fed. Reg.88394). Gifts that implicate the Beneficiary Inducements CMP that exceed these dollar limits are not prohibited, but are analyzed on a case-by-case basis for compliance under the statute. This nominal value guidance applies to the value of in-kind items and services, not to the value of incentive payments in the form of cash or cash equivalents (such as gift cards or items which can be used as cash). Cash and cash-equivalent payments under $75 would not be covered by this guidance.

c. The following regulatory safe harbors may be applicable and reviewed by the Care Compass Entities in relation to potential programs authorized by the Care Compass Entities' Board of Directors. These are not exhaustive and certain programs may be reviewed on a case-by-case basis as allowed under the standards and advisory opinions published by OIG.

i. **Local Transportation**. As used in Section 1128B of the CMP Act, remuneration does not include free or discounted local transportation made available by an eligible entity primarily suppling health care items.

ii. **Value-Based Arrangements**. Three safe harbors for certain remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better coordinated and managed patient care. The below safe harbors vary by the types of renumeration protected, level of financial risk assumed by the parties, and types of safeguards included as safe harbor conditions. Detailed references in Source Citations are attached as Appendix B.

1. Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (§ 1001.952(ee));
2. Value-Based Arrangements with Substantial Downside Financial Risk (§ 1001.952(ff)); and
3. Value-Based Arrangements with Full Financial Risk (§ 1001.952(gg)).

iii. **Patient Engagement**. A safe harbor (§ 1001.952(hh)) for certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency. There is a $500 cap per beneficiary on this safe harbor.

iv. **Centers for Medicare and Medicaid Services ("CMS")-Sponsored Models**. A safe harbor (§ 1001.952(ii)) for certain remuneration provided in connection with a CMS-sponsored model (as defined in the proposed rule), intended to reduce the

need for separate and distinct fraud and abuse waivers for new CMS-sponsored models.

v. **Cybersecurity Technology and Services**. A safe harbor (§ 1001.952(jj)) for donations of cybersecurity technology and services.

II. Operational Standards and Forms

a. Operational standards will include the following:
   i. Assessment of the Care Compass Entities' programs to identify potential benefits to Medicare or Medicaid recipients that may come within the definition of prohibited remuneration;
   ii. Identification of appropriate exceptions or safe harbors that may apply – note that these may not be exclusive and multiple areas outlined above may be applicable;
   iii. Assessment of a case-by-case review for situations where a benefit is necessary for success of a program or engagement, but does not fit within any exception or safe harbor;
   iv. Inclusion of the Director of Compliance, or designee, in final assessment;
   v. Care Compass Entities Leadership approval;
   vi. Coordination of standards with the Care Compass Entities' Networks and/or Affected Individuals; and
   vii. Development of safeguards and Responsibility Standards for Medicare/Medicaid covered individuals, as applicable to exception or safe harbor requirements.

CCN Board Approval History: 11/8/2022, 8/08/2023, 8/13/2024, 6/10/2025

CCC Board Approval History: 9/12/2023, 9/24/2024

IPA Board Approval History: 9/12/2023, 9/24/2024

Compliance Committee Review History: 11/1/2022, 7/28/2023, 7/24/2024, 5/22/2025

Policy Revisions:

Date	Revision Log	Updated By
7/18/2022	Original Creation	Cathy Petrak
7/13/2023	Added "Affiliated Entities" throughout to update to an enterprise-wide policy; updated Partner to "Participant" and Corporate Compliance and Privacy Officer title to "Director of Compliance" throughout; updated "Staff" and "CCN Network" definition; included federal regulation reference in "Nominal 'In-Kind' Gifts" section; updated safe harbors as they are no longer proposed	Cathy Petrak
6/12/2024	Removed "proposed new" from Cybersecurity Technology and Services as the safe harbor is no longer proposed	Cathy Petrak

5/12/2025	Updated "Affiliated Entities" to "Care Compass Entities" throughout. added "Affected Individuals" definition and updates where applicable	Cathy Petrak

This Policy shall be reviewed periodically, but not less than once every 12 months, and updated consistent with the requirements established by the Board of Directors, Care Compass Network's Leadership Team, Federal and State law(s) and regulations, and applicable accrediting and review organizations.

APPENDIX A

Legal Background

The Federal anti-kickback statute provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs, including Medicare and Medicaid. Healthcare providers and others may voluntarily seek to comply with statutory and regulatory safe harbors so that they have the assurance that their business practices will not be subject to any anti-kickback statute enforcement action (see 42 CFR § 1001.952). Safe harbors from any potential violation of both the anti-kickback statue and Civil Monetary Penalties ("CMP") relating to beneficiary/recipient inducements may be applicable to certain activities of the Care Compass Entities.

Arrangements that do not fit in a safe harbor may be analyzed on a case-by-case basis, including whether the parties had the requisite criminal intent. CMP prohibiting beneficiary inducements provides for the imposition of CMPs against any person who offers or transfers remuneration to a Medicare or State healthcare program beneficiary that the person knows, or should know, is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program, such as Medicaid.

APPENDIX B

Source Citations and Supplementary Regulatory Guidance

December 2, 2020 Final Rule Adopting New and Significant Safe Harbors in Relation to Beneficiary Inducements:
https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

Selected Sample Guidance:
https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

OIG Favors Value-Based Payment (VBP) Flexibility Involving Meal Cards or Similar "in-kind" Incentives: https://www.federalregister.gov/d/2020-26072/p-1170

"As we stated in the preamble to the OIG Proposed Rule, we would consider a voucher for a particular tool or support (e.g., a meal voucher or a voucher for a taxi) to satisfy the safe harbor's in-kind requirement. However, consistent with our treatment of these issues in prior regulations,[59] we consider debit cards, rebate checks, and most gift cards to be cash equivalents and not a protected form of in-kind remuneration under this safe harbor.

We are not, however, departing from OIG's existing guidance regarding limited-use gift cards.[60] Gift cards that can be redeemed only for certain categories of items (such as fuel-only gift cards redeemable at gas stations) could meet the in-kind requirement under this safe harbor. Gift cards meet the in-kind requirement only if their potential use is limited to certain categories of items or services that meet the conditions of the safe harbor. For instance, a gift card for a service that delivers the ingredients necessary for a healthy meal would meet the in-kind requirement and could be protected if the other conditions of the safe harbor are satisfied. Gift cards offered by large retailers or online vendors that sell a wide variety of items (e.g., big-box stores) could easily be diverted from their intended purpose or converted to cash; we would consider such gift cards to be cash equivalents and therefore not eligible for protection under this safe harbor.

Comment: A commenter posited that when gift cards are furnished to patients within the Value-Based Enterprise (VBE) context, the financial model of VBEs serves as an inherent safeguard against unnecessary and excessive utilization. The commenter asserted that when a VBE is financially at risk for improving outcomes, the VBE likely would not furnish gift cards to patients to drive unwarranted utilization and would be financially incentivized to encourage only beneficial utilization that improves health and helps manage the total cost of care.

Response: Although we recognize that VBEs assuming downside financial risk may have incentives to avoid offering tools and supports to beneficiaries that could drive medically unnecessary utilization, we are not, as discussed above, requiring VBE participants under this safe harbor to assume some degree of financial risk. We believe that some of the risks associated with fee-for-service payment systems—such as overutilization—may continue to exist in VBEs where VBE participants continue to be paid on a fee-for-service basis. Therefore, there is a risk that VBEs would furnish gift cards to patients to drive

inappropriate utilization, but such conduct would not be protected by this safe harbor and may implicate the Federal anti-kickback statute.

Comment: Several commenters urged OIG to protect cash, cash equivalents, and gift cards under this safe harbor but to attach additional safe harbor conditions to such means of remuneration. For example, a commenter suggested that cash, cash equivalents, and gift cards should be protected as a reward for taking a particular action, but that remuneration should be provided only after a patient has taken the required action. Another commenter suggested that OIG protect cash, cash equivalents, and gift cards but impose a separate monetary cap that parallels OIG's nominal value guidance. The commenter also urged OIG to consider requiring that any patient eligible to receive a cash or cash-equivalent incentive would need to be an "established patient" as defined in the local transportation safe harbor, paragraph 1001.952(bb).

Other safeguards recommended by commenters specific to cash, cash equivalents, and gift cards include: Prohibiting the advertising of rewards; tying incentives to outcomes associated with the prescribed course of treatment; a requirement that incentives cannot be utilized to generate business or otherwise promote the utilization of unnecessary or inappropriate items and services; limiting the use of such incentives to items that promote health and wellness, such as nutritious food, exercise equipment, or health monitoring and tracking devices; and requiring entities to have an evidence-based reason to believe that cash, cash equivalents, or gift cards can increase patient adherence to recommended medical guidance. A commenter suggested that retrospective evaluation and auditing could be used to identify any potentially fraudulent activity relating to cash, cash equivalents, and gift cards.

Response: We appreciate the commenters' suggestions for additional safe harbor conditions specific to the provision of cash, cash equivalents, and gift cards. Based on longstanding program integrity concerns, the final safe harbor only protects in-kind remuneration to include limited types of gift cards as described further above. OIG historically has had significant concerns about providing protection for providers' and other health care stakeholders' offers of cash or cash equivalents to patients, and our oversight experience suggests that cash and cash-equivalent remuneration raises substantial fraud and abuse risks, including the potential for inappropriate utilization of medically unnecessary items and services and improper patient steering. OIG tailored the final safe harbor's safeguards to in-kind tools and supports; therefore, it is not necessary to adopt additional conditions recommended by commenters specific to the provision of cash, cash equivalents, and gift cards.

Comment: Commenters noted that cash and cash equivalents are a useful way to address social determinants of health and noted that cash and cash equivalents could facilitate patient access to transportation, counseling and coaching, meal preparation, existing and emerging self-monitoring health technologies, and other supports that promote independence and positive health outcomes.

Response: We recognize that cash and cash equivalents may be a useful way to address social determinants of health. We remain concerned, however, for the reasons explained above, that cash or cash-equivalent remuneration to Federal health care program beneficiaries presents an elevated risk of fraud and abuse, and we are finalizing our proposal to protect only in-kind remuneration. Parties can structure a wide range of arrangements involving in-kind remuneration to address social determinants of health under the final safe harbor. For example, in lieu of cash, protected tools and supports could include vouchers or limited-use gift cards (e.g., to address transportation access to medical appointments to advance adherence to a follow up care plan, a ride share voucher or gas card could be protected, provided all other safe harbor

conditions are satisfied). Arrangements involving cash or cash equivalents used to address social determinants of health are not necessarily illegal; they would need to be evaluated under the anti-kickback statute on a case-by-case basis, including the intent of the parties.

Comment: A commenter asserted that expanding the safe harbor to protect gift cards, discount cards, and coupons toward future services would support the viability of smaller independent practices that operate in consolidated markets and are competing against hospitals and health systems.

Response: We appreciate the commenter's concern regarding consolidation and the potential effects of our safe harbors on competition. This final safe harbor protects certain, limited categories of gift cards in accordance with OIG's previous guidance on cash equivalents and limited-use gift cards. We note that discount cards and coupons may qualify as protected in-kind remuneration as long as the other conditions of this safe harbor are satisfied. We do not, however, intend for this safe harbor to protect waivers or reductions in patient cost-sharing obligations, as discussed below. For example, a coupon designed to cover only a patient's cost-sharing obligation would not be protected by this safe harbor. We also note that to the extent parties wish to have safe harbor protection for any discounts offered to beneficiaries, they would need to comply with the terms of the discount safe harbor at paragraph 1001.952(h) in order to receive safe harbor protection. Finally, to the extent the commenter is referencing gift cards, discount cards, and coupons that would reward patients for seeking care, such arrangements may not satisfy the prohibition on marketing and patient recruitment at paragraph 1001.952(hh)(6).

Comment: A number of commenters offered general support for extending safe harbor protection to cash, cash equivalents, and gift cards provided to patients as rewards or incentives to promote various behaviors, including attending necessary appointments, adherence to a treatment regimen, or participation in a substance abuse treatment or behavioral modification program. Several commenters cited a body of research suggesting that cash incentives can be effective at improving patient engagement and adherence or behavioral modification. For example, a commenter cited behavioral economics research findings that even nominal amounts of cash or cash-equivalent remuneration can produce substantial improvements in overall health outcomes when used as an incentive to motivate patients to lead healthier lifestyles.

Commenters also noted that gift cards may be employed as rewards for healthy patient behaviors and activities in a number of other contexts, including pursuant to certain Section 1115 waiver programs, some Medicaid managed care organizations, and programs or initiatives related to Medicaid Incentives for the Prevention of Chronic Diseases.

Response: In the OIG Proposed Rule, we solicited comments on including gift cards when they are provided to patients with certain conditions, such as substance abuse disorders and behavioral health conditions, as part of an evidence-based treatment program for the purpose of effecting behavioral change. We appreciate the responses from commenters and understand that incentives can effectively drive patient adherence to treatment programs, lead patients to follow healthier lifestyles, or effect other behavioral changes.

For example, we recognize that research shows that contingency management interventions are the most effective currently available treatment for stimulant use disorders. Substance use disorder treatment programs utilizing contingency management often involve payments to the patient in the form of the opportunity to earn vouchers, gift cards, or even, in some models, salaries in exchange for desired

prosocial behaviors or meeting specified goals. We also understand and acknowledge that there is a growing problem with stimulant (e.g., cocaine and methamphetamine) co-use with opioids. Combatting the opioid epidemic, including ensuring that patients have access to effective treatment programs, has been a top priority for the Administration, the Department, and OIG. In addition, many treatments involving contingency management interventions have been developed over decades by scientists supported by the Federal government through the National Institutes of Health.

After weighing the potential benefits of contingency management and other programs designed to motivate beneficial behavioral change with the potential risks to program integrity—and understanding that many of these programs involve cash and cash-equivalent payments to patients—we are not expanding the patient engagement and support safe harbor to include cash and cash-equivalent payments offered as part of contingency management interventions or other programs to motivate beneficial behavioral changes. This does not mean that all such cash or cash-equivalent payments are unlawful, but they would be subject to case-by-case analysis under the Federal anti-kickback statute and Beneficiary Inducements CMP. In addition, we emphasize—as further discussed below—that in-kind remuneration and certain limited-use gift cards offered as part of contingency management interventions or other programs to motivate beneficial behavioral changes could receive protection under the patient engagement and support safe harbor if all safe harbor conditions are satisfied. Indeed, OIG's final rule offers many opportunities for those treating patients for substance use disorders to improve the coordination and management of patient care through value-based arrangements between providers that band together to improve care, the provision of in-kind incentives to patients to motivate them to meet treatment goals, and broader flexibilities for transportation arrangements under the existing local transportation safe harbor, which would meet an identified need for patients in rural areas seeking treatment. While not all such arrangements implicate the fraud and abuse statutes, arrangements involving community recovery support systems such as clubhouses and peer-to-peer focused support services would have broader access to safe harbor protection under the final rule.

With respect to nominal amounts of cash or cash-equivalent remuneration mentioned by the commenter, we understand that some industry stakeholders believe OIG's guidance permits cash and cash-equivalent incentive payments up to $75. This is a misunderstanding of OIG's guidance. The Conference Committee report accompanying the enactment of the Beneficiary Inducements CMP expressed Congress' intent that inexpensive gifts of nominal value be permitted.[61] OIG has interpreted inexpensive gifts of nominal value to mean in-kind items and services with a retail value of no more than $15 per item or $75 in the aggregate per beneficiary on an annual basis.[62] Gifts that implicate the Beneficiary Inducements CMP that exceed these dollar limits are not prohibited but are analyzed on a case-by-case basis for compliance under the statute. We highlight, however, that this nominal value guidance applies to the value of in-kind items and services, not to the value of incentive payments in the form of cash or cash equivalents. In other words, cash and cash-equivalent payments under $75 would not be covered by this guidance. Moreover, this guidance applies only with respect to the Beneficiary Inducements CMP and not to the Federal anti-kickback statute. Furthermore, we are aware that some industry stakeholders may be under a misimpression that OIG prohibits contingency management program incentives above $75. There is no OIG-imposed $75 limitation on contingency management program incentives. Rather, the Federal anti-kickback statute may constrain the ability of individuals or entities to offer contingency management program incentives of any value to Federal health care program beneficiaries, depending on the facts of the arrangement. Moreover, in-kind incentives above the $75 annual, aggregate limit, and all cash or cash-

equivalent incentives regardless of the amount, must be analyzed on the basis of their specific facts for compliance with the Beneficiary Inducements CMP.

With respect to contingency management program incentives and other programs that offer incentives to motivate healthy behaviors—whether above or below $75 in value—we offer the following observations. In-kind remuneration in connection with such programs can fit in the patient engagement and support safe harbor if all safe harbor conditions are met (including the $500 annual cap). As further explained in this section, the final safe harbor protects certain limited-use gift cards that advance one or more of the enumerated goals at paragraph 1001.952(hh)(3)(vi) and meet other safe harbor conditions, including that the remuneration must have a direct connection to the coordination and management of care of the target patient population. To the extent that a program involves salary payments to a bona fide employee for services furnished by the employee, the payments might qualify under the existing safe harbor for employees at paragraph 1001.952(i).
If a contingency management incentive that implicates the Federal anti-kickback statute, Beneficiary Inducements CMP, or both does not satisfy an existing safe harbor or exception (as applicable), that does not mean that such incentive automatically violates the statutes and is illegal. Contingency management incentive arrangements that do not comply with a safe harbor must be analyzed on a case-by-case basis for compliance with the Federal anti-kickback statute and Beneficiary Inducements CMP. In addition, incentives that are included in a service covered by a Federal health care program (i.e., the coverage includes the incentive itself) would not implicate the Federal anti-kickback statute or the Beneficiary Inducements CMP, provided that the applicable billing and coverage rules are followed including collection of any applicable patient cost-sharing obligations. In addition, incentives offered as part of a CMS-sponsored model may qualify for protection under the new safe harbor at paragraph 1001.952(ii). Further, we are aware that some incentives may be provided pursuant to or in connection with other government-sponsored demonstrations or other government-sponsored programs (including studies initiated, organized, funded, and managed by the National Institutes of Health). Participation in and adherence to the requirements of such demonstrations or programs would be a relevant factor in assessing the intent of the parties and the risk posed by the arrangement.[63] Incentives offered to commercially insured patients or uninsured patients would not implicate the statutes. Application of the statutes is discussed in further detail in Sections II.B and II.C of this preamble.

With respect to incentives in the form of cash or cash equivalents, we are concerned about heightened fraud and abuse risk. As noted in the OIG Proposed Rule, OIG historically has had significant concerns with allowing providers and others to offer cash or cash equivalents to patients, and our oversight and enforcement experience suggests that cash incentives can result in medical identity theft and misuse of patients' Medicare numbers, lead to inappropriate utilization (in the form of medically unnecessary items and services), and cause improper patient steering (including patients selecting a provider because the provider offers the most valuable incentives and not because of the quality of care the provider furnishes).[64]

Moreover, in the area of substance use disorder treatment, OIG and its law enforcement partners have substantial enforcement experience that demonstrates the pervasiveness of fraud in treatment programs that serve neither the best interests of patients nor taxpayers. For example, OIG has participated in enforcement actions resulting from allegations of significant fraud by substance use disorder treatment facilities, or “sober homes,” that take advantage of individuals with substance abuse disorders.[65]

We preclude cash or cash equivalents from protection under this safe harbor in recognition of the critical need to protect vulnerable patients from fraud. That said, as stated above, arrangements involving cash or cash equivalents used to promote adherence or healthy behavior modification do not necessarily violate the Federal anti-kickback statute; they would need to be evaluated under the anti-kickback statute on a case-by-case basis, including the intent of the parties. Parties may seek an OIG advisory opinion if they want assurance that their arrangement(s) comply with the statutes or would not be subject to OIG administrative enforcement sanctions, but having an advisory opinion is not mandatory. Declining to seek an OIG advisory opinion is not evidence that parties have improper intent under the Federal anti-kickback statute.

As stated above, in-kind incentives in connection with contingency management or other motivational programs can fit in the final safe harbor if all conditions are met. We note that offering incentives to patients as a reward for accessing care may not satisfy the prohibition on marketing and patient recruitment at paragraph 1001.952(hh)(6), depending on the facts and circumstances. We also emphasize that remuneration offered as a reward or incentive is not protected if it results in a beneficiary being furnished medically unnecessary care or inappropriate items or services reimbursed by a Federal health program, pursuant to the condition at paragraph 1001.952(hh)(3)(iv).

Finally, to the extent that existing safe harbors might not address all facets of contingency management incentive programs, we are considering addressing them in future rulemaking.

Comment: A commenter urged OIG to consider extending safe harbor protection to benefits such as direct payments from a provider to utility companies and the direct provision of technology (e.g., electronic scales and tablets to provide continuing condition-specific education).

Response: Because the beneficiary does not directly receive cash or cash-equivalent remuneration, we consider the specific examples provided by the commenter to be in-kind remuneration, which may be protected by this safe harbor if the other conditions of the safe harbor are satisfied.

Comment: A commenter observed that Congress has recognized the value of providing incentive payments to patients in allowing Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program to make payments to patients who receive qualifying primary care services from providers participating in those ACOs.

Response: We recognize that the ACO Beneficiary Incentive Program, which is administered by CMS as part of the Medicare Shared Savings Program, allows an ACO to make incentive payments to beneficiaries of up to $20 per qualifying service as an incentive to encourage utilization of medically necessary primary care services if certain eligibility, recordkeeping, and notification requirements are met. Nothing in the new patient engagement and support safe harbor would prevent ACOs from continuing to participate in that program or from structuring ACO Beneficiary Incentive Payment programs to satisfy the requirements of the new safe harbor set forth at paragraph 1001.952(kk), which protects payments under the ACO Beneficiary Incentive Program. Although we are not protecting similar incentives in this safe harbor, this decision does not reflect the programmatic value of the ACO Beneficiary Incentives.

The patient engagement and support safe harbor will protect tools and supports furnished outside of the context of a program administered and monitored by CMS. Without that programmatic oversight, we

believe the safeguards in this final rule, including limiting safe harbor protection to in-kind remuneration, are appropriate and necessary to protect Federal health care programs and beneficiaries from harms associated with fraud and abuse.

Comment: A commenter urged OIG to update its 2016 Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries to revise its interpretation of "nominal value" from $15 per instance to $20 per instance, and from $75 in the aggregate per year to $100 in the aggregate per year.

Response: We decline commenter's request to update our guidance on "nominal value" [66] in this rulemaking. We note that our nominal value guidance focuses only on OIG's Beneficiary Inducements CMP authorities, and not the anti-kickback statute.