

Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Care Redesign Program within the Maryland Total Cost of Care Model

December 14, 2018

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 the Maryland Total Cost of Care Model under Section 1115A of the Act and is implementing the Care Redesign Program (CRP) within this model. This Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Care Redesign Program within the Maryland Total Cost of Care Model (Notice) is established pursuant to section 1115A(d)(1) of the Act. Before the date of this Notice, the Secretary had not issued any fraud and abuse waivers that would apply to the Maryland Total Cost of Care Model. The waivers in this Notice protect specific financial arrangements that are entered into only pursuant to the CRP within the Maryland Total Cost of Care Model and that are described in the Care Redesign Program Participation Agreement for the Maryland Total Cost of Care Model, as amended from time to time (TCOC Participation Agreement), and in the applicable waiver. The waivers in this Notice do not apply to other arrangements that may be entered into pursuant to the Maryland Total Cost of Care Model or any other model or initiative.

Arrangements entered into as part of the CRP within the Maryland Total Cost of Care Model must meet all of the conditions of the applicable waiver in this Notice to receive waiver protection. Many of the arrangements that we intend to protect under this Notice already exist because they were entered into as part of the Care Redesign Program within the Maryland All-Payer Model. These pre-existing arrangements were the subject of an earlier notice of waivers: the Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Care Redesign Program within the Maryland All-Payer Model (All-Payer Model Notice), which was issued by the Secretary on April 27, 2017.¹

We intend for waiver protection under the All-Payer Model Notice to transition seamlessly into waiver protection under this Notice. Compared to the All Payer Model Notice, this Notice does not impose any new conditions for waiver protection other than requiring that the Hospital have entered into a TCOC Participation Agreement. Thus, any ongoing arrangement entered into on or before December 31, 2018, that qualifies for waiver protection under the All-Payer Model Notice will also meet the conditions of the relevant waiver set forth in this Notice and will not require restructuring or modification to receive continued waiver protection so long as the Hospital has entered into a TCOC Participation Agreement. Such arrangements will receive ongoing waiver protection until the date the relevant waiver period ends as set forth below. For ongoing arrangements, provided the Hospital has entered into a TCOC Participation Agreement, the Incentive Payment Waiver, Intervention Resource Waiver and Downstream Incentive Payment Waiver set forth in Part I of this Notice function as an effective continuation of the Incentive Payment Waiver, Intervention Resource Waiver, and Downstream Incentive Payment Waiver, respectively, as set forth in the All-Payer Model Notice.

¹ The All-Payer Model Notice is available at <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/downloads/2017-Fraud-And-Abuse-Waiver.pdf>.

This Notice is composed of two parts. Part I sets forth the three waivers established for the CRP within the Maryland Total Cost of Care Model and the specific conditions that must be met to qualify for each waiver. Each 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.

I. The Waivers and Applicable Requirements

Terms defined in the TCOC Participation Agreement that are used in this Notice have the meanings set forth in the TCOC Participation Agreement. These terms include, but are not limited to, the following: Allowable CRP Interventions, Approved Track Implementation Protocol, Care Partner, Care Partner Arrangement, CRP Intervention, CRP Track, Downstream Care Partner, Downstream Care Partner Arrangement, Downstream Incentive Payment, Hospital, Incentive Payment, Incentive Payment Methodology, Incentive Payment Pool, Intervention Resource, Intervention Resource Allocation, Medicare FFS Beneficiary, Performance Period, PGP Care Partner, and PGP Member.

A. Incentive Payment 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 the distribution of Incentive Payments from: (i) a Hospital to a Care Partner; and (ii) a Hospital to a PGP Care Partner's Downstream Care Partners, provided all of the following conditions are met:

1. The Hospital has entered into a TCOC Participation Agreement.
2. The Hospital has entered into a written Care Partner Arrangement with the Care Partner that specifies the Incentive Payment Methodology for each CRP Track in which the Care Partner will participate and the Allowable CRP Interventions the Care Partner may perform.
3. The Hospital does not select the Care Partner using any criteria that directly reflect past or anticipated referrals.
4. In implementing and performing under the Care Partner Arrangement, neither party gives remuneration to induce, or receives remuneration in return for, business unrelated to the Allowable CRP Interventions for the CRP Track(s) in which the Care Partner is participating.
5. The Incentive Payment is calculated using, and distributed in accordance with, the Incentive Payment Methodology set forth in the relevant Approved Track Implementation Protocol.
6. The Hospital must maintain documentation of the Care Partner Arrangement and the payment of any Incentive Payments; retain such documentation for at least ten (10)

years following the last Incentive Payment; and make such documentation available to the Secretary upon request. All documentation must be created in advance of or contemporaneous with the correlating event (e.g., documentation of the Hospital's payment of an Incentive Payment must be created in advance of or contemporaneous with the distribution of such payment).

7. The TCOC Participation Agreement does not provide that this Incentive Payment Waiver is inapplicable.

The waiver period for distributions that meet all of the preceding conditions will start on the date of this Notice and will end one year after the earlier of: (i) the effective date of termination or expiration of the TCOC Participation Agreement; (ii) the effective date of termination or expiration of the Care Partner Arrangement; (iii) the effective date of termination of the CRP Track pursuant to which the Incentive Payment is made; (iv) the effective date of the Hospital's termination or withdrawal from the CRP Track pursuant to which the Incentive Payment is made; or (v) the effective date of termination of the Hospital's relevant Approved Track Implementation Protocol.

B. Intervention Resource 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 the distribution of Intervention Resources from: (i) a Hospital to a Care Partner that is not a PGP Member; (ii) a Hospital to a PGP Care Partner's Downstream Care Partners and PGP Members; and (iii) a PGP Care Partner to its Downstream Care Partners and PGP Members, provided all of the following conditions are met:

1. The Hospital has entered into a TCOC Participation Agreement.
2. The Hospital has entered into a written Care Partner Arrangement with the Care Partner that specifies the nature and amount of Intervention Resources the Hospital will distribute to the Care Partner and the Allowable CRP Interventions the Care Partner may perform.
3. The nature and amount of Intervention Resources must relate to improving or maintaining quality of care.
4. The Hospital does not select the Care Partner using any criteria that directly reflect past or anticipated referrals.
5. In implementing and performing under the Care Partner Arrangement, neither party gives remuneration to induce, or receives remuneration in return for, business unrelated to the Allowable CRP Interventions for the CRP Track(s) in which the Care Partner is participating.
6. The Hospital must maintain documentation of the Care Partner Arrangement and the distribution of the Intervention Resources; retain such documentation for at least ten

(10) years following the termination of the Care Partner Arrangement; and make such documentation available to the Secretary upon request. All documentation must be created in advance of or contemporaneous with the correlating event (e.g., documentation of distribution of an Intervention Resource must be created in advance of or contemporaneous with distribution of such Intervention Resource).

7. Any electronic health records software provided as an Intervention Resource must be interoperable (as defined in 42 C.F.R. § 411.351) or satisfy 42 C.F.R. § 411.357(w)(2) (condition related to interoperability in the physician self-referral law exception for electronic health records) at the time it is provided to the Care Partner. Neither the Hospital, nor any person on the Hospital's behalf, may take any action to limit or restrict the use, compatibility, or interoperability of such electronic health records software with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services).
8. The TCOC Participation Agreement does not provide that this Intervention Resource Waiver is inapplicable.

The waiver period for distributions that meet all of the preceding conditions will start on the date of this Notice and will end on the earlier of: (i) the effective date of termination or expiration of the TCOC Participation Agreement; (ii) the effective date of termination or expiration of the Care Partner Arrangement; (iii) the effective date of termination of the CRP Track pursuant to which the Intervention Resource is distributed; (iv) the effective date of the Hospital's termination or withdrawal from the CRP Track pursuant to which the Intervention Resource is distributed; or (v) the effective date of termination of the Hospital's relevant Approved Track Implementation Protocol.

C. Downstream Incentive Payment 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 the distribution of Downstream Incentive Payments from a PGP Care Partner to a Downstream Care Partner, provided all of the following conditions are met:

1. The PGP Care Partner has entered into a written Downstream Care Partner Arrangement with the Downstream Care Partner that specifies the Incentive Payment Methodology for each CRP Track in which the Downstream Care Partner will participate and the Allowable CRP Interventions the Downstream Care Partner may perform.
2. In implementing and performing under the Downstream Care Partner Arrangement, neither party gives remuneration to induce, or receives remuneration in return for, business unrelated to the Allowable CRP Interventions for the CRP Track(s) in which the Downstream Care Partner is participating.

3. The Downstream Incentive Payment is calculated using, and distributed in accordance with, the Incentive Payment Methodology set forth in the relevant Approved Track Implementation Protocol and the PGP Care Partner does not retain any portion of the Incentive Payment from the Hospital allocated as a Downstream Incentive Payment to that Downstream Care Partner.
4. The Hospital's distribution of the Incentive Payment to the PGP Care Partner must satisfy the conditions of the Incentive Payment Waiver or otherwise comply with the Federal anti-kickback statute and the Federal physician self-referral law.
5. The PGP Care Partner must maintain documentation of the Downstream Care Partner Arrangement and the payment of any Downstream Incentive Payments; retain such documentation for at least ten (10) years following the last Downstream Incentive Payment; and make such documentation available to the Secretary upon request. All documentation must be created in advance of or contemporaneous with the correlating event (e.g., documentation of payment of the Downstream Incentive Payment must be created in advance of or contemporaneous with the distribution of such payment).
6. The TCOC Participation Agreement does not provide that this Downstream Incentive Payment Waiver is inapplicable.

The waiver period for distributions that meet all of the preceding conditions will start on the date of this Notice and will end one year after the earlier of: (i) the effective date of termination or expiration of the TCOC Participation Agreement; (ii) the effective date of termination or expiration of the Downstream Care Partner Arrangement; (iii) the effective date of termination of the CRP Track pursuant to which the Downstream Incentive Payment is made; (iv) the effective date of the Hospital's termination or withdrawal from the CRP Track pursuant to which the Incentive Payment is made; or (v) the effective date of termination of the Hospital's relevant Approved Track Implementation Protocol.

II. Explanation of Waiver Requirements

The waivers set forth in this Notice have been developed in consultation with the Innovation Center, which is administering and testing the CRP within the Maryland Total Cost of Care Model. The CRP is intended to promote quality of care, care coordination, and cost reduction in the State of Maryland. In accordance with section 1115A(d)(1) of the Act, the Secretary has determined that these waivers are necessary to carry out testing of the CRP within the Maryland Total Cost of Care Model. The objective of the waiver conditions is to ensure that protected arrangements are consistent with the model; are subject to safeguards designed to mitigate the risk of fraud and abuse; and can be readily monitored and audited. In addition to the conditions set forth in these waivers, the TCOC Participation Agreement includes requirements that are designed to promote program integrity and lessen the risk of fraud and abuse within the CRP.

The first and second waivers in this Notice (Incentive Payment Waiver and Intervention Resource Waiver) apply to distributions of Incentive Payments and Intervention Resources by a Hospital. Both waivers require that the Hospital have entered into a Care Partner Arrangement with the Care Partner. Under a Care Partner Arrangement, the Care Partner participates in a CRP Track and may receive Incentive Payments, Intervention Resources, or both from the Hospital in exchange for

performing Allowable CRP Interventions. The third waiver (Downstream Incentive Payment Waiver) protects a particular financial arrangement (Downstream Care Partner Arrangement) between a PGP Care Partner and Downstream Care Partners.

A. Commentary Applicable to Specific Waivers

1. Incentive Payment Waiver

The Incentive Payment Waiver protects certain arrangements for the distribution of Incentive Payments. The intent of the Incentive Payment Waiver is to allow the relevant parties to distribute Incentive Payments without risking sanctions under the Federal anti-kickback statute or the Federal physician self-referral law.

For the purposes of the waivers, the term Incentive Payment has the same meaning as in the TCOC Participation Agreement, where it is defined as “a monetary payment made by the Hospital directly to a Care Partner solely for Allowable CRP Interventions actually performed on a Medicare FFS Beneficiary by the Care Partner during a Performance Period.” Under the TCOC Participation Agreement, as well as for the purposes of the waivers, a CRP Intervention is generally an intervention designed to improve or support one or more of the following: care management and care coordination, population health, access to care, risk stratification, evidence-based care, patient experience, shared decision-making, reduction of medical error rates, or operational efficiency (subject to additional detail as set forth in the TCOC Participation Agreement).

The Incentive Payment Waiver sets forth certain requirements that must be satisfied to qualify for waiver protection. For purposes of this waiver, in selecting its Care Partners, the Hospital must not use any criteria that directly relate to past or anticipated referrals. For the purposes of this condition, “referral” includes referrals by the Care Partner or other business generated by, between, and among the Hospital, Care Partner, and any individual or entity affiliated with the Hospital or Care Partner (including a PGP Member in the case of a PGP Care Partner). Nothing in this waiver is intended to preclude a Hospital from considering a potential Care Partner’s depth (or lack thereof) of professional experience in making a selection, nor from using a selection criterion that considers whether a potential Care Partner (including PGP Members, if applicable) has performed or would perform a reasonable minimum number of Allowable CRP Interventions as necessary to ensure the quality of care furnished by the potential Care Partner (including PGP Members, if applicable). By contrast, this waiver would not protect the distribution of Incentive Payments if, by way of example, the Hospital employed a selection method that used a criterion that directly relates to referrals, such as a requirement that a prospective Care Partner has generated or will generate a specific volume of Medicare referrals for the Hospital.

The waiver further provides that in implementing and performing under the Care Partner Arrangement, neither the Hospital nor the Care Partner can give or receive anything of value in return for or to induce business unrelated to the Allowable CRP Interventions set forth in the Care Partner Arrangement for the relevant CRP Track. In other words, waiver protection is available only for the offer and distribution of Incentive Payments in exchange for Allowable CRP Interventions. No additional arrangements, including arrangements related to business outside the CRP, are protected.

The Incentive Payment Waiver, like the TCOC Participation Agreement, requires the Incentive Payment to be calculated using, and distributed in accordance with, the Incentive Payment Methodology set forth in the relevant Approved Track Implementation Protocol.

In order to satisfy the waiver's documentation requirements, the Hospital and Care Partner must have a written Care Partner Arrangement that specifies at least the following: (1) the Incentive Payment Methodology for each CRP Track in which the Care Partner will participate; and (2) the Allowable CRP Interventions the Care Partner may perform. The Hospital must also maintain documentation of the payment of any Incentive Payments. The Hospital must retain the written Care Partner Arrangement and payment documentation for at least 10 years following the last Incentive Payment and make such documentation available to the Secretary upon request. All documentation must be created in advance of or contemporaneous with the correlating event. For example, the Hospital and Care Partner may document a written Care Partner Arrangement in advance of the parties' performance under such arrangement while the payment of an Incentive Payment may be documented contemporaneous with such payment.

For the purposes of satisfying the Incentive Payment Waiver's documentation obligations, and to minimize the burden on Hospitals, a Hospital will be deemed to meet the requirements of the Incentive Payment Waiver's second and sixth conditions if it meets all of the terms set forth at sections 6.3(a), 6.3(b)(i), (iv), and 6.6(i) of the TCOC Participation Agreement (which relate to documentation).

The Incentive Payment Waiver protects the distribution of Incentive Payments to participating Care Partners, as well as to Downstream Care Partners who receive their share of an Incentive Payment from their physician group practice that is a Care Partner. The downstream shares are referred to in the TCOC Participation Agreement and this Notice as Downstream Incentive Payments. The separate Downstream Incentive Payment Waiver covers the payments from a physician group practice that is a PGP Care Partner to its practice members, employees, or contractors who are Downstream Care Partners. In combination, these two waivers are intended to protect the full distribution of Incentive Payment funds contemplated under the TCOC Participation Agreement, whether by the Hospital or a PGP Care Partner, provided such distributions satisfy all waiver conditions. We note that the Downstream Incentive Payment Waiver requires that the arrangement for the distribution of the Incentive Payment (from the Hospital to the PGP Care Partner) from which the "downstream" payment is derived must satisfy the Incentive Payment Waiver or otherwise comply with the Federal anti-kickback statute and the Federal physician self-referral law.

The waiver period for the distribution of Incentive Payments under a Care Partner Arrangement begins as of the date of this Notice, but all conditions of the waiver must be met in order to trigger its protection. Such protection continues only so long as all criteria for the waiver continue to be met and ends one year after the earliest of the occurrence of one of several events listed in the waiver. The additional year after the occurrence of one of the listed events are intended to allow the parties, where necessary, sufficient time to conduct certain post-participation operations, including the Maryland Health Services Cost Review Commission's Incentive Payment Pool calculation processes and the Hospital's calculation and distribution of Incentive Payments.

2. Intervention Resource Waiver

The Intervention Resource Waiver protects certain arrangements for the distribution of Intervention Resources from a Hospital. The intent of this waiver is to allow the relevant parties flexibility to negotiate and enter into arrangements to distribute Intervention Resources without risking sanctions under the Federal anti-kickback statute or the Federal physician self-referral law.

The Care Partner Arrangement governs the distribution of Intervention Resources. The Innovation Center has set forth certain programmatic requirements in the TCOC Participation Agreement that limit the amount and nature of Intervention Resources that a Hospital may provide pursuant to its Care Partner Arrangements. As to the amount, the TCOC Participation Agreement prohibits the Hospital from expending, in the aggregate, more funding on Intervention Resources than the Intervention Resource Allocation set forth in the Hospital's relevant Approved Track Implementation Protocol, which has been approved by CMS and the State. Similarly, the Hospital must only provide the Intervention Resources specified in this Approved Track Implementation Protocol.

The Intervention Resource Waiver contains conditions related to documentation of the Care Partner Arrangement that must be met to qualify for waiver protection. Under condition 2 of the waiver, the Hospital must have entered into a written Care Partner Arrangement with the Care Partner that specifies the nature and amount of Intervention Resources to be distributed and the Allowable CRP Interventions that may be performed. Under condition 6 of the waiver, the Hospital must maintain documentation of the Care Partner Arrangement and the distribution of the Intervention Resources, retain such documentation for at least 10 years following termination of the Care Partner Arrangement, and make such documentation available to the Secretary upon request. All documentation must be created in advance of or contemporaneous with the correlating event. For the purposes of satisfying the Intervention Resource Waiver's documentation obligations and to minimize burden on a Hospital, the Hospital will be deemed to meet the requirements of the Intervention Resource Waiver's second and sixth conditions if it meets all of the terms set forth at sections 6.3(a), 6.3(b)(i), (iv), and 6.5(h) of the TCOC Participation Agreement (which relate to documentation).

For purposes of this waiver, in selecting its Care Partners, the Hospital must not use any criteria that directly relate to past or anticipated referrals. For the purposes of this condition, "referral" includes referrals by the Care Partner or other business generated by, between, and among the Hospital, Care Partner, and any individual or entity affiliated with the Hospital or Care Partner (including a PGP Member in the case of a PGP Care Partner). Nothing in this waiver is intended to preclude a Hospital from considering a potential Care Partner's depth (or lack thereof) of professional experience in making a selection, nor from using a selection criterion that considers whether a potential Care Partner (including PGP Members, if applicable) has performed or would perform a reasonable minimum number of Allowable CRP Interventions as necessary to ensure the quality of care furnished by the potential Care Partner (including PGP Members, if applicable). By contrast, this waiver would not protect the distribution of Intervention Resources if, by way of example, the Hospital employed a selection method that used a criterion that directly relates to referrals, such as a requirement that a prospective Care Partner has generated or will generate a specific volume of Medicare referrals for the Hospital.

In addition, for waiver purposes, the nature and amount of Intervention Resources must relate to improving or maintaining quality of care for patients; this condition ensures that protection extends only to remuneration in the form of Intervention Resources that further a core patient-centeredness goal of the CRP. This waiver condition is particularly important because the CRP contemplates the potential use of Intervention Resources by a recipient PGP Care Partner's members, employees, and contractors who are not themselves Care Partners or Downstream Care Partners. In applying this condition, a Hospital may take into account: (1) the Care Partner's need to improve the quality of care it furnishes relative to other Care Partners; and (2) the Care Partner's opportunity to perform Allowable CRP Interventions and care management related to Allowable CRP Interventions relative to other Care Partners.

The waiver further provides that in implementing and performing under the Care Partner Arrangement, neither the Hospital nor the Care Partner can give or receive anything of value in return for or to induce business unrelated to the Allowable CRP Interventions contemplated in the Care Partner Arrangement. In other words, waiver protection is available only for the offer and distribution of Intervention Resources in exchange for performing Allowable CRP Interventions. No additional arrangements, including arrangements related to business outside the CRP, are protected.

Any electronic health records software distributed as an Intervention Resource must be interoperable. For purposes of this waiver, the electronic health records software must either be interoperable (as defined in 42 C.F.R. § 411.351) or satisfy the provisions at 42 C.F.R. § 411.357(w)(2) (condition related to interoperability in the physician self-referral law exception for electronic health records) at the time it is provided to the Care Partner.² Arrangements involving the distribution of electronic health records software that has limited or restricted interoperability due to action taken by the Hospital (or by any person on the Hospital's behalf) would fail to satisfy this condition. This Intervention Resource Waiver does not protect distributions of Intervention Resources that result in data and referral lock-in.

The waiver period for the distribution of Intervention Resources under a Care Partner Arrangement begins as of the date of this Notice, but all conditions of the waiver must be met in order to trigger its protection. Such protection continues only so long as all criteria for the waiver continue to be met and ends upon the occurrence of one of several events listed in the waiver. Unlike the Incentive Payment Waiver and the Downstream Incentive Payment Waiver, the waiver period ends immediately upon occurrence of one of the listed events; thus, any continued use of the Intervention Resources by the Care Partner (including PGP Members, if applicable) must comply with the terms of the TCOC Participation Agreement and all relevant fraud and abuse laws and regulations.

3. Downstream Incentive Payment Waiver

The Downstream Incentive Payment Waiver protects the distribution of Downstream Incentive Payments from a PGP Care Partner to a Downstream Care Partner in exchange for the performance of Allowable CRP Interventions. As noted above, the intent of this waiver is to allow the relevant

² 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.

parties to distribute Downstream Incentive Payments without risking sanctions under the Federal anti-kickback statute or the Federal physician self-referral law.

The waiver provides that in implementing and performing under the Downstream Care Partner Arrangement, neither the PGP Care Partner nor the Downstream Care Partner can give or receive anything of value in return for or to induce business unrelated to the Allowable CRP Interventions set forth in the Downstream Care Partner Arrangement. In other words, waiver protection is available only for the offer and distribution of Downstream Incentive Payments in exchange for Allowable CRP Interventions. No additional arrangements, including arrangements related to business outside the CRP, are protected.

The Downstream Incentive Payment Waiver, like the TCOC Participation Agreement, requires the Downstream Incentive Payment to be calculated using, and distributed in accordance with, the Incentive Payment Methodology set forth in the relevant Approved Track Implementation Protocol.

Like the other waivers set forth in this Notice, this waiver requires advance or contemporaneous documentation of the arrangement and payments covered by the waiver as well as the retention of such documentation for 10 years. The Downstream Incentive Payment Waiver applies only if the distribution of the “upstream” Incentive Payment from which the “downstream” payment is derived satisfied all requirements of the Incentive Payment Waiver or otherwise complied with the Federal anti-kickback statute and the Federal physician self-referral law.

Similar to the Incentive Payment Waiver, the waiver period for the distribution of Downstream Incentive Payments under a Downstream Care Partner Arrangement begins as of the date of this Notice, but all conditions of the waiver must be met in order to trigger its protection. Such protection continues only so long as all criteria for the waiver continue to be met and ends one year after the earliest of the occurrence of one of several events listed in the waiver. The additional year are intended to allow the parties, where necessary, sufficient time to conduct certain post-participation operations, including the Maryland Health Services Cost Review Commission’s Incentive Payment Pool calculation processes, the Hospital’s calculation and distribution of Incentive Payments, and the PGP Care Partner’s distribution of Downstream Incentive Payments.

B. General Limitations

- The waivers set forth in Part I of this Notice apply to arrangements that squarely meet all of the conditions pertaining to the particular waiver. 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 entire 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 these waivers. Parties need not apply for an individualized 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 a 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), or 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 TCOC Participation Agreement.
- We reserve the right to reconsider any waiver and, where the public interest requires, to modify or terminate a waiver on a prospective basis with respect to some or all Hospitals, Care Partners, Downstream Care Partners, or PGP Members. The modification, suspension, or termination of part or all of a 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. A condition of each waiver is that the TCOC Participation Agreement has not been amended to provide that the waiver is inapplicable.

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

Dated: [December 13, 2018]

/Seema Verma/

Seema Verma
Administrator
Centers for Medicare & Medicaid Services

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

Dated: [December 14, 2018]

/Daniel R. Levinson/

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