

Notice of Waiver of Certain Fraud and Abuse Laws in Connection With the Comprehensive Kidney Care Contracting Options of the Kidney Care Choices Model

Section 1115A(d)(1) of the Social Security Act (Act) authorizes the Secretary to waive certain fraud and abuse laws as may be necessary solely for purposes of carrying out testing by the Center for Medicare and Medicaid Innovation (Innovation Center) of certain innovative payment and service delivery models. The Innovation Center is testing, through the Comprehensive Kidney Care Contracting (CKCC) Options of the Kidney Care Choices Model (Model) under section 1115A(b) of the Act, an alternative payment model for nephrology care of patients with late-stage Chronic Kidney Disease (CKD) Stages 4 or 5 and End-Stage Renal Disease (ESRD) that aims to increase accountability for outcomes, while reducing Medicare spending. Pursuant to section 1115A(d)(1) of the Act, this Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Comprehensive Kidney Care Contracting Options of the Kidney Care Choices Model (Notice) establishes a waiver applicable to arrangements entered into by specified individuals and entities participating in the Implementation Period of the CKCC Options of the Model.

This Notice is composed of two parts. Part I sets forth the waiver established for the Implementation Period of the CKCC Options of the Model and the conditions that must be met to qualify for the waiver. The waiver protects certain startup arrangements related to the quality, care coordination, and cost-reduction goals of the CKCC Options of the Model, in preparation for participation in the performance period. This waiver protects only arrangements that meet all of the listed conditions and applies only with respect to the specific laws cited in the waiver. Part II consists of commentary explaining the waiver requirements set forth in Part I as well as general limitations.

I. The Waiver and Applicable Requirements

Terms defined in the participation agreement for the Implementation Period (Implementation Period Participation Agreement) that are used in this Notice have the meanings set forth in the Implementation Period Participation Agreement, as amended from time to time. These terms include but are not limited to, the following: CKD Stages 4 or 5, ESRD, Implementation Period, KCE, KCE Activities, KCE Participant, Performance Period Participation Agreement, Preferred Provider, and Start Date.

Implementation Period Waiver

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Federal physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to any start-up arrangement between the KCE and one or more KCE Participants or Preferred Providers or both, provided all of the following conditions are met:

1. The KCE has entered into an Implementation Period Participation Agreement with

CMS.

2. All parties enter into, and undertake, the arrangement with the good faith intent to participate in the performance period of the CKCC Options of the Model that begins immediately after the expiration of the Implementation Period Participation Agreement, pursuant to a Performance Period Participation Agreement entered into by CMS and the KCE.
3. In establishing the terms of the arrangement, no party shall give or receive remuneration in return for, or to induce the referral of, items or services furnished to Federal health care program beneficiaries who are not aligned to the KCE.
4. For arrangements involving the exchange of information technology used predominantly to create, maintain, transmit, or receive electronic health records, such information technology must be interoperable, as defined in the Implementation Period Participation Agreement.
5. The KCE's governing body has made a *bona fide* determination, consistent with each governing body member's fiduciary duty to the KCE, that the arrangement is reasonably related to the performance of KCE Activities during the Implementation Period and has authorized the arrangement.
6. The arrangement and its authorization by the governing body are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement and the documentation of the authorization must be contemporaneous with the authorization. All such documentation must be retained by the KCE, KCE Participant, and Preferred Provider, as applicable, for at least 10 years following completion of the arrangement and promptly made available to the Secretary upon request. The documentation must identify at least the following:
 - a. A description of the arrangement, including all parties to the arrangement; the date of the arrangement; the purpose(s) of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); evidence of the public disclosure of the arrangement, as required by the terms of this waiver; and the financial or economic terms of the arrangement.
 - b. The date and manner of the governing body's authorization of the arrangement. The documentation of the authorization must include the basis for the *bona fide* determination by the KCE's governing body that the arrangement is reasonably related to the performance of KCE Activities during the Implementation Period.
7. A description of the arrangement is publicly disclosed and maintained on a public-facing website belonging to the KCE no later than 60 days after the effective date of the arrangement, through the earlier of the expiration or termination date of the

Implementation Period Participation Agreement. The posted arrangement must be clearly labeled as an arrangement for which waiver protection is sought and the description of the arrangement must include all information specified in Part I, paragraph 5(a) of this Notice, except the financial or economic terms of the arrangement.

8. The Implementation Period Participation Agreement does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver will begin on the Start Date of the Implementation Period and end: (i) upon the expiration of the Implementation Period Participation Agreement for a KCE that enters into a Performance Period Participation Agreement with a performance period that begins immediately after the expiration of the Implementation Period Participation Agreement; or (ii) for a KCE that does not enter into a Performance Period Participation Agreement with a performance period that begins immediately after the expiration of the Implementation Period Participation Agreement, 90-days after the earlier of the expiration of the Implementation Period Participation Agreement or the date on which the KCE voluntarily terminates the Implementation Period Participation Agreement. Notwithstanding the foregoing, if CMS terminates the Implementation Period Participation Agreement for any reason, the waiver period will end on the date of the termination notice.

II. Explanation of Waiver Requirements

The waiver set forth in this Notice has been developed in consultation with the Innovation Center, which is administering and testing the CKCC Options of the Model. In accordance with Section 1115A(d)(1) of the Act, the Secretary has determined that this waiver is necessary to carry out the testing of the CKCC Options of the Model. As a general matter, the waiver is intended to allow the KCE to negotiate and enter into certain start-up arrangements during the Implementation Period of the CKCC Options of the Model, with KCE Participants, or Preferred Providers (or both) in preparation for participation in the performance period of the CKCC Options of the Model. The conditions of the waiver are intended to ensure that protected arrangements: (i) are consistent with the quality, care coordination, and cost-reduction goals of the CKCC Options of the Model; (ii) are subject to safeguards designed to mitigate the risk of fraud and abuse; and (iii) can be readily monitored and audited.

Arrangements must meet all of the conditions of the waiver in this Notice to receive waiver protection. This waiver does not waive any requirement or prohibition set forth in the Implementation Period Participation Agreement; it waives only the Federal anti-kickback statute and physician self-referral law with respect to arrangements permitted by both the Implementation Period Participation Agreement and the waiver.

Waiver Conditions

1. *Good Faith Intent*

As a threshold matter, the waiver requires that the KCE have a signed, Implementation Period Participation Agreement with CMS. In addition, any arrangements entered into by a KCE for which waiver protection is sought, must be undertaken with the good faith intent to participate in the performance period of the CKCC Options of the Model that begins immediately after the expiration of the Implementation Period Participation Agreement, pursuant to a Performance Period Participation Agreement entered into by CMS and the KCE. This waiver will not protect arrangements entered into by a KCE that simply seek to take advantage of the regulatory flexibility afforded by the waiver. Thus, and for example, we would consider arrangements that are isolated in nature or that are intended solely to further the individual financial or business interest of the KCE, KCE Participants, or Preferred Providers, to lack the requisite good faith intent that this waiver condition requires.

2. *No Inducement for the Referral of Items or Services Provided to Federal Health Care Program Beneficiaries Not Aligned to the KCE*

The waiver further requires that, in establishing the terms of the arrangement for the performance of KCE Activities during the Implementation Period, no party shall give or receive remuneration in return for, or to induce the referral of, items or services provided to Federal health care program beneficiaries who are not aligned to the KCE pursuant to Article 5 of the Implementation Period Participation Agreement. This waiver condition is consistent with the terms and conditions of the Implementation Period Participation Agreement. We will interpret this waiver condition in a manner consistent with how CMS interprets the corresponding program requirement.

3. *Interoperability*

For arrangements involving the exchange of information technology used predominantly to create, maintain, transmit, or receive electronic health records, such technology must be interoperable, as defined in the Implementation Period Participation Agreement, in order to meet this waiver requirement. This waiver condition is consistent with the terms and conditions of the Implementation Period Participation Agreement. We will interpret this waiver condition in a manner consistent with how CMS interprets the corresponding program requirement.

4. *Bona Fide Determination that Arrangement is Reasonably Related to Performance of KCE Activities*

The waiver also requires that the KCE governing body make a *bona fide* determination that the arrangement is reasonably related to the performance of KCE Activities during the Implementation Period and authorize the arrangement. This *bona fide* determination must be consistent with each governing body member's fiduciary duty to the KCE, as set forth in the Implementation Period Participation Agreement. Thus, in making any such determination,

each governing body member must act in a manner that is consistent with his or her fiduciary duty to the KCE, including the duty of loyalty.

Moreover, we expect the KCE governing body's *bona fide* determination will be thoughtful and deliberative in nature; "rubber stamping" of an arrangement would not meet this waiver requirement. Factors we may consider when evaluating whether the KCE's governing body's determination is *bona fide* could include, for example, the degree to which there is a clearly articulated rationale for the determination and authorization, the proximity in time between the establishment of the arrangement and the governing body's corresponding determination and authorization, and evidence of self-dealing or conflicts of interest.

With respect to whether an arrangement is reasonably related, *i.e.*, has a close nexus, to the performance of KCE Activities during the Implementation Period, we note that this waiver condition should be interpreted consistent with the definition of KCE Activities. Accordingly, we anticipate arrangements reasonably related to the performance of KCE Activities during the Implementation Period will relate to planning and promoting future accountability for the quality, cost, and overall care for aligned beneficiaries. Such activities must be start-up in nature and could for example, be intended to facilitate the KCE's, KCE Participants', and Preferred Providers' assumption of financial risk, as applicable, or participation in care coordination activities during the performance period of the CKCC Options of the Model, pursuant to a Performance Period Participation Agreement with CMS.¹ Arrangements reasonably related to the performance of KCE Activities during the Implementation Period will not include the provision of direct patient care.

5. *Transparency Conditions*

Lastly, the waiver includes several conditions intended to facilitate transparency for each protected arrangement. In particular, the waiver requires that each party to an arrangement maintain contemporaneous documents and records for a defined time period relating to both the details of the arrangement itself and the governing body's authorization. While we are not specifying the form of such documentation, it must be made available to the Secretary promptly upon request. For example, upon request, a KCE must have documentation detailing the basis or bases for its governing body's decision that an arrangement is reasonably related to the performance of KCE Activities during the Implementation Period, contemporaneous with the governing body's determination. The determination itself should also be documented.

The waiver also requires that each arrangement be publicly disclosed and maintained on a public-facing website. While the waiver condition itself details the required information that must be disclosed, we note that posted arrangements should be clearly labeled as an arrangement for which waiver protection is sought and that the identifying information should

¹ The list of start-up arrangements as identified in the Medicare Shared Savings Program Pre-Participation Waiver, may be representative of the types of start-up arrangements that KCEs may enter into, and that may qualify under this Implementation Period waiver, provided they are reasonably related to the performance of KCE Activities. *See* 80 FR 66726, 66730-31, 66733 (Oct. 29, 2015).

be sufficient to allow individuals conducting an electronic internet search using a widely available search engine to readily locate the website. If parties to the arrangement make a material amendment or modification to the publicly disclosed arrangement, the amendment or modification should be disclosed in the same manner as required by the waiver condition and be identified as an amendment or modification.

This public-facing website must be made available to the general public no later than 60 days after the effective date of the arrangement and be maintained at least through the earlier of the expiration or termination date of the Implementation Period Participation Agreement. We note that whereas the waiver only imposes this public disclosure requirement for a finite time period, parties must make documentation demonstrating compliance with this waiver condition available to the Secretary, upon request, e.g., through screenshots of the webpage or other means.

In requiring such transparency related provisions, it is our intent for these conditions to: (i) deter criminal or fraudulent conduct, in recognition that secrecy is a common element to such arrangements; (ii) inform and educate the public, regulators, and parties involved with the KCE about the KCE's arrangements; and (iii) incentivize the KCE and members of its governing body to exercise due diligence when establishing arrangements to ensure compliance with all waiver requirements.

Waiver Time Period

The waiver will begin on the Start Date of the Implementation Period. The end date of the waiver will depend upon whether the KCE: (i) elects to enter into a Performance Period Participation Agreement with a performance period that begins immediately after the expiration of the Implementation Period Participation Agreement; (ii) voluntarily terminates the Implementation Period Participation Agreement prior to its expiration date; or (iii) is terminated by CMS from the CKCC Options of the Model.

Accordingly, for those KCEs that enter into a Performance Period Participation Agreement with a performance period that begins immediately after the expiration of the Implementation Period Participation Agreement, the waiver will terminate upon the expiration of the Implementation Period Participation Agreement (at which point in time, additional fraud and abuse waivers may be issued, if necessary, to provide seamless continued protection for the arrangements that meet all waiver conditions).

For a KCE that does not enter into a Performance Period Participation Agreement with a performance period that begins immediately after the expiration of the Implementation Period Participation Agreement, the waiver ends 90-days after the earlier of the expiration of the Implementation Period Participation Agreement or the date on which the KCE voluntarily terminates the Implementation Period Participation Agreement. Of import, this 90-day "tail" period: (i) only protects arrangements that were in place and otherwise qualified for the waiver at the time the waiver expired or terminated; and (ii) is for the sole purpose of providing parties sufficient time to unwind their arrangements, as necessary.

If CMS terminates a KCE's Implementation Period Participation Agreement for any reason, the waiver period will end on the date of the termination notice. In such circumstances, CMS has determined that a KCE is not acceptable for participation in the CKCC Options of the Model, and we believe that it is appropriate to terminate waiver protection immediately. Waiver protection would terminate not only for the KCE, but also for all parties to the applicable arrangement(s).

General Limitations

- The waiver set forth in Part I of this Notice applies to arrangements that squarely meet all of the conditions pertaining to the waiver. If an arrangement does not meet all of the waiver conditions, it does not qualify for waiver protection.
- The waiver does not provide retrospective protection; an arrangement must meet all of the waiver conditions during the period for which waiver protection is sought.
- Apart from meeting applicable waiver conditions, no special action (such as submission of a separate application for a waiver) is required by parties to be covered by the waiver.
- A waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (i) does not implicate the specific fraud and abuse law; (ii) implicates the law, but fits within an existing exception or safe harbor; or (iii) otherwise complies with the law. Arrangements that do not fit in this waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the Federal physician self-referral law (section 1877 of the Act), the Federal anti-kickback statute (sections 1128B(b)(1) and (2) of the Act), and any other applicable law.
- Nothing in this Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other applicable Federal or State laws and regulations, including, but not limited to, any anti-fraud laws, other than those specified above. Nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations under the Implementation Period Participation Agreement.
- We reserve the right to reconsider this waiver and, where the public interest requires, to modify or terminate the waiver on a prospective basis with respect to some or all entities and individuals specified in the waiver. The modification, suspension, or termination of part or all of the waiver does not require advance notice. We anticipate, however, that the circumstances under which no advance notice would be provided would be limited to egregious conduct that poses an imminent risk of harm to programs or patients.

As to section 1877(a) of the Social Security Act:

Dated: September 9, 2020

/Seema Verma/

Seema Verma
Administrator
Centers for Medicare & Medicaid Services

As to sections 1128B(b)(1) and (2) of the Social Security Act:

Dated: September 11, 2020

/Christi A. Grimm/

Christi A. Grimm
Principal Deputy Inspector General
Office of Inspector General
Department of Health and Human Services