

Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the
Comprehensive ESRD Care Initiative Non-LDO Model

July [15], 2015

Section 1115A(d)(1) of the Social Security Act (Act) authorizes the Secretary of Health and Human Services (Secretary) to waive certain specified fraud and abuse laws as may be necessary solely for purposes of carrying out the testing by the Center for Medicare & Medicaid Innovation (CMMI) of certain innovative payment and service delivery models. This Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive ESRD Care Initiative Non-LDO Model (Notice) is issued pursuant to this authority. The Comprehensive ESRD Care Initiative (CEC) is being tested under section 1115A(b) of the Act.

This Notice is composed of two parts. Part I sets forth the specific conditions that must be met to qualify for a waiver. Each waiver protects only arrangements that meet all of the listed conditions. Each waiver applies only with respect to the specific laws cited in the waiver. Part II consists of commentary explaining the waiver requirements of Part I. The waivers established by this Notice apply only to the CEC. These waivers are not applicable outside of the CEC.

The waivers established by this Notice employ some of the same terminology used in the Comprehensive ESRD Care Initiative Participation Agreement (CEC Agreement) between the Centers for Medicare & Medicaid Services (CMS) and the ESCO (as defined below) setting forth the Parties' respective duties and responsibilities under the CEC. Some terms are defined in Section I.A below. Where possible and appropriate, terms have the same meanings in this Notice as they have in the CEC Agreement. To the extent that terms have different definitions in the CEC Agreement and this Notice, terms have the meanings ascribed to them in Section I.A of this Notice.

As further described in Part I, the waivers in this Notice address the following financial arrangements that have been identified by CMMI as necessary to test the CEC, provided that all waiver conditions are satisfied:

1. Distributions of Shared Savings Payments to Participants or the Company;
2. Patient Engagement Incentives;
3. ESCO Health Information Technology Provided to Participants;
4. Performance-Based Payments to Physicians who are Participants;
5. Care Coordination Arrangements; and
6. Remuneration Furnished by the Company to the ESCO for ESCO Support, ESCO Health Information Technology, and Patient Engagement Incentives.

Part I: Waivers: Definitions and Conditions

A. Definitions

CEC Agreement means the “Participation Agreement (Non-LDO – CEC Model)” entered into by the ESCO, the Company, and the Centers for Medicare & Medicaid Services (collectively, “the Parties”), which sets forth the Parties’ respective duties and responsibilities under the CEC.¹

Company means the dialysis organization referred to as “the Company” in the CEC Agreement.

Dialysis Facility means an entity that provides outpatient maintenance dialysis services (including Hospital-Based Dialysis Facilities and Home Dialysis training and support services) either as a Medicare-enrolled entity or as an operating division of a Medicare-enrolled entity that is owned in whole or in part by the Company.

ESCO means the ESRD Seamless Care Organization participating in the CEC as identified in the CEC Agreement.

ESCO Beneficiary means a Medicare beneficiary who has been aligned to the ESCO using the methodology described in Section 1.1 of Appendix B to the CEC Agreement.

ESCO Health Information Technology means nonmonetary remuneration consisting of items and services in the form of software, hardware, or other information technology, or support staff or training services related to information technology, provided by the ESCO or a Participant Owner (“Donor”) to a Participant and necessary and used predominantly to create, interpret, maintain, transmit, or receive clinical and related information that is necessary to support and facilitate communication, care coordination, and improved health outcomes for ESCO Beneficiaries.

ESCO Participant List means the list of the Participants that are approved by CMS for participation in the CEC, as updated from time to time in accordance with Section IV.B.3-.5 of the CEC Agreement.

ESCO Provider/Supplier means an individual or entity that (1) is a Medicare-enrolled provider or supplier identified by an NPI or CCN; (2) bills for items and services furnished to Medicare beneficiaries under a Medicare billing number assigned to the TIN of a Participant Owner or Participant Non-Owner; (3) has agreed to participate in the CEC pursuant to a written agreement with the ESCO; (4) may, but is not required to, receive Shared Savings Payments; and (5) is included on the ESCO Participant List.

ESCO Purpose means the purpose as set forth at Section IV.A.1 of the CEC Agreement.

¹ We use the term *CEC Agreement* in this Notice for clarity. It has the same meaning as the term *Agreement* in the CEC Agreement itself.

ESCO Support means one or more of the following when provided in compliance with the terms of the CEC Agreement: (1) the provision of clinical support services, such as case managers, care coordinators, and clinical training, when used predominantly for ESCO Beneficiaries; (2) accommodations for Rounding Practitioners to co-locate or conduct rounds at a Dialysis Facility, including related administrative services; or (3) other items or services necessary to coordinate care, such as administrative, quality management, or data services necessary to delivery, documentation, and assessment of care coordination services. ESCO Support excludes ESCO Health Information Technology.

Medically Necessary means reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Nephrologist means a physician, as defined at section 1861(r)(1) of the Act, who specializes in kidney health and the treatment of kidney diseases.

Participant means an individual or entity that is a Participant Owner, a Participant Non-Owner, or an ESCO Provider/Supplier and that is not a Prohibited Participant.

Participant Non-Owner means an individual or entity that (1) is a Medicare-enrolled provider or supplier identified by a TIN and either a NPI or a CCN; (2) does not have any direct or indirect ownership or investment interest in the ESCO; (3) has agreed to participate in the CEC pursuant to a written agreement with the ESCO; (4) may, but is not required to, receive Shared Savings Payments; and (5) is included on the ESCO Participant List.

Participant Owner means an individual or entity that (1) is a Medicare-enrolled provider or supplier identified by a TIN and either a NPI or a CCN; (2) has a direct ownership or investment interest in the ESCO; (3) has agreed to participate in the CEC pursuant to a written agreement with the ESCO; (4) may, but is not required to, receive Shared Savings Payments; and (5) is included on the ESCO Participant List.

Performance Year means the 12-month period beginning on January 1 of each year during the term of the CEC Agreement, except that the first Performance Year of the CEC Agreement will begin on July 1, 2015, and end on December 31, 2016. The second Performance Year will begin on January 1, 2017, and end on December 31, 2017. The third Performance Year will begin on January 1, 2018, and end on December 31, 2018. If the CEC Agreement is renewed, the fourth Performance Year will begin on January 1, 2019, and end on December 31, 2019, and the fifth Performance Year will begin on January 1, 2020, and end on December 31, 2020. (To the extent the definition in the CEC Agreement is different, the CEC Agreement definition controls.)

Prohibited Participant means an individual or entity that is: (1) a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier; (2) an ambulance supplier; (3) a drug or device manufacturer; or (4) excluded or otherwise prohibited from participation in the Medicare or Medicaid programs.

Rounding Practitioner means any of the following who provides services pursuant to Section IV.D.8 of the CEC Agreement: (1) a physician (as defined at section 1861(r)(1) of the Act) who

is not a Nephrologist; or (2) a physician assistant, nurse practitioner, or clinical nurse specialist (as such terms are defined at section 1861(aa)(5) of the Act).

Effective Date, Home Dialysis, Hospital-Based Dialysis Facilities, Non-LDO, Shared Savings, and Shared Savings Payments have the same meanings ascribed to them in the CEC Agreement.

B. Waivers and Associated Conditions

1. Waiver for Distributions of Shared Savings Payments to Participants or the Company

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law) and section 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to distributions of Shared Savings through Shared Savings Payments made by an ESCO to a Participant or the Company or by a Participant Owner or a Participant Non-Owner to an ESCO Provider/Supplier, provided all of the following conditions are met:

- a) The ESCO and the Company have entered into a CEC Agreement and are in compliance with Sections IV.A.1-3, IV.A.7-8, IV.B.1.b-c, IV.C.1-8, IV.C.10, IV.D.1-2, IV.D.4, V.D., V.E, and XII of the CEC Agreement.
- b) The Shared Savings are earned by the ESCO during the term of its CEC Agreement, even if the actual Shared Savings Payment occurs after expiration of the CEC Agreement.
- c) Any Participant that receives a Shared Savings Payment was a Participant during the Performance Year in which the Shared Savings were earned by the ESCO.
- d) The party making the Shared Savings Payment (whether directly or indirectly) does not add conditions, limitations, or restrictions to the receipt or use of the Shared Savings Payment other than those permitted in the CEC Agreement.
- e) The ESCO or Participant making the Shared Savings Payment documents in writing the amount, date, and recipient of the Shared Savings Payment contemporaneously with the distribution of the Shared Savings Payment. The ESCO or Participant shall retain the documentation for at least 10 years following the end of the last Performance Year and shall make the documentation available promptly to the ESCO (if retained by the Participant), the Secretary, or the Inspector General of the Department of Health and Human Services (Inspector General) upon request.
- f) The Shared Savings Payment is not made to reduce or limit Medically Necessary care.
- g) The CEC Agreement, as amended from time to time, does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will begin on the Effective Date of the CEC Agreement and shall end on the earlier of:

- (1) 90 days after CMS's payment of Shared Savings for the last Performance Year in which the CEC Agreement was in effect;
- (2) the date on which the settlement report for the last Performance Year in which the CEC Agreement was in effect becomes final for a Performance Year in which CMS owes no Shared Savings; or
- (3) in a final Performance Year for which CMS is not obligated to issue a settlement report pursuant to Section XIII.C.2 of the CEC Agreement, the date that is the later of:
 - (i) 90 days after CMS's payment of Shared Savings for the immediately preceding Performance Year, or
 - (ii) the date on which the settlement report for the immediately preceding Performance Year became final if CMS owed no Shared Savings for that Performance Year.

2. Waiver for Patient Engagement Incentives

Pursuant to section 1115A(d)(l) of the Act, section 1128A(a)(5) of the Act (relating to the beneficiary inducements Civil Monetary Penalty Law (CMP)) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to items or services provided by the ESCO, a Dialysis Facility that is a Participant, or a Nephrologist who is a Participant, to an ESCO Beneficiary ("Patient Engagement Incentives") if all of the following conditions are met:

- a) The ESCO and the Company have entered into a CEC Agreement and are in compliance with Sections IV.A.1-3, IV.B.1.c, IV.A.7-8, IV.C.1-8, IV.C.10, V.D, V.E, V.F, and XII of the CEC Agreement.
- b) The items and services provided are reasonably related to medical care provided to the ESCO Beneficiary by a Nephrologist who is a Participant, a Dialysis Facility that is a Participant, or an ESCO Provider/Supplier.
- c) The items or services are provided in-kind.
- d) The items or services are:
 - i. technology that is reasonably related to the ESCO Purposes if all of the following conditions are met:

1. The technology involves goods or services used to facilitate ESCO Beneficiary communication, health monitoring, or telehealth encounters;
 2. The technology advances adherence to a treatment regime, adherence to a drug regime, adherence to a care plan, or management of a chronic disease or condition;
 3. The terms of Appendix F to the CEC Agreement are met; and
 4. The ESCO or Participant providing the technology does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the ESCO Beneficiary possesses or has obtained technology equivalent to the technology provided.
- ii. oral nutrition supplements, subject to the terms of Appendix G to the CEC Agreement; or
 - iii. non-emergency transportation, subject to the terms of Appendix H to the CEC Agreement and all of the following conditions:
 1. The transportation is provided for the purpose of the ESCO Beneficiary receiving Medically Necessary items and services from a Participant; and
 2. The transportation is made available to all similarly situated ESCO Beneficiaries under a uniform policy and does not include air, luxury, or ambulance-level transportation.
- e) The availability of the items or services is not advertised or promoted except that an ESCO Beneficiary may be made aware of the availability of the items or services at the time the ESCO Beneficiary could reasonably benefit from them.
 - f) The ESCO or Participant providing the items or services documents the terms and conditions of each arrangement in writing before providing the items or services. The ESCO or Participant providing the items or services documents contemporaneously with the provision of the item or service and in writing the recipient, the item or service, the value of the item or service, and the date the item or service was provided. The ESCO or Participant providing the items or services shall retain the documentation for at least 10 years after the end of the last Performance Year, and shall make the documentation available promptly to the ESCO (if retained by the Participant), the Secretary, or the Inspector General upon request.
 - g) The governing body of the ESCO makes and duly authorizes a bona fide determination that the arrangement for the provision of the Patient Engagement Incentive is reasonably

related to the ESCO Purpose before the incentive is provided. The governing body of the ESCO shall date and document in writing such approval, including the basis for its determination, contemporaneously with its decision-making process. The ESCO shall retain this documentation for at least 10 years following the end of the last Performance Year and make it available promptly to the Secretary or the Inspector General upon request.

- h) The costs of the items or services are not shifted to any Federal health care program.
- i) The CEC Agreement, as amended from time to time, does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will begin on the Effective Date of the CEC Agreement and will end on the earlier of (1) the date on which the CEC Agreement has been terminated, or (2) the expiration date of the last Performance Year under the CEC Agreement, provided that the ESCO Beneficiary may keep items received before the end of the waiver period and receive the remainder of any service initiated before the end of the waiver period.

3. Waiver for ESCO Health Information Technology Provided to Participants

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law) and section 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to ESCO Health Information Technology provided by the ESCO or a Participant Owner (collectively, "Donor") to a Participant, provided all of the following conditions are met:

- a) The ESCO and the Company have entered into a CEC Agreement and are in compliance with Sections IV.A.1-3, IV.A.7-8, IV.B.1.c, IV.C.1-8, IV.C.10, IV.D.1-2, IV.D.6, V.D, V.E, and XII of the CEC Agreement.
- b) The arrangement involves exclusively items or services that meet the definition of ESCO Health Information Technology.
- c) The arrangement is entered into between the Donor and the Participant after the Effective Date of the CEC Agreement.
- d) The ESCO Health Information Technology provided is in-kind;
- e) Any electronic health records software that is provided is interoperable (as defined in 42 C.F.R. § 411.351) or satisfies 42 C.F.R. § 411.357(w)(2) (related to interoperability) at the time it is provided to the recipient.
- f) Any hardware provided is necessary to operate software provided by the Donor, and the Participant receiving it does not possess hardware that is capable of operating the software.

- g) The Donor, or any person on the Donor's behalf, does not take any action to limit or restrict the use, compatibility, or interoperability of the ESCO Health Information Technology provided.
- h) The eligibility of a Participant for the ESCO Health Information Technology and the amount or nature of the ESCO Health Information Technology are determined in a manner that does not directly take into account the volume or value of referrals or other business generated between the parties, any other Participant, the Company, or any individual or entity affiliated with a Participant or the Company. For purposes of this paragraph (h), the arrangement is deemed not to directly take into account the volume or value of referrals or other business generated if any one of the following conditions is met:
 - i. All Participants are offered comparable items or services, but if a Participant possesses equivalent items or services, that Participant shall not receive duplicative items or services;
 - ii. All similarly situated Participants (*e.g.*, all Participant Non-Owners or all physician practices) are offered comparable items or services, but if a Participant possesses equivalent items or services, that Participant shall not receive duplicative items or services;
 - iii. The determination is based on the Participant's overall use of health information technology (without regard to the use of technology in connection with referrals made to the Donor; another Participant; the Company; or any individual or entity affiliated with a Participant or the Company);
 - iv. The determination is based on the Participant's success or difficulty in reporting quality measures (as required under Section VII.B of the CEC Agreement), satisfying minimum quality performance standards (as set forth in Appendix D of the CEC Agreement), or reporting and satisfying performance-based metrics used to calculate a performance-based payment (as set forth in Section IV.D.5 of the CEC Agreement); or
 - v. The determination is based solely on the overall level or scope of care coordination activities undertaken by the Participant.
- i) The Participant does not make the receipt of the ESCO Health Information Technology, or the amount or nature of the ESCO Health Information Technology, a condition of doing business with the Donor, another Participant, the Company, or any individual or entity affiliated with a Participant or the Company.
- j) The ESCO Health Information Technology does not duplicate what the Participant already has.

- k) The Donor documents the terms and conditions of each arrangement in writing, specifying the ESCO Health Information Technology to be provided by the Donor to the Participant, before the ESCO Health Information Technology is provided. The Donor documents contemporaneously with the provision of the ESCO Health Information Technology and in writing the identity of the recipient and the dates the items or services were provided under the arrangement. The Donor shall retain the documentation for at least 10 years following the end of the last Performance Year and shall make it available promptly to the ESCO (if retained by the Participant Owner), the Secretary, or the Inspector General upon request.
- l) The governing body of the ESCO makes and duly authorizes a bona fide determination that the arrangement for the provision of the ESCO Health Information Technology is reasonably related to the ESCO Purpose before the Donor provides it to a Participant. The governing body of the ESCO shall date and document in writing such approval, including the basis for its determination, contemporaneously with its decision-making process. The ESCO shall retain this documentation for at least 10 years following the end of the last Performance Year and make it available promptly to the Secretary or the Inspector General upon request.
- m) The ESCO Health Information Technology is not provided to incentivize Participants to reduce or limit Medically Necessary care.
- n) The costs of the items or services are not shifted to any Federal health care program.
- o) The CEC Agreement, as amended from time to time, does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will begin on the Effective Date of the CEC Agreement and will end on the earlier of (1) the date on which the CEC Agreement has been terminated, or (2) the expiration date of the last Performance Year under the CEC Agreement.

4. Waiver for Performance-Based Payments to Physicians Who Are Participants

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law) and section 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to performance-based payments made pursuant to Section IV.D.5 of the CEC Agreement by the ESCO to certain physicians who are Participants, provided all of the following conditions are met:

- a) The ESCO and the Company have entered into a CEC Agreement and are in compliance with Sections IV.A.1-3, IV.A.7-8, IV.B.1.c, IV.C.1-8, IV.C.10, IV.D.1-2., IV.D.5, V.D, V.E, and XII of the CEC Agreement.

- b) The performance-based payments are provided by the ESCO to a Participant who is a physician, as defined in section 1861(r)(1) of the Act.
- c) The performance-based payments are made based only on Medically Necessary services personally performed by the physician for ESCO Beneficiaries in furtherance of the ESCO Purpose during the term of the CEC Agreement pursuant to a methodology based on performance-based metrics, accurate reporting on such metrics, and such other criteria as may be specified by CMS.
- d) Eligibility for performance-based payments is determined uniformly for similarly situated physicians and the methodology for determining the performance-based payments does not take into account, directly or indirectly, the volume or value of any items or services other than those services described in subparagraph 4(c) of this waiver that are personally performed by the physician receiving the payment.
- e) The performance-based payments are made only after the physician reports to the ESCO the quality or other data necessary to determine whether the metric has been met. The physician must certify the accuracy and completeness of such data when it is reported to the ESCO.
- f) The ESCO making the performance-based payment shall have the authority to recoup any payments made to the physician if the payment is made based on false or inaccurate data reported by the physician (or his or her practice).
- g) The physician does not make the receipt of the performance-based payment, or the amount of the performance-based payment, a condition of doing business with the ESCO, another Participant, the Company, or any individual or entity affiliated with the ESCO, another Participant, or the Company.
- h) The ESCO documents the terms and conditions of each arrangement in writing before providing any performance-based payment. The ESCO documents in writing the amount, date, basis for, and recipient of the performance-based payment contemporaneously with distributing the performance-based payment. The ESCO shall retain the documentation for at least 10 years following the end of the last Performance Year and shall make it available promptly to the Secretary or the Inspector General upon request.
- i) The governing body of the ESCO makes and duly authorizes a bona fide determination that the performance-based payments are reasonably related to the ESCO Purpose before the ESCO makes such payment to the physician. The governing body of the ESCO shall date and document in writing such approval, including the basis for its determination, contemporaneously with its decision-making process. The ESCO shall retain this documentation for at least 10 years following the end of the last Performance Year and make it available promptly to the Secretary or the Inspector General upon request.

- j) The performance-based payment is not made to reduce or limit Medically Necessary care.
- k) The costs of performance-based payments are not shifted to any Federal health care program.
- l) The CEC Agreement, as amended from time to time, does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period takes effect on the Effective Date of the CEC Agreement and shall end on the earlier of:

- (1) 90 days after CMS's payment of Shared Savings for the last Performance Year in which the CEC Agreement was in effect;
- (2) the date on which the settlement report for the last Performance Year in which the CEC Agreement was in effect becomes final; or
- (3) in a final Performance Year for which CMS is not obligated to issue a settlement report pursuant to Section XIII.C.2 of the CEC Agreement, the date that is the later of:
 - (i) 90 days after CMS's payment of Shared Savings for the immediately preceding Performance Year, or
 - (ii) the date on which the settlement report for the immediately preceding Performance Year became final if CMS owed no Shared Savings for that Performance Year.

5. Waiver for Care Coordination Arrangements

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law) and section 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to ESCO Support provided by the ESCO or a Participant Owner to a Participant, if all of the following conditions are met:

- a) The ESCO and the Company have entered into a CEC Agreement and are in compliance with Sections IV.A.1-3, IV.A.7-8, IV.B.1.c, IV.C.1-8, IV.C.10, IV.D.1-2, and XII of the CEC Agreement and
 - i. Section IV.D.7 of the CEC Agreement if the ESCO provides support services as described in that section;
 - ii. Section IV.D.8 of the CEC Agreement if the ESCO provides for co-location and rounding as described in that section; or

- iii. the conditions listed in Section IV.D.7.a-h of the CEC Agreement for other care coordination items or services that meet the definition of ESCO Support.
- b) The arrangement involves exclusively items or services that meet the definition of ESCO Support.
- c) The arrangement is entered into between the Participants after the Effective Date of the CEC Agreement, and if the ESCO funds the arrangement, the ESCO shall also be a party to the arrangement.
- d) The ESCO or Participant Owner who provides the ESCO Support documents the terms and conditions of the arrangement in writing, specifying the ESCO Support to be provided, before providing the ESCO Support. The ESCO or Participant Owner who provides the ESCO Support documents contemporaneously with the provision of the items or services provided and in writing the identity of the recipient and dates the items or services were provided under the arrangement. The ESCO or Participant Owner who provides the ESCO Support shall retain the documentation for at least 10 years following the end of the last Performance Year and shall make it available promptly to the ESCO, (if retained by the Participant Owner), the Secretary, or the Inspector General upon request.
- e) The governing body of the ESCO makes and duly authorizes a bona fide determination that the arrangement is reasonably related to the ESCO Purpose before the arrangement commences. The governing body of the ESCO shall date and document in writing such approval, including the basis for its determination, contemporaneously with its decision-making process. The ESCO shall retain this documentation for at least 10 years following the end of the last Performance Year and make it available promptly to the Secretary or the Inspector General upon request.
- f) The ESCO Support is not provided to incentivize Participants to reduce or limit Medically Necessary care.
- g) The costs of the items or services are not shifted to any Federal health care program.
- h) The CEC Agreement, as amended from time to time, does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will begin on the Effective Date of the CEC Agreement and will end on the earlier of (1) the date on which the CEC Agreement has been terminated, or (2) the expiration date of the last Performance Year under the CEC Agreement.

6. Waiver for Remuneration Furnished by the Company to the ESCO for ESCO Support, ESCO Health Information Technology, and Patient Engagement Incentives

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law, section 1128(A)(a)(5) of the Act (relating to the beneficiary inducement CMP), and section 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to remuneration from the Company to the ESCO that is used for ESCO Support, ESCO Health Information Technology, or Patient Engagement Incentives (as defined in the Waiver for Patient Engagement Incentives), if all of the following conditions are met:

- a) The ESCO and the Company have entered into a CEC Agreement and are in compliance with Sections IV.A.1-3, IV.A.7-8, IV.C.1-8, IV.B.1.c, IV.C.10, IV.D.1-.2, and XII of the CEC Agreement.
- b) The Company provides the remuneration to the ESCO and not directly to any Participant, individual, or entity.
- c) Neither the Company nor any affiliate or agent, including any parent, subsidiary, or joint venture of the Company, earmarks the remuneration for any specific Participant or ESCO Beneficiary. The Company may specify that the remuneration should be used for ESCO Support, ESCO Health Information Technology, or Patient Engagement Incentives.
- d) The remuneration provided by the Company to the ESCO is used solely by the ESCO to fund arrangements for ESCO Support, ESCO Health Information Technology, or Patient Engagement Incentives that meet the applicable requirements of Section IV of the CEC Agreement and either comply with the laws described above or meet the requirements of an applicable waiver in this Notice.
- e) Neither the Company nor any affiliate or agent, including any parent, subsidiary, or joint venture of the Company, adds any conditions, restrictions, or limitations to the provision or use of remuneration used to fund ESCO Support, ESCO Health Information Technology, or Patient Engagement Incentives, except that the Company may require that funded activities comply with the CEC Agreement or an applicable waiver in this Notice.
- f) The arrangement is set forth in a written agreement signed by the ESCO and the Company before the remuneration is provided that specifies the amount of the remuneration and the terms and conditions for payment of the remuneration. The ESCO and Company must contemporaneously document in writing the dates the remuneration was provided under the arrangement. The ESCO shall retain the documentation for at least 10 years following the end of the last Performance Year and shall make it available promptly to the Secretary or the Inspector General upon request.
- g) The governing body of the ESCO makes and duly authorizes a bona fide determination that the remuneration is reasonably related to the ESCO Purpose and that its use is solely for ESCO Support, ESCO Health Information Technology, or Patient Engagement

Incentives before the Company provides it to the ESCO. The governing body of the ESCO shall date and document in writing such approval, including the basis for its determination, contemporaneously with its decision-making process. The ESCO shall retain this documentation for at least 10 years following the end of the last Performance Year and make it available promptly to the Secretary or the Inspector General upon request.

- h) The remuneration is not provided to reduce or limit Medically Necessary care.
- i) The costs of the remuneration or any funded activities are not shifted to any Federal health care program.
- j) The CEC Agreement, as amended from time to time, does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the Effective Date of the CEC Agreement and will end on the earlier of (1) the date on which the CEC Agreement has been terminated; (2) the date on which the agreement described in Section I.B.6.f of this Notice terminates; or (3) the expiration date of the last Performance Year under the CEC Agreement.

Part II: Explanation of Waiver Requirements

Part II of this Notice contains commentary explaining certain waiver requirements set forth in Part I of this Notice.

A. Commentary Applicable to All Waivers in this Notice

This Notice pertains only to arrangements that are part of the CEC being administered by CMMI; this Notice has no applicability to other programs or arrangements, even those that may bear some similarity to the arrangements described in this Notice.

Each waiver set forth in Part I of this Notice applies to arrangements that squarely meet all of the conditions pertaining to that particular waiver. A waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement (1) does not implicate the specific fraud and abuse law; (2) implicates the law, but fits within an existing exception or safe harbor, as applicable; or (3) otherwise complies with the law. Arrangements that do not fit in a waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the Physician Self-Referral Law (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), and the beneficiary inducements CMP (section 1128A(a)(5) of the Act). Failure to fit in a waiver is not, in and of itself, a violation of the laws. If an arrangement complies with existing law, it does not need to fit under a waiver.

Each waiver protects only arrangements that meet *all* of the listed conditions. If an arrangement does not meet all of the waiver conditions, it does not qualify for waiver protection. Waivers do

not provide retrospective protection: an arrangement must meet all of the waiver conditions during the period for which waiver protection is sought.

The waivers in this Notice have been developed in consultation with CMMI, which is administering and testing the CEC Model. Section 1115A(d)(1) of the Act specifies the legal standard that has guided development of these waivers. Under this standard, the Physician Self-Referral Law, the Federal anti-kickback statute, and the Beneficiary Inducements CMP may be waived “as may be necessary solely for purposes of carrying out the testing” of the CEC Model. CMMI has determined that the arrangements covered by these waivers are necessary to carry out the testing of the CEC Model.²

The waivers in this Notice only apply to the individuals and entities specifically enumerated in the waivers. Readers are cautioned to examine each waiver carefully to determine the particular types of individuals and entities that are eligible to use the waiver. For example, the Company is not eligible for all waivers.

If the Company is not a Participant Owner, it is only eligible for those waivers in which it is specifically named:

- the Waiver for Distributions of Shared Savings Payments to Participants or the Company; and
- the Waiver for Remuneration Furnished by the Company to the ESCO for ESCO Support, ESCO Health Information Technology, and Patient Engagement Incentives.

If the Company is a Participant Owner, it is also eligible for:

- the Waiver for ESCO Health Information Technology Provided to Participants; and
- the Waiver for Care Coordination Arrangements.

² This Notice does not waive the “gainsharing” CMP (section 1128A(b)(1) and (2) of the Act). Section 512 of the Medicare Access and CHIP Reauthorization Act of 2015, 114 P.L. 10, revised the statute so that it prohibits hospitals from making payments, directly or indirectly, to induce physicians “to reduce or limit *medically necessary* services” provided to Medicare or Medicaid beneficiaries. 114 P.L. 10, *512, 129 Stat. 87 (emphasis added). Because the statute no longer prohibits payments made by hospitals to induce physicians to reduce or limit medically unnecessary services, no waiver of the gainsharing CMP is needed.

These waivers are intended to protect only arrangements³ that are an integral part of CEC. Providers, suppliers, and others participating in the CEC, including the Company, may have a variety of arrangements among themselves (or involving others) that are not part of the CEC. Such arrangements are not protected by the waivers in this Notice. To reinforce this, the waivers require the governing body of the ESCO to make and duly authorize a bona fide determination that the arrangement is reasonably related to the ESCO Purpose (as defined in Section I.A above) before the arrangement commences or items or services are provided to recipients.⁴ The documentation of the approval must include the basis for determining that the arrangement is reasonably related to the ESCO Purpose. The standard for reasonableness is objective and fact-based. Under the CEC Agreement, the governing body of the ESCO must act solely in the interests of the ESCO and not of any constituent part. The Waiver for Remuneration Furnished by the Company also requires the governing body to approve the use of the remuneration solely for one of the purposes enumerated in the waiver. In each instance, the governing body's approval, including the basis for determining that the arrangement is reasonably related to ESCO Purpose, must be documented contemporaneously with the governing body's decision-making process.

Each waiver in this Notice requires that the ESCO and the Company have entered into a CEC Agreement with CMMI and are in full compliance with sections of the CEC Agreement specified in each waiver. The design of the waivers is premised on the expectation that the requirements of the CEC Agreement will, in the first instance, mitigate risks of fraud and abuse. In general, the enumerated terms and conditions are those focused on accountability, transparency, compliance, and program integrity. The sections of the CEC Agreement listed in each waiver are also tailored to the specific type of financial arrangement covered by the waiver. For example, the waiver for Patient Engagement Incentives specifically requires compliance with sections of the CEC Agreement that establish program rules for such incentives. Readers are cautioned to review the lists of terms and conditions closely and to consult the applicable CEC Agreement to ensure compliance. For any arrangement described in the Notice, there may be conditions in a waiver that are in addition to the requirements of the CEC Agreement. If an arrangement does not meet all of the waiver conditions, it does not qualify for waiver protection. Each waiver includes additional conditions specific to the type of arrangement to which the waiver applies.

Taken in combination, the goal of the waiver conditions is to ensure that protected financial arrangements are consistent with the quality, care coordination, and cost reduction goals of the CEC Model; are subject to safeguards designed to mitigate the risk of fraud and abuse (including, for example, risks of harms such as overutilization, underutilization, increased costs, and inappropriate patient steering); and can readily be monitored and audited. It is not the intent of these waivers to protect financial arrangements that are misused to induce or reward the

³ For ease of reference throughout this document, "arrangements" includes the payments and remuneration protected under the waivers.

⁴ The governing body condition does not apply to the Waiver for Distributions of Shared Savings Payments to Participants or the Company because Shared Savings are earned only after CMS-set quality and performance goals are met and thus distributions of Shared Savings Payments are integral to the CEC Model when administered in accordance with the CEC.

referral of items or services. Misuse of the waivers could include, by way of example only, arrangements to induce or reward, explicitly or implicitly, the referral of beneficiaries who are not aligned with the ESCO under CEC; arrangements to induce or reward the referral of ESCO Beneficiaries that do not promote the quality, care coordination, and reduced cost goals of the ESCO and the CEC; arrangements to induce or reward referrals to or from parties not affiliated with the ESCO, even if they furnish items or services to ESCO Beneficiaries; arrangements involving “pay to play” payments or fees to participate in the ESCO or the CEC; and arrangements involving *quid pro quo* remuneration in exchange for, or to induce, specific volumes or categories of referrals or referrals of specific patients.

The waivers are designed to preclude such abusive arrangements. HHS intends to monitor the CEC for program integrity. If these or other abuses occur, CMS and OIG will take appropriate steps, including, for example, enforcement by CMS of corrective action and termination provisions of the CEC Agreement or modification or rescission of this Notice.

To be protected by a waiver, arrangements must be documented in writing and the parties specified in each waiver must timely create, maintain, and produce the specific documentation required by the terms of the waiver. Documentation establishing the arrangement must be contemporaneous with the initiation of the arrangement. Documentation of information about the operation of an arrangement (for example, dates and amounts of remuneration under an arrangement) must be contemporaneous with the information being documented. In general, the waivers do not require documentation to be maintained in any particular form. Documentation may be maintained in paper or electronic format, provided it is a viewable format. The waiver documentation requirements do not replace, and may be in addition to, any documentation requirements in the CEC Agreement. The party or parties specified in the waiver shall retain the required documentation for at least 10 years following the end of the last Performance Year under the relevant CEC Agreement. The required documentation must be made available promptly to the ESCO (if the waiver requires the documentation to be retained by the Participant), the Secretary, or the Inspector General upon request.⁵ This condition is intended to promote transparency of arrangements and the ability of ESCOs and the government to monitor and audit for compliance with program rules and the fraud and abuse laws.

Where applicable, the waivers preclude the shifting of costs to any Federal health care program. This term is not intended to preclude use of Shared Savings Payments to fund care coordination, ESCO Support, health information technology, or patient engagement incentives that otherwise meet waiver conditions.

The period for all waivers will start on the Effective Date of the CEC Agreement. Each waiver has a specific end point stated in the waiver section. The waiver timeframes are intended to align with the terms of the CEC Agreement, including, where necessary, a reasonable period after the end of the ESCO’s participation in the CEC to allow for certain post-participation operations under the CEC Agreement, including calculation and distribution of final year Shared Savings

⁵ The Inspector General, as noted in Section I.B.1.e above, refers to the Inspector General of the Department of Health and Human Services.

Payments or payment of performance-based payments funded with final year Shared Savings Payments.

Nothing in this Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other Federal or State laws and regulations. Nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations under the CEC Agreement or any other agreement. Apart from meeting applicable waiver conditions, no special action (such as the submission of a separate application for a waiver) is required for an arrangement to be covered by these waivers.

We reserve the right to reconsider the waivers and to suspend, modify, or terminate the waivers on a prospective basis for any reason consistent with the public interest and with respect to all participants in the CEC or with respect to specific participants. Suspension, modification, or termination of the waivers does not require advance notice and is effective upon notice to the ESCO of such suspension, modification, or termination. 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. Each waiver provides that it is not applicable if the CEC Agreement is amended to provide that the waiver is inapplicable. This term permits CMMI to preclude protection under the waiver as part of an amendment to the CEC Agreement.

B. Commentary Applicable to Specific Waivers

1. Waiver for Distributions of Shared Savings Payments to Participants or the Company

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Section II.A of this Notice, above.

The Waiver for Distributions of Shared Savings Payments to Participants and the Company addresses the application of the Physician Self-Referral Law and the Federal anti-kickback statute. This waiver protects only those Shared Savings Payments made to Participants or the Company by the ESCO or to an ESCO Provider/Supplier by a Participant Owner or Participant Non-Owner. The waiver does not apply if Shared Savings Payments are made to reduce or limit Medically Necessary care. The waiver does not protect any other payments made under the CEC or any payments that are not part of the CEC.

To obtain waiver protection, the Shared Savings Payments must be distributed in accordance with the requirement of Section IV.D.4.c of the CEC Agreement that such payments be made only in a manner that recognizes the recipient's financial or other contributions towards the ESCO Purpose, such as the recipient's performance on quality measures identified in Appendix D of the CEC Agreement. The party making the distribution (whether directly or indirectly)⁶ shall not add conditions, limitations, or restrictions to the receipt or use of the payments.

⁶ An example of an indirect distribution would be when an ESCO makes a Shared Savings Payment to a Participant Owner or Participant Non-Owner and requires that the Participant Owner or Participant Non-Owner place conditions on any distributions of the Shared Savings Payment to ESCO Provider/Suppliers.

Consistent with Section IV.B.1.e of the CEC Agreement, the party making the distribution would not violate this prohibition by requiring compliance with the terms of the CEC Agreement. On the other hand, the ESCO or Participant Owner may not require the recipient, for example, to pay someone else a share of the Shared Savings Payment, to direct business or referrals to an ESCO Participant or the Company, to use the funds to purchase items or services from the ESCO, a Participant, the Company, or another entity, or to invest or reinvest in the ESCO or another entity.

The Shared Savings must be earned by the ESCO during the term of its CEC Agreement. Participants receiving Shared Savings Payments must have been Participants during the Performance Year in which the Shared Savings were earned by the ESCO. This condition serves to tie Shared Savings Payment distributions to Participants who likely contributed to achieving the Shared Savings.

The ESCO and Participant Owners may distribute the Shared Savings in any manner that complies with existing law. The waiver, however, only protects Shared Savings Payments, which under the CEC Agreement may only be distributed by the ESCO to the Company or Participants, or by a Participant Owner or Participant Non-Owner to an ESCO Provider/Supplier. The CEC Model requires that all Participants abide by the terms of the CEC Agreement, either directly through the CEC Agreement itself or indirectly through agreements with the ESCO. Thus, the waiver does not protect the distribution of Shared Savings except as Shared Savings Payments.

For Performance Years for which CMS is obligated to issue a settlement report, the waiver period takes effect on the Effective Date of the CEC Agreement and shall expire 90 days after CMS's payment of Shared Savings for the last Performance Year in which the CEC Agreement was in effect, or the date on which the settlement report for the last Performance Year in which the CEC Agreement was in effect becomes final. In the case of a final Performance Year for which CMS is not obligated to issue a settlement report pursuant to Section XIII.C.2 of the CEC Agreement, the waiver period shall expire on the later of (1) 90 days after CMS's payment of Shared Savings for the immediately preceding Performance Year, or (2) the date on which the settlement report for the immediately preceding Performance Year became final if CMS owed no Shared Savings for that Performance Year. This waiver period is intended to allow for the distribution of Shared Savings Payments that are received by the ESCO after the end of the last Performance Year.

2. Waiver for Patient Engagement Incentives

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Section II.A of this Notice, above.

The Waiver for Patient Engagement Incentives addresses the application of the Beneficiary Inducements CMP and the Federal anti-kickback statute to the provision of certain items and services to ESCO Beneficiaries. This is the only waiver that applies to financial arrangements with ESCO Beneficiaries. This waiver is intended to protect incentives used to promote patient-centered care, encourage involvement of ESCO Beneficiaries in their health care, and further the

purposes of the CEC Model to promote quality of care, care coordination, and lower costs for ESCO Beneficiaries. The waiver is not intended to protect inducements to ESCO Beneficiaries to generate business for particular providers or suppliers. We note that the CEC Agreement expressly prohibits ESCOs, Participants, and the Company from providing gifts or other remuneration to Medicare beneficiaries to induce them to receive items or services from the ESCO, its Participants, or the Company (Section V.F.2).⁷

This waiver protects the three types of patient engagement incentives specifically contemplated under the CEC Agreement: technology, oral nutrition supplements, and non-emergency transportation. For these arrangements to be protected, all relevant conditions of the CEC Agreement and all conditions of the waiver in this Notice must be squarely met. The waiver does not protect any other types of incentives, items, or services provided to ESCO Beneficiaries. (Nothing in this Notice prevents parties from structuring arrangements for patient engagement incentives if they can do so in a manner that complies with existing law. In some cases, parties may be able to use existing exceptions, *e.g.*, the preventive care or financial need exceptions.) The waiver only applies to items or services provided to ESCO Beneficiaries, not any other Federal health care program beneficiaries.

The items and services protected by this waiver must be provided to the ESCO Beneficiary by the ESCO, a Dialysis Facility that is a Participant, or a Nephrologist who is a Participant. The waiver focuses on these parties because they are in the best position to furnish incentives reasonably related to the ESCO Beneficiary's medical care under the CEC Model. If the Company is a Participant Dialysis Facility that is a Participant, it is eligible for this waiver. If the Company is not a Dialysis Facility that is a Participant, this waiver does not protect incentives it offers to ESCO Beneficiaries.⁸ This waiver also does not protect incentives offered to ESCO Beneficiaries by other types of Participants, Participant Owners, or Participant Non-Owners. This waiver does not protect arrangements between or among the ESCO, Participants, the Company, or any other individual or entity related to patient engagement incentives. Among other things, the waiver does not protect arrangements with manufacturers, suppliers, or other vendors. All such arrangements must be evaluated for compliance under existing law. The waiver is limited to the arrangement between the ESCO Beneficiary and the ESCO, Dialysis Facility, or Nephrologist furnishing the incentive.

All incentives must be provided in-kind. Gift cards, coupons, cash, or other cash equivalents are not covered by this waiver, nor are waivers of cost-sharing amounts. The in-kind requirement means that ESCO Beneficiaries must receive the actual technology or oral nutrition supplements, and not funds to purchase these products. Transportation must be provided in-kind. ESCO Beneficiaries may not be given cash reimbursement for transportation costs such as bus or taxi fare or gasoline. ESCO Beneficiaries may be given prepaid vouchers redeemable solely for transportation services pursuant to a contractual arrangement between the party arranging for the transportation and the transportation provider.

⁷ The CEC Agreement expressly permits the provision of items or services to ESCO Beneficiaries in compliance with all applicable laws and regulations.

⁸ See Part I for a discussion of the waivers for which the Company may be eligible.

Protected incentives must be reasonably related to medical care provided to an ESCO Beneficiary by a Nephrologist who is a Participant or an ESCO Provider/Supplier. The standard for reasonableness is objective and fact-based. For example, technology in the form of a device to monitor and transmit medical indications and symptoms could be reasonably related to the ESCO Purpose, but a device that solely plays games would not be. Similarly, transportation to medical appointments or to pick up prescriptions could be protected, but transportation to entertainment or recreational events or to run errands would not be.

The availability of the technology, oral nutrition supplements, and non-emergency transportation shall not be advertised or promoted. ESCO Beneficiaries may be made aware of the availability of these incentives at the time that the ESCO Beneficiary could reasonably benefit from the particular incentive. For example, the availability of oral nutrition supplements should not be used to incentivize beneficiaries to seek services from a Participant, but could be offered to an ESCO Beneficiary once his or her Nephrologist determines that they are Medically Necessary or could be beneficial. Similarly, ESCOs should not generally advertise that they provide transportation or technology; however, the ESCO or a Participant may inform specific ESCO Beneficiaries who need or could benefit from particular technology or transportation that it is available.

Protection for each category of patient incentive is subject to compliance with the conditions in Section V.F of the CEC Agreement and the corresponding appendix to the CEC Agreement. Technology is governed by Appendix F, oral nutrition supplements by Appendix G, and non-emergency transportation by Appendix H. Appendices F and H provide a monetary limit to the technology and transportation incentives that may be provided to an ESCO Beneficiary under the CEC. CMMI has included these limits to ensure that the incentives are provided in a manner consistent with the CEC Model and are not misused. In order to be protected by this waiver, the patient engagement incentives must adhere to these limits. If the ESCO or Participant wishes to provide more than the allotted amount of items or services, the arrangement must be independently evaluated on a case-by-case basis for compliance with the Federal anti-kickback statute, the Beneficiary Inducements CMP, and the CEC Agreement.

In the case of technology, the technology must be reasonably related to the ESCO Purpose and, consistent with Section V.F.2 of the CEC Agreement, it must involve goods or services used to facilitate ESCO Beneficiary communication, health monitoring, and telehealth encounters, and it must advance adherence to a treatment regime; adherence to a drug regime; adherence to a care plan; or management of a chronic disease or condition. These waiver conditions help ensure that the technology is closely aligned with the CEC Model; this waiver is not intended to protect items or services given to patients outside the scope of the CEC Model.

The ESCO or Participant providing technology cannot have actual knowledge or act in reckless disregard of the fact that the ESCO Beneficiary already possesses or has obtained equivalent technology to the technology provided. This condition is intended to mitigate the risk of excessively valuable inducements that might steer patients inappropriately (for example, a second home computer), and to ensure that patient engagement incentives protected under this waiver are closely aligned with the medical care of the ESCO Beneficiary. If an ESCO Beneficiary already has the necessary technology, such as a smartphone with which the ESCO

Beneficiary can operate and receive the benefit of health monitoring applications – and many do⁹ – the provision of equivalent technology may serve as an inappropriate inducement to obtain services from a particular provider or company rather than an incentive to promote the engagement of the ESCO Beneficiary in his or her care. An ESCO Beneficiary who has some necessary technology, such as a smartphone, may not have all necessary technology, *e.g.*, applications or high speed connections capable of running necessary software.

Any transportation provided under this waiver must be made available to all similarly situated ESCO Beneficiaries under a uniform policy (for example, all similarly situated patients are eligible for the same type and level of transportation). Transportation shall not include air, luxury, or ambulance-level transportation.

The waiver period starts on the Effective Date of the CEC Agreement and ends on the earlier of (1) the date on which the CEC Agreement has been terminated, or (2) the expiration date of the last Performance Year under the CEC Agreement. To support continuity of care and avoid unintended effects on ESCO Beneficiaries who may be receiving otherwise protected incentives at the time the waiver period ends, the waiver provides that, for waiver purposes, the ESCO Beneficiary may keep items received before the end of the waiver period and receive the remainder of any service initiated before the end of the waiver period.

3. Waiver for ESCO Health Information Technology Provided to Participants

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Section II.A of this Notice, above.

The Waiver for Health Information Technology Provided to Participants addresses the application of the Physician Self-Referral Law and the Federal anti-kickback statute. This waiver protects the provision of ESCO Health Information Technology. ESCO Health Information Technology is defined above to include software, hardware, or other information technology, or support staff or training services related to information technology that is necessary and used predominately to create, interpret, maintain, transmit, or receive clinical and related information that in turn is necessary to support and facilitate communication, care coordination, and improved health outcomes for ESCO Beneficiaries. To be covered by this waiver, the technology must be provided by the ESCO or a Participant Owner (collective, “Donor”) to a Participant. The waiver does not cover technology provided by the Company or a Participant Non-Owner or any other individual or entity.

The ESCO Health Information Technology must be in the form of nonmonetary remuneration, that is, it must be provided in-kind. The ESCO Health information Technology shall not be

⁹ See ALEXANDRA GATES, ET AL., THE HENRY J. KAISER FAMILY FOUNDATION, PROFILES OF MEDICAID OUTREACH AND ENROLLMENT STRATEGIES: USING TEXT MESSAGING TO REACH AND ENROLL UNINSURED INDIVIDUALS INTO MEDICAID AND CHIP.(2014) <http://kff.org/medicaid/issue-brief/profiles-of-medicare-outreach-and-enrollment-strategies-using-text-messaging-to-reach-and-enroll-uninsured-individuals-into-medicare-and-chip/> (accessed on June 23, 2015).

furnished through gift cards, coupons, cash payments, or any other cash equivalent form. Hardware is not protected unless it is necessary to operate software provided by the Donor, and the Participant receiving it does not possess hardware capable of operating the software. In general, given the nature of the individuals and entities participating in the CEC Model, we expect that most, if not all, will have the hardware needed to operate the software provided. We note that we would consider it an abuse, and not protected, if a Donor were to provide a computer with only one operating system to a Participant that already has a computer with a different operating system, if the donated software can run on either operating system.

Any ESCO Health Information Technology in the form of software must be interoperable. For purposes of this waiver, this means it must satisfy the provisions at 42 C.F.R. § 411.357(w)(2) (related to interoperability for the exception for electronic health records)¹⁰ at the time it is provided to the recipient. Donors, or anyone on their behalf, may not take any action to limit or restrict the use, compatibility, or interoperability of the technology. Engaging in information blocking, for example, would cause a donation arrangement to fail to meet this condition.

Both the eligibility to receive the technology and the amount or nature of the technology, cannot *directly* take into account the volume or value of referrals or other business generated between the parties, any other Participant, the Company, or any individual or entity affiliated with the Company. The goal of this condition is to attenuate any tie between the provision of valuable technology and referral streams. The waiver includes examples of arrangements that are not considered to, solely for the purposes of this waiver, directly take into account the volume or value of referrals. These examples are listed in subsection (h)(i)-(v) of the waiver. Arrangements that fit in one of the examples are deemed not to directly take into account the volume or value of referrals or other business generated for purposes of this waiver only.¹¹ The examples in subsection (h)(i)-(v) are based on the specific circumstances and needs of the CEC. In other contexts, the examples or similar examples might relate directly to the volume or value of business. Similarly, the waiver makes clear that the recipient of the technology shall not condition its current or future business on receiving ESCO Health Information Technology.

The Donor shall not furnish ESCO Health Information Technology that duplicates what the Participant already has. A purpose of this provision is to ensure that Donors do not provide redundant items or services. For example, if a Participant has four tablets to operate a care coordination program and four tablets are sufficient for the program, a Donor shall not give the Participant more tablets. Similarly, if a Participant is using the same software as the Donor, but is using an earlier version of the software, the Donor shall not provide the Participant with a more recent version of the software unless, for example, it improves user-friendliness or makes it more current.

¹⁰ We note that identical provisions exist under the Federal anti-kickback statute. 42 C.F.R. § 1001.952(y)(2). For ease, we have selected one standard for this Notice.

¹¹ We note that section IV.D.6.h of the CEC Agreement contains similar, but not identical provisions, to those in this waiver. In particular, this waiver looks broadly at potential business generated not just for the ESCO, Participants, and the Company, but at business generated for affiliates and at actions taken not just by Donors but also persons acting on their behalf.

The waiver period starts on the Effective Date of the CEC Agreement and ends on the earlier of (1) the date on which the CEC Agreement has been terminated or (2) the expiration date of the last Performance Year under the CEC Agreement.

4. Waiver for Performance-Based Payments to Physicians Who Are Participants

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Section II.A of this Notice, above.

This waiver correlates with the payments described at Section IV.D.5 of the CEC Agreement, which permits certain performance-based payments made by the ESCO to Physicians who are Participants. This waiver addresses the application of the Physician Self-Referral Law and the Federal anti-kickback statute to these payments.

This waiver only protects payments to physicians who are Participants under the CEC Agreement and who are physicians as defined in section 1861(r)(1) of the Act. The waiver does not apply to payments made to any other type of health care provider or supplier. Protected payments may only be made by the ESCO. Performance-based payments are only protected if (1) they are made solely based on the performance of medically-necessary services for ESCO Beneficiaries; (2) those services are personally performed by the physician receiving the payments for ESCO Beneficiaries during the term of the CEC Agreement; (3) they further the ESCO Purpose; and (4) they are made pursuant to a methodology based on performance-based metrics, accurate reporting on such metrics, and such other criteria as may be specified by CMS in the CEC Agreement. Performance-based payments determined on the basis of services provided to other patients or on the basis of services furnished by others are not covered by this waiver.

Eligibility for performance-based payments must be determined uniformly for all similarly situated Physicians and the methodology for determining the payments shall not take into account, directly or indirectly, the volume or value of referrals for any items or services other than services the physician personally performed in order to earn the performance-based payments. In other words, this waiver does not protect payments that are related in any manner to referrals of items or services other than those specifically covered in Section IV.D.5.a of the CEC Agreement. For example, if a performance-based payment is offered for fistula installation by a vascular surgeon in compliance with all CEC requirements, waiver protection will not be available if any portion of that payment relates to any item or service other than the specific fistula installation surgery services.

In addition, we have included an anti-solicitation provision to preclude waiver protection for potentially abusive arrangements in which a physician might seek additional payments in exchange for referral business. The intent of this waiver is to protect performance-based payments that arise from care redesign and efficiencies for the ESCO. To this end, physicians shall not condition the receipt or amount of any performance-based payment on doing business with the ESCO, another Participant, the Company, or any individual or entity affiliated with the ESCO, another Participant, or the Company.

The programmatic goal of performance-based payments in the CEC is to encourage changes in physicians' clinical care that foster care that is better for patients and more efficient in accordance with evidence-based standards. To this end, we would expect that the amount of the performance-based payment would be no more than necessary to encourage the desired change in clinical care. Moreover, we do not expect payments would be offered in situations where there is no corresponding prospective change in clinical practice (*i.e.*, the physician is already practicing in the desired way on a consistent basis). We would expect that payments would be small relative to the associated Medicare payment to the physician for the service. Payments that are disproportionately large, that are not associated with prospective changes in clinical care, or that contain other indicia that the payments exceed what is reasonably necessary to change clinical care would warrant heightened scrutiny to ensure that the payments are not vehicles to disguise payments for referrals.

In order to qualify for the waiver, all payments must be made only after the physician who personally performed the services has reported the quality data necessary to determine whether the physician is eligible for the payment. The physician must certify the accuracy and completeness of the data when it is reported to the ESCO. If a payment is made to a physician based on false or inaccurate data, the ESCO must have the authority to recoup that payment.

For Performance Years for which CMS is obligated to issue a settlement report, the waiver period takes effect on the Effective Date of the CEC Agreement and shall expire 90 days after CMS's payment of Shared Savings for the last Performance Year in which the CEC Agreement was in effect, or the date on which the settlement report for the last Performance Year in which the CEC Agreement was in effect becomes final. In the case of a final Performance Year for which CMS is not obligated to issue a settlement report pursuant to Section XIII.C.2 of the CEC Agreement, the waiver period shall expire on the later of (1) 90 days after CMS's payment of Shared Savings for the immediately preceding Performance Year, or (2) the date on which the settlement report for the immediately preceding Performance Year became final if CMS owed no Shared Savings for that Performance Year. Although performance-based payments must be earned for services performed during the term of the CEC Agreement, this waiver period recognizes CMMI's intent that ESCOs may choose to use Shared Savings Payments to make performance-based payments.

5. Waiver for Care Coordination Arrangements

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Section II.A of this Notice, above.

The Waiver for Care Coordination Arrangements addresses the application of the Physician Self-Referral Law and the Federal anti-kickback statute to ESCO Support provided by the ESCO or a Participant Owner to a Participant.

For purposes of this Notice, ESCO Support is defined in three parts:

- (i) clinical support services, such as case managers, care coordinators, and clinical training used predominantly for ESCO Beneficiaries;

(ii) accommodations for Rounding Practitioners to co-locate or conduct rounds at a Dialysis Facility, including related administrative services; or

(iii) other items and services necessary to coordinate care, such as administrative, quality management, and data services necessary to the delivery, documentation, and assessment of care coordination services.

This definition of ESCO Support is intended to address the range of care coordination activities contemplated by the CEC Agreement as integral to the CEC Model and consistent with the ESCO Purpose. The definition excludes ESCO Health Information Technology, which is addressed by a separate waiver. To be protected, the ESCO Support arrangement must involve exclusively items or services that meet the definition of ESCO Support. Mixed use arrangements or arrangements that combine ESCO Support with other items or services are not protected. We note that parties are free to structure arrangements under existing safe harbors and exceptions, including those related to personal services arrangements, rental arrangements, and employment arrangements.

As a threshold requirement, ESCO Support must comply with enumerated CEC Agreement requirements. Notably, support services described in Section IV.D.7 of the CEC Agreement must comply with the requirements of that section, and Co-location and Rounding described in Section IV.D.8 of the CEC Agreement must comply with the requirements of that section. Other care coordination items and services that are not support services or co-location and rounding, as defined in the CEC Agreement, must meet the requirements of IV.D.7a-h of the CEC Agreement as if those services were specifically listed in that section.

This waiver does not protect arrangements entered into before the Effective Date of the CEC Agreement. If the ESCO funds the arrangement, the ESCO must also be a party to the arrangement.

The waiver period starts on the Effective Date of the CEC Agreement and will end on the earlier of (1) the date on which the CEC Agreement has been terminated, or (2) the expiration date of the last Performance Year under the CEC Agreement.

6. Waiver for Funding Furnished by the Company to the ESCO for ESCO Support, ESCO Health Information Technology, and Patient Engagement Incentives

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Section II.A of this Notice, above. Also, the commentary on the specific waiver applicable to the activities that could be funded by the Company are incorporated by reference.

This waiver addresses the applicability of the Physician Self-Referral Law and the Federal anti-kickback statute to certain remuneration provided by the Company to the ESCO. It is intended to address the situation that arises when the Company is not itself a Participant in the ESCO but will provide capital to fund ESCO activities that further the ESCO Purpose and the CEC Model. CMMI has determined that such funding is necessary to carry out the testing of the CEC Model.

This waiver requires that the funding be given to the ESCO because the ESCO is best positioned to ensure that the funds are used more effectively to promote the ESCO Purpose, that all such funding from the Company for the ESCO Purpose can be readily identified, and to ensure transparency and accountability for such funding and its usage. The ESCO must ensure that the funds are properly used under the terms of the waiver. The ESCO has an obligation under the terms of the CEC Agreement to operate independently from the interests of the Company, or Company agents or affiliates, where those interests do not align with the ESCO Purposes.

Specifically, the remuneration must be used to fund ESCO Support, ESCO Health Information Technology, or Patient Engagement Incentives. The arrangements must either meet the terms of an applicable waiver or otherwise comply with the law. The Company (or an affiliate or agent) may not earmark the funding for a specific Participant or ESCO Beneficiary. The Company may designate funding for one of the categories: ESCO Support, ESCO Health Information Technology, or Patient Engagement Incentives. The ESCO must decide on the particular use of the funds. The Company may require that funded activities comply with the CEC Agreement or an applicable waiver in this Notice. It may not otherwise add conditions, restrictions, or limitations on the provision or use of the remuneration. This would include any conditions, restrictions, or limitations related to the volume or value of business generated for or by the Company, its affiliates (including any subsidiary, parent, or joint venture), any Participant, or any other individual or entity.

The waiver period will start on the Effective Date of the CEC Agreement and will end on the earlier of (1) the date on which the CEC Agreement has been terminated; (2) the date on which the agreement between the ESCO and the Company terminates; or (3) the expiration date of the last Performance Year under the CEC Agreement.

As to section 1877(a) of the Act:

Dated: [July 15, 2015]

/Andrew M. Slavitt/

Andrew M. Slavitt
Acting Administrator,
Centers for Medicare & Medicaid Services.

As to section 1128A(a)(5), and sections 1128B(b)(1) and (2) of the Act:

Dated: [July 15, 2015]

/Daniel R. Levinson/

Daniel R. Levinson,
Inspector General,
Department of Health and Human Services.