



Centers for Medicare & Medicaid Services
Center for Medicare & Medicaid Innovation
State Innovations Group
7500 Security Blvd. WB-06-05
Baltimore, MD 21244

**Care Redesign Program
Participation Agreement
(Maryland All-Payer Model)**

CARE REDESIGN PROGRAM PARTICIPATION AGREEMENT

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PARTICIPATION AGREEMENT

This Participation Agreement (“**Agreement**”) is between _____ (“**Hospital**”); the Centers for Medicare and Medicaid Services (“**CMS**”); and the Maryland Department of Health (“**MDH**”) and the Maryland Health Services Cost Review Commission (“**HSCRC**”) (collectively, the “**State**” and each a “**State Party**”).

CMS is the federal agency that administers the Medicare, Medicaid, and Children’s Health Insurance Programs.

The State regulates the operation and reimbursement of hospitals in Maryland.

The Hospital is an acute care hospital located in Maryland.

Under section 1115A of the Social Security Act (the “**Act**”), the CMS Center for Medicare and Medicaid Innovation (“**Innovation Center**”) is authorized to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children’s Health Insurance Program expenditures while maintaining or improving the quality of care for Medicare, Medicaid, or Children’s Health Insurance Program beneficiaries. Pursuant to section 1115A of the Act, CMS created the Maryland All-Payer Model to test whether hospital population-based payments accelerate delivery system reform, improve patient-centered care and population health, and reduce or slow the rate of increase in health care costs.

On February 11, 2014, CMS and the State entered into the Maryland All-Payer Model Agreement (“**Model Agreement**”) to implement the Maryland All-Payer Model. The Maryland All-Payer Model establishes performance measures that limit the allowed growth in all-payer hospital revenues, requires savings to the Medicare program of at least \$330 million over five years, and requires Maryland hospital reimbursement models to transition away from fee-for-service reimbursement to global and population-based reimbursement models over the term of the Model Agreement.

Pursuant to the Model Agreement, the HSCRC and the Hospital executed an agreement in 2014 governing the Hospital’s population-based payments for inpatient and outpatient hospital services under the Maryland All-Payer Model, including its Medicare revenues.

On May 1, 2017, CMS and the State subsequently executed the Maryland All-Payer Model First Amendment (“**First Model Amendment**”) to implement the care redesign program. The care redesign program is intended to enable hospitals to incent physicians and other health care providers to engage in care redesign activities that will support state-wide efforts to reduce the growth in total cost of care (“**TCOC**”) for Medicare beneficiaries and facilitate the State’s transformation to a TCOC reimbursement model.

In July 2017, CMS and the State implemented the care redesign program by entering into a participation agreement with each hospital that wished to participate in the program.

On June 19, 2018, CMS and the State executed the Maryland All-Payer Model Second Amendment (“**Second Model Amendment**”) to add the Medicare Performance Adjustment (“**MPA**”), which will support state-wide efforts to reduce the growth in total cost of care (“**TCOC**”) for Medicare beneficiaries and facilitate the State’s transformation to a TCOC reimbursement model. The implementation of the MPA necessitated certain modifications to the care redesign program and the termination of original participation agreements.

The Hospital wishes to participate in the care redesign program as modified by the Second Model Amendment, and the State wishes to further the objectives of the Model Agreement through the implementation of this program.

The parties therefore agree as follows:

ARTICLE I Agreement Term

- 1.1 Effective Date.** The effective date of this Agreement (“**Effective Date**”) will be the date it is signed by the last party to sign it (as indicated by the date associated with that party’s signature).
- 1.2 Term of Agreement.** The term of this Agreement begins on the Effective Date and ends on December 31, 2018, unless sooner terminated in accordance with Article XVI.

ARTICLE II Definitions

“**Allowable CRP Interventions**” means the CRP Interventions set forth in the Hospital’s Approved Track Implementation Protocol.

“**Approved Track Implementation Protocol**” means a Track Implementation Protocol that has been completed by the Hospital and approved by the HSCRC and CMS in accordance with section 3.5.

“**Care Partner**” means a provider or supplier who (1) is enrolled in Medicare; (2) provides items and services to Maryland Medicare Beneficiaries; (3) satisfies any applicable Care Partner Qualifications; (4) is identified on the Care Partner List; and (5) has a written Care Partner Arrangement with the Hospital.

“**Care Partner Arrangement**” means a financial arrangement between the Hospital and a Care Partner pursuant to which the Care Partner participates in a CRP Track and may receive Incentive Payments, Intervention Resources, or both, in exchange for performing Allowable CRP Interventions.

“**Care Partner List**” means the list, as may be updated in accordance with section 5.3, of Care Partners and Downstream Care Partners approved by CMS to participate in the CRP.

“**Care Partner Qualifications**” means additional criteria, as set forth in the relevant Track Implementation Protocol, with which a Care Partner must comply in order to participate in a CRP Track and receive Incentive Payments, Intervention Resources, or both and with

which a Downstream Care Partner must comply in order to participate in a CRP Track and receive Downstream Incentive Payments.

“Change in Control” means a change in ownership or control of the Hospital, including any transaction or series of transactions by which (i) more than 50% of the equity securities, (ii) voting control, (iii) the right to appoint a majority of the governing body, (iv) the right to approve or directly implement the general management, or (v) all or substantially all of the assets of the Hospital are held by different persons or entities immediately after such transaction or series of related transactions than before such transaction or series of related transactions (whether by merger, consolidation, reorganization, combination, sale or transfer of equity securities or otherwise).

“CRP” stands for the “care redesign program” established by CMS and the State pursuant to the Model Agreement.

“CRP Beneficiary” means a Medicare FFS Beneficiary who either resides within the Service Area of the Hospital or receives items or services at the Hospital.

“CRP Calendar” has the meaning set forth in section 3.3.

“CRP Committee” has the meaning set forth in section 3.4.

“CRP Intervention” means an activity or process, available under a CRP Track and set forth in the relevant Track Implementation Protocol, that is designed to improve or support one or more of the following: (1) care management and care coordination; (2) population health; (3) access to care; (4) risk stratification; (5) evidence-based care; (6) patient experience; (7) shared-decision making; (8) the reduction of medical error rates; or (9) operational efficiency.

“CRP Report” means the report the Hospital submits to the HSCRC and CMS, in accordance with Article IX.

“CRP Track” means a care redesign initiative developed by the HSCRC, the MDH, and CMS, and implemented by the Hospital with the assistance of Care Partners.

“Downstream Care Partner” means an individual who is a PGP Member of a PGP Care Partner and who (1) is enrolled in Medicare; (2) provides items and services to Maryland Medicare Beneficiaries; (3) satisfies any applicable Care Partner Qualifications; (4) is identified on the Care Partner List; and (5) has a Downstream Care Partner Arrangement with its PGP Care Partner.

“Downstream Care Partner Arrangement” means a financial arrangement between a PGP Care Partner and a Downstream Care Partner pursuant to which the Downstream Care Partner participates in a CRP Track and receives Downstream Incentive Payments in exchange for performing Allowable CRP Interventions.

“Downstream Incentive Payment” means a monetary payment made by the PGP Care Partner to a Downstream Care Partner solely for Allowable CRP Interventions actually

performed on a Medicare FFS Beneficiary by the Downstream Care Partner during the Performance Period.

“FFS” stands for “fee for service.”

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations as amended from time to time.

“Incentive Payment” means 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 the Performance Period.

“Incentive Payment Methodology” means the methodology, as determined in accordance with the Model Agreement, for calculating Incentive Payments and Downstream Incentive Payments for a CRP Track.

“Incentive Payment Pool” means the aggregate amount of Incentive Payments, as determined by the HSCRC in accordance with Appendix 9 of the Model Agreement, that the Hospital may pay to all of its Care Partners in a CRP Track for the Performance Period.

“Intervention Resource” means nonmonetary remuneration furnished by the Hospital directly to a Care Partner for the purpose of assisting the Care Partner (or, in the case of a Care Partner that is a PGP, its PGP Members) in performing care management and the CRP Interventions for Medicare FFS Beneficiaries.

“Intervention Resource Allocation” means a monetary amount, as determined by the HSCRC in accordance with Appendix 9 of the Model Agreement, and specified in the relevant Approved Track Implementation Protocol that the Hospital may use to fund Intervention Resources during the Performance Period.

“IP Failure” stands for “implementation protocol failure” and means the failure of the Hospital as determined by the HSCRC, to comply with one or more of the Hospital’s Approved Track Implementation Protocols.

“IP Failure Notice” has the meaning set forth in section 15.5.

“Maryland Medicare Beneficiary” means a Medicare FFS Beneficiary who resides within the Service Area of any Regulated Maryland Hospital or receives items and services at a Regulated Maryland Hospital.

“Medicare FFS Beneficiary” means an individual enrolled in Medicare Part A or Part B.

“MPA” stands for “Medicare performance adjustment” and means the percentage by which a Regulated Maryland Hospital’s Medicare FFS payments will be adjusted by CMS in accordance with the Second Model Amendment.

“Medically Necessary” means reasonable and necessary Medicare-covered services for

diagnosing or treating an illness or injury, or for improving the functioning of a malformed body member.

“**NPI**” stands for “national provider identifier.”

“**NPP**” stands for “non-physician practitioner.”

“**PAU**” stands for “potentially avoidable utilization” and means the utilization of health care items and services, including care furnished to treat complications during a hospital admission, which may be unnecessary or is avoidable through improved efficiency, care coordination, or effective community-based care.

“**PAU Savings**” means the Medicare cost savings the Hospital is deemed to have achieved for a CRP Track through the reduction of PAU and other savings that the Hospital achieved as a result of the reduced PAU, as determined by the HSCRC in accordance with section 3.8.

“**Performance Period**” means the period of time when one or more CRP Tracks is in effect. The Performance Period will begin July 1, 2018 and end December 31, 2018.

“**PGP**” stands for “physician group practice.”

“**PGP Care Partner**” means a Care Partner that is a PGP.

“**PGP Member**” or “**Member of the PGP**” means a physician or NPP who is an owner or employee of a PGP or has entered into a contract with a PGP, and who has reassigned to the PGP his or her right to receive Medicare payment.

“**Physician Incentive Payment Cap**” means the maximum amount of Incentive Payments that a Care Partner who is an individual physician or NPP or a Downstream Care Partner may receive during the Performance Period, as calculated in accordance with section 6.6(h).

“**PIP**” stands for “performance improvement plan” and means a plan that the Hospital must implement, as required by the HSCRC or CMS, to address an IP Failure of the Hospital or one of its Care Partners or Downstream Care Partners under an Approved Track Implementation Protocol or this Agreement.

“**Program Integrity Screening**” means a review of an individual’s or entity’s program integrity history, which may include Medicare program exclusions or other sanctions, current or prior law enforcement investigations or administrative actions, affiliations with individuals or entities that have a history of program integrity issues, and other information pertaining to the trustworthiness of the individual or entity, including information obtained from the State.

“**Regulated Maryland Hospital**” means a hospital located in Maryland for which payments are regulated by the State for all payers including Medicare and that is listed in Appendix 1 of the Model Agreement, as updated from time to time.

“**Service Area**” means the geographic area served by the Hospital, as such area is defined pursuant to a written agreement between the Hospital and the HSCRC governing payment for the Hospital’s services.

“**TIN**” stands for “taxpayer identification number” and means the number assigned to an entity or person by the Internal Revenue Service or Social Security Administration.

“**Track Implementation Protocol**” means a form that has been approved by CMS, in accordance with the Model Agreement, that is designed to be completed by the Hospital and to set forth the Hospital’s plan for implementing a CRP Track.

ARTICLE III CRP Requirements

3.1 General. The Hospital is eligible to participate in the CRP only if it is a Regulated Maryland Hospital.

3.2 CRP Tracks. The Hospital shall participate in at least one CRP Track during the Performance Period. The Hospital shall engage one or more Care Partners to perform Allowable CRP Interventions. Failure to participate in at least one CRP Track will result in termination of this Agreement.

3.3 CRP Calendar. CMS shall maintain a calendar setting forth the deadlines for various activities to be conducted by the parties in implementing the CRP (“**CRP Calendar**”). Each party shall comply with the deadlines specified in the CRP Calendar that correspond to its obligations under this Agreement. CMS may update the CRP Calendar without the consent of the Hospital or a State Party.

- (a) The State shall ensure that the CRP Calendar is available to the Hospital electronically at all times.
- (b) The State shall notify the Hospital in writing within 7 days of any changes made to the CRP Calendar.
- (c) CMS shall not update the CRP Calendar in a manner that changes a deadline to a date that is less than 30 days before the effective date of such change.

3.4 CRP Committee

- (a) The Hospital shall establish and maintain a committee to oversee and monitor its implementation of the CRP (“**CRP Committee**”). The Hospital shall require the CRP Committee to comply with all applicable terms of this Agreement.
- (b) During the Performance Period, at least one CRP Committee member must be a Medicare FFS Beneficiary living in the Hospital’s Service Area.
- (c) The CRP Committee shall monitor the Hospital’s implementation of the CRP, in accordance with section 11.2 as applicable, to ensure compliance

with this Agreement and each of the Hospital's Approved Track Implementation Protocols.

- (d) The CRP Committee shall oversee the Hospital's implementation of the CRP by conducting at least the following activities:
 - (i) For each CRP Track in which the Hospital is participating, assisting the Hospital in selecting the Allowable CRP Interventions;
 - (ii) Providing a forum for sharing ideas, identifying problems, and developing solutions between the Hospital and the Hospital's Care Partners and Downstream Care Partners;
 - (iii) Offering the internal leadership to ensure the integrity of and opportunity for success of the CRP and each CRP Track in which the Hospital is participating; and
 - (iv) Conducting a qualitative analysis by the CRP Committee on the status of the Allowable CRP Interventions and offering suggestions to the Hospital on how implementing the Allowable CRP Interventions could be improved.
- (e) The CRP Committee shall report annually to the Hospital's governing body on the status of the implementation of each CRP Track and the Hospital's adherence to and implementation of its compliance program, as described in section 11.2
- (f) Notwithstanding anything to the contrary in this Agreement, the CRP Committee shall not have any role in governing the Hospital or its medical staff, which remain under the control of the Hospital.
- (g) By the deadlines specified in the CRP Calendar and in a form and manner determined by CMS, the Hospital must notify CMS and the State of the initial composition of its CRP Committee and any changes to the composition of its CRP Committee. Upon receiving any such notice, CMS or the State may take one or more of the actions set forth in section 15.4 if CMS or the State determines the change compromises the integrity of the CRP, the Maryland All-Payer Model, the Medicare program or other federal health programs, or the safety of Medicare beneficiaries.

3.5 Submission and Review of Track Implementation Protocols

- (a) The Hospital may participate in a CRP Track only if it has an Approved Track Implementation Protocol for that CRP Track. The Hospital shall implement each CRP Track in accordance with this Agreement and the relevant Approved Track Implementation Protocol.

- (b) By the deadlines specified in the CRP Calendar, the HSCRC shall make a Track Implementation Protocol available to the Hospital for each of the CRP Tracks available for the Performance Period.
- (c) The Hospital shall complete a Track Implementation Protocol for each CRP Track in which it intends to participate during the Performance Period. The Track Implementation Protocol completed by the Hospital must be the Track Implementation Protocol most recently approved by CMS for the CRP Track in accordance with the Model Agreement. When completing a Track Implementation Protocol, the Hospital shall follow all instructions in that document.
- (d) By the deadlines specified in the CRP Calendar, the Hospital shall submit each of its completed Track Implementation Protocols to the HSCRC for review. The Hospital shall promptly submit to the HSCRC any additional information that the HSCRC determines is necessary to complete its review.
- (e) The HSCRC shall review each of the Hospital's completed Track Implementation Protocols for compliance with the terms of the Model Agreement. The HSCRC may approve, reject, or request modifications to a Track Implementation Protocol submitted by the Hospital, and the HSCRC may deny funding, in whole or in part, for one or more Intervention Resources specified in the Hospital's Track Implementation Protocol.
 - (i) If the HSCRC approves a completed Track Implementation Protocol, it shall submit the document to CMS for review by the deadlines specified in the CRP Calendar. The HSCRC shall ensure that the Track Implementation Protocol submitted for CMS review specifies the Hospital's Intervention Resource Allocation and all other required information.
 - (ii) If the HSCRC rejects a completed Track Implementation Protocol, the Hospital will not participate in the relevant CRP Track during the Performance Period.
- (f) CMS shall promptly review each completed Track Implementation Protocol submitted for its review by the HSCRC.
 - (i) If CMS does not reject the Track Implementation Protocol by the deadlines specified in the CRP Calendar, the Track Implementation Protocol is deemed approved by CMS and constitutes an "Approved Track Implementation Protocol," as defined in Article II. The effective date of the Approved Track Implementation Protocol will be the first day of the Performance Period.
 - (ii) If CMS rejects the Track Implementation Protocol, the Hospital will not participate in the relevant CRP Track during the Performance Period. CMS may reject a Track Implementation Protocol that has been approved by the HSCRC only if it determines that:

- (A) The Track Implementation Protocol does not include the PAU Savings Methodology (as defined in Appendix 9 of the Model Agreement), the Incentive Payment Methodology, and the Care Partner Qualifications set forth in the relevant, most recently CMS approved Track Implementation Protocol;
 - (B) The Track Implementation Protocol does not include the Intervention Resource Allocation, if any; or
 - (C) The Track Implementation Protocol compromises the integrity of the CRP Track, the CRP, the Maryland All-Payer Model, the Medicare program, other federal health care programs, or the safety of Medicare beneficiaries.
- (g) The HSCRC shall provide to the Hospital a copy of the Approved Track Implementation Protocol for each CRP Track in which the Hospital will participate during the Performance Period, by the deadlines specified in the CRP Calendar.

3.6 Amendment of Approved Track Implementation Protocols

- (a) If the Hospital wishes to or is required to amend an Approved Track Implementation Protocol effective on a date other than the first day of the Performance Period, it must complete and submit to the HSCRC the Track Implementation Protocol most recently approved by CMS for the CRP Track in accordance with the Model Agreement.
- (b) The HSCRC shall promptly review the completed Track Implementation Protocol. The HSCRC may approve, reject or request modifications to the completed Track Implementation Protocol.
 - (i) If the HSCRC approves the completed Track Implementation Protocol, it shall submit the document to CMS for review. The HSCRC shall ensure that the completed Track Implementation Protocol submitted for CMS review specifies the Hospital's Intervention Resource Allocation, if any, and all other required information.
 - (ii) If the HSCRC rejects the completed Track Implementation Protocol, the Hospital shall continue to implement the CRP Track in accordance with the Approved Track Implementation Protocol that the Hospital sought to amend, unless the HSCRC notifies the Hospital otherwise.
- (c) CMS shall promptly review the completed Track Implementation Protocol submitted for its review by the HSCRC.

- (i) If CMS does not reject the completed Track Implementation Protocol within 30 days after receipt, it is deemed approved by CMS and constitutes an “Approved Track Implementation Protocol.” Such Approved Track Implementation Protocol is effective on the date it is approved or deemed approved unless a different effective date is specified in the document, and the Approved Track Implementation Protocol that was previously in effect ceases to be effective.
- (ii) If CMS rejects the completed Track Implementation Protocol, the Hospital shall continue to implement the CRP Track in accordance with the Approved Track Implementation Protocol that the Hospital sought to amend, unless CMS notifies the Hospital otherwise. CMS may reject the completed Track Implementation Protocol only for the reasons set forth in section 3.5(f)(ii).

3.7 Retention of Track Implementation Protocols. In accordance with section 11.4, the Hospital shall retain the Approved Track Implementation Protocol for each CRP Track in which it is participating. The Hospital shall ensure the CRP Committee has access to all of its Approved Track Implementation Protocols for the full duration of the Performance Period, in order for the CRP Committee to fulfill its responsibilities under this Agreement.

3.8 Incentive Payment Pool and PAU Savings

- (a) The Hospital may make an Incentive Payment for the Performance Period to one or more Care Partners for a CRP Track only if –
 - (i) The HSCRC has determined an Incentive Payment Pool for the CRP Track; and
 - (ii) The Incentive Payment is made pursuant to a Care Partner Arrangement that complies with section 6.6 of this Agreement.
- (b) The HSCRC shall calculate PAU Savings using a methodology that has been approved by CMS in accordance with the Model Agreement, which is set forth in the CRP Hospital’s Approved Track Implementation Protocol.

In a form and manner determined by the HSCRC and by the deadlines specified in the CRP Calendar, the HSCRC shall notify the Hospital of its PAU Savings and Incentive Payment Pool for the relevant CRP Track and Performance Period.

- (c) The Hospital shall not distribute an Incentive Payment to a Care Partner participating in a CRP Track until the HSCRC has notified the Hospital of the relevant Incentive Payment Pool. If the Hospital contests the Incentive Payment Pool in accordance with paragraph (f) of this section 3.8, below, the Hospital shall not distribute any Incentive Payments to any Care Partner

participating in the relevant CRP Track until the Incentive Payment Pool is deemed final in accordance with paragraph (f)(iii) of this section 3.8.

- (d) The Hospital shall not distribute an Incentive Payment to a Care Partner until the Care Partner has reported the number of Allowable CRP Interventions it performed during the Performance Period, or portion thereof, for which the Incentive Payment is calculated.
- (e) For any CRP Track in the Performance Period, the aggregate amount of Incentive Payments distributed by the Hospital must not exceed the Incentive Payment Pool for that CRP Track.
- (f) Contestation of Errors. The Hospital may contest the HSCRC's calculation of PAU Savings and the Incentive Payment Pool in accordance with the following:
 - (i) The Hospital may contest mathematical errors in the calculation of PAU Savings and the Incentive Payment Pool, but the methodology used to determine PAU Savings and the Incentive Payment Pool is not subject to review.
 - (ii) If the Hospital wishes to contest errors in the calculation of PAU Savings or the Incentive Payment Pool, it must provide a written notice of error and supporting documentation to the HSCRC no later than 30 days after the date on which the HSCRC notified the Hospital of the amount of its PAU Savings and Incentive Payment Pool.
 - (iii) If the HSCRC receives a timely notice of error for either or both calculations, the HSCRC shall respond in writing within 30 days to either confirm or reject the notice of error.
 - (A) If the HSCRC confirms the error, the HSCRC shall revise the relevant calculation and notify the Hospital in writing of the revised PAU Savings and Incentive Payment Pool. The revised amounts are deemed final on the date of the HSCRC's written response.
 - (B) If the HSCRC rejects the notice of error, the HSCRC shall notify the Hospital in writing that the relevant calculations are correct and are deemed final on the date of the HSCRC's written response.

3.9 Physician Incentive Payment Cap. The Hospital shall not distribute an Incentive Payment to a PGP Care Partner or to a Care Partner that is a physician or NPP until CMS has notified the Hospital of the Physician Incentive Payment Cap for the relevant Performance Period.

3.10 Interaction with Other Medicare Initiatives. Hospitals, Care Partners, and Downstream Care Partners may participate in other Medicare initiatives, including the Medicare Shared Savings Program, if the terms of such initiatives do not prohibit their participation. However, CMS may amend this Agreement without the consent of the State or the Hospital as may be necessary to avoid duplicative accounting for items and services furnished by a provider or supplier, or any other participant in an existing or future Medicare program, demonstration, or model other than the CRP. CMS shall provide at least 90 days written notice of any such amendment.

3.11 Notice of Certain Events.

- (a) The Hospital shall notify CMS and each State Party within 60 days after discovering that the Hospital or any Care Partner or Downstream Care Partner:
 - (i) Is excluded from participating in a Federal healthcare program, including Medicare;
 - (ii) Has had its Medicare billing privileges revoked; or
 - (iii) Has had its licensure or accreditation status terminated or suspended by a health licensing authority or accrediting organization.
- (b) The Hospital shall notify CMS and each State Party within 60 days after discovering that the Hospital or any Care Partner or Downstream Care Partner is under investigation or action by HHS (including HHS Office of Inspector General and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including without limitation being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the federal government is a party.

3.12 Notice of a Change in Control. The Hospital shall notify CMS and the State in writing in accordance with section 18.1 at least 90 days prior to any proposed Change in Control. After review of such notice, CMS or the State may terminate this Agreement or take one or more actions set forth in section 15.4 to address program integrity vulnerabilities or other concerns regarding the proposed Change in Control. CMS and the State shall use reasonable efforts to review the notice of Change in Control within 30 days.

ARTICLE IV Track Termination and Hospital Withdrawal From a Track

4.1 Track Termination. A CRP Track may be terminated only by CMS or a State Party in accordance with the Model Agreement. If CMS or the State terminates a CRP Track, the terminating party shall provide written notice of termination to each of the other parties. Such notice shall specify the reason for termination of the CRP Track, the effective date of such termination, and if applicable, whether the Hospital will be prohibited after such effective date from distributing Incentive Payments.

No later than 5 business days after the date of such termination notice, the Hospital shall provide written notice of the effective date of such termination to each Care Partner participating in the relevant CRP Track.

4.2 Track Withdrawal. The Hospital may withdraw from a CRP Track only by providing written notice to CMS and each State Party at least 90 days prior to the effective date of withdrawal. Such notice shall specify the reason for withdrawal and the effective date of withdrawal. The Hospital shall provide at least 60 days advance written notice of withdrawal from a CRP Track to each Care Partner participating in the relevant CRP Track.

4.3 Consequences of Track Termination and Withdrawal

- (a) If CMS or a State Party terminates a CRP Track, or if the Hospital withdraws from a CRP Track, and such track is the only CRP Track in which the Hospital is participating, this Agreement will terminate in accordance with section 16.1.b.
- (b) If CMS or a State Party terminates a CRP Track, or the Hospital withdraws from a CRP Track and such track is not the only CRP Track in which the Hospital is participating --
 - (i) The Hospital shall distribute any Incentive Payments owed to a Care Partners for Allowable CRP Interventions performed by the Care Partner prior to the termination or withdrawal, unless CMS or the State prohibits the Hospital from distributing an Incentive Payment to one or more Care Partners;
 - (ii) The Hospital shall not distribute any new Intervention Resources to its Care Partners;
 - (iii) If after the effective date of termination or withdrawal, the Hospital continues to make available any Intervention Resource already distributed to its Care Partners, the Hospital shall charge the Care Partner fair market value for the use of the Intervention Resource as of the effective date of termination or withdrawal.

ARTICLE V Care Partners

5.1 General

- (a) The Hospital shall enter into a Care Partner Arrangement with each Care Partner identified on the Care Partner List. The Hospital shall not enter into a Care Partner Arrangement with any individual who is a PGP Member of a PGP Care Partner.
- (b) The Hospital shall require a PGP Care Partner to have a Downstream Care Partner Arrangement that requires each Downstream Care Partner identified

on the Care Partner List to comply with the applicable terms of this Agreement.

- (c) An individual or entity will be included on the Care Partner List as a Care Partner or Downstream Care Partner only upon the prior written approval of CMS.
- (d) CMS may periodically monitor the program integrity history of the Hospital, Care Partners, and Downstream Care Partners.
- (e) CMS may remove an individual or entity from the Care Partner List pursuant to section 15.1(b). If CMS removes an individual or entity from the Care Partner List, it shall notify the Hospital and each State Party in writing of the effective date of removal.
- (f) The inclusion of an individual or entity on a Care Partner List does not imply or constitute a determination that the Care Partner or Downstream Care Partner has no program integrity issues and does not preclude CMS or any other government authority from enforcing any and all applicable laws, rules and regulations or from initiating or continuing any audit, investigation, evaluation, or inspection of a Care Partner or Downstream Care Partner.

5.2 Care Partner List

- (a) By the deadlines specified in the CRP Calendar, and at such other times as mutually agreed to by the State and CMS, the Hospital must submit to CMS a proposed Care Partner List for the Performance Period. The proposed Care Partner List must identify each proposed Care Partner by name, NPI, billing TIN, and such other information as may be specified by CMS, and must specify each CRP Track in which the proposed Care Partner is expected to participate. If any proposed Care Partner is a PGP, the proposed Care Partner List must identify each proposed Downstream Care Partner by the PGP name, billing TIN of the PGP, and the name and NPI of each proposed Downstream Care Partner who is a PGP Member of that PGP.
- (b) CMS shall conduct a Program Integrity Screening on each individual or entity identified on the proposed Care Partner List. CMS may reject any proposed Care Partner or Downstream Care Partner, or remove an individual or entity identified on the Care Partner List. After reviewing the Program Integrity Screening results, CMS shall submit to the Hospital, by the deadlines specified in the CRP Calendar, an approved Care Partner List identifying the individuals and entities that it has approved to be Care Partners and Downstream Care Partners for the Performance Period.
- (c) The Hospital shall review the CMS approved Care Partner List and make any necessary corrections to it, including the removal of any individuals or entities that are not enrolled in Medicare, do not provide items and services to Maryland Medicare Beneficiaries, do not satisfy the relevant Care Partner

Qualifications, or with whom the Hospital does not yet have a fully executed written Care Partner Arrangement. The Hospital shall not make any additions to this list at this time. The Hospital shall certify that the list (as corrected, if applicable) is a true, accurate, and complete list of all individuals and entities that CMS has approved to be Care Partners or Downstream Care Partners, and that the list identifies all individuals and entities with whom, in the case of Care Partners, the Hospital has a fully executed Care Partner Arrangement.

- (d) The Hospital shall submit the certified Care Partner List to CMS by the deadlines specified in the CRP Calendar and shall update the list in accordance with section 5.3.

5.3 Changes to the Care Partner List

- (a) Additions. Except at such times and in such manner as CMS may permit, the Hospital shall not request the addition of any individual or entity to the Care Partner List or increase the number of CRP Tracks in which a Care Partner participates. Any such requests shall be made in accordance with the procedures set forth in section 5.2, except that CMS need not conduct a Program Integrity Screening in the case of a request to make a late addition to the certified Care Partner List or a request to increase the number of CRP Tracks in which a Care Partner or Downstream Care Partner is participating. For purposes of this paragraph, a request to make a “late addition” to the certified Care Partner List is a request to add an individual or entity that appeared on the CMS approved Care Partner List submitted to the Hospital by CMS pursuant to section 5.2(b) but did not appear on the Care Partner List that was certified by the Hospital pursuant to section 5.2(c). Any late addition to a certified Care Partner List will become effective on the date the request is approved by CMS.
- (b) Removals. In a form and manner specified by CMS, the Hospital shall notify CMS no later than 30 days after an individual or entity has ceased to be a Care Partner or Downstream Care Partner, or ceased participation in one or more CRP Tracks. The Hospital shall include in the notice the date on which the individual or entity ceased to be a Care Partner or Downstream Care Partner, or ceased to participate in one or more CRP Tracks. The removal of the individual or entity from the Care Partner List or from the relevant CRP Track will be effective on the date the individual or entity ceased to be a Care Partner or Downstream Care Partner, or ceased to participate in the relevant CRP Track. For purposes of this Agreement, an individual or entity ceases to be a Care Partner or Downstream Care Partner when they no longer satisfy the definition of “Care Partner” or “Downstream Care Partner” in Article II of this Agreement.
- (c) Effect of Exclusion. If a Care Partner or Downstream Care Partner is excluded from participation in Medicare, Medicaid, or any federal health care program, the Care Partner or Downstream Care Partner is removed

from the Care Partner List effective no later than the effective date of exclusion.

5.4 Care Partner List Access and Retention

- (a) CMS shall maintain all Care Partner Lists in a manner that permits the State and the Hospital to review and access the lists during the term of this Agreement.
- (b) The Hospital shall maintain copies of its current and historical Care Partner Lists in accordance with section 11.4.

ARTICLE VI Care Partner Arrangements

6.1 General

- (a) The Hospital shall not distribute any Incentive Payments or Intervention Resources to an individual or entity other than a Care Partner with whom the Hospital has a fully executed written Care Partner Arrangement.
- (b) The Hospital shall provide all Intervention Resources and make all Incentive Payments in accordance with a Care Partner Arrangement that complies with all of the criteria set forth in this Article VI.
- (c) The Hospital shall ensure that its compliance program includes oversight of its own compliance with its Care Partner Arrangements and its compliance with the terms of this Agreement.
- (d) The requirements of this Article VI survive 120 days after the termination of this Agreement or for such longer period of time as CMS may specify in advance written notice to the Hospital.

6.2 Care Partner Selection Criteria. The Hospital shall develop, maintain, and use written policies for selecting individuals and entities to be Care Partners. The policies must reflect the Care Partner Qualifications, if any, for the CRP Track and must contain criteria related to the quality of care delivered by the potential Care Partner (including PGP Members, if applicable) and must not be based directly on the volume or value of past or anticipated referrals or other business generated by, between, or among the Hospital, potential Care Partner, or any individual or entity affiliated with the Hospital or potential Care Partner (including a PGP Member in the case of a Care Partner that is a PGP).

6.3 Care Partner Arrangement Requirements. The Hospital shall ensure that each Care Partner Arrangement complies with the following criteria:

- (a) The arrangement is in writing, legally binds the parties to comply with the terms of the arrangement, and is in existence before Allowable CRP Interventions are performed by the Care Partner.
- (b) The arrangement specifies the following:

- (i) Each CRP Track in which the Care Partner will participate and the Allowable CRP Interventions, as set forth in the relevant Approved Track Implementation Protocol, that the Care Partner may perform;
 - (ii) The Care Partner Qualifications;
 - (iii) The mechanism through which the Care Partner must report to the Hospital the number of Allowable CRP Interventions it has performed (or, in the case of a PGP Care Partner, its Downstream Care Partners have performed) and the frequency of such reporting; and
 - (iv) The financial or economic terms of the Care Partner Arrangement for each CRP Track in which the Care Partner is participating, including the frequency and Incentive Payment Methodology for Incentive Payments and the nature and amount of Intervention Resources.
- (c) The arrangement complies with all relevant laws and regulations, including all applicable fraud and abuse laws and all applicable payment and coverage requirements.
 - (d) The arrangement requires the Care Partner and its employees and contractors, if any, to comply with the applicable terms of this Agreement (including requirements regarding PIPs, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS, the State, or their designees) and all other applicable laws and regulations, including fraud and abuse laws. The Hospital shall provide a copy of this Agreement and the Hospital's relevant Approved Track Implementation Protocols to each Care Partner.
 - (e) The arrangement requires the Care Partner to use a Certified Electronic Health Record Technology to create a summary record of care formatted according the standard adopted at 45 CFR 170.205(a)(3) that includes, where applicable, the Common Clinical Data Set as defined by 45 CFR 170.102. The arrangement shall also require the Care Partner to electronically transmit such summary to a state-designated health information exchange in more than 10 percent of the instances when the Care Partner transitions or refers a patient to another setting of care.
 - (f) The arrangement requires the Care Partners to comply with the requirements set forth in Article VIII, except that references to "Hospital" are replaced with "Care Partner."
 - (g) The arrangement requires the Care Partner to be in compliance with all Medicare provider enrollment requirements at 42 CFR 424.500 et seq., including having a valid and active TIN, NPI, or other identifier and reporting all changes to enrollment information to CMS consistent with 42 CFR 424.516.

- (h) The arrangement requires the Care Partner to use, as defined by the implementing regulations at 42 CFR 412 and 42 CFR 495, a state-designated health information exchange.
- (i) The individual's or entity's participation as a Care Partner in the relevant CRP Track must be voluntary and without penalty for nonparticipation.
- (j) The arrangement does not induce the Hospital or a Care Partner to reduce or limit Medically Necessary services to any Medicare beneficiary.
- (k) The arrangement complies with the requirements set forth in sections 6.5 and 6.6, regarding Incentive Payment and Intervention Resource requirements and section 6.4, regarding PGP Care Partners, if applicable.
- (l) The arrangement requires the Hospital to comply with the notification requirements in sections 4.1, 4.2, and 16.5(b) and to provide prompt written notice to the Care Partner of the effective date of termination of the Hospital's relevant Approved Track Implementation Protocol.

6.4 Additional Care Partner Arrangement Requirements for PGP Care Partners.

If the Care Partner is a PGP Care Partner, the Hospital shall ensure the Care Partner Arrangement complies with the following additional criteria:

- (a) The arrangement prohibits the PGP Care Partner from distributing a Downstream Incentive Payment to an individual or entity other than a Downstream Care Partner with whom the PGP Care Partner has a Downstream Care Partner Arrangement.
- (b) The arrangement requires the PGP Care Partner to distribute all Downstream Incentive Payments in accordance with a Downstream Care Partner Arrangement that complies with all of the criteria set forth in Article VII.
- (c) The arrangement requires the PGP Care Partner to maintain records of the information specified in section 7.3(f) in accordance with section 11.4.
- (d) The arrangement requires the PGP Care Partner to terminate any Downstream Care Partner Arrangement pursuant to remedial action imposed by CMS or a State Party under section 15.1.
- (e) The arrangement prohibits or suspends the PGP Care Partner's ability to distribute a Downstream Incentive Payment to a Downstream Care Partner pursuant to remedial action imposed by CMS or a State Party under section 15.1 and requires the Hospital to recalculate Incentive Payments to account for any Downstream Incentive Payments that were improperly distributed during such a prohibition or suspension.
- (f) The arrangement requires the PGP Care Partner to have a Downstream Care Partner Arrangement with each Downstream Care Partner that complies

with Article VII and requires the Downstream Care Partner to comply with Article VIII, except that references to “Hospital” are replaced with “Downstream Care Partner.”

6.5 Intervention Resource Requirements

- (a) If the Hospital provides Intervention Resources, it shall provide Intervention Resources only to an individual or entity that is identified on the Care Partner List for the relevant CRP Track during the Performance Period except that the Hospital shall not provide Intervention Resources to a Care Partner that is a PGP Member.
- (b) The Hospital shall provide only the Intervention Resources specified in the Hospital’s relevant Approved Track Implementation Protocol.
- (c) For the Performance Period and for each CRP Track in which the Hospital is participating, the Hospital shall not provide an Intervention Resource to any Care Partner unless the Hospital’s relevant Approved Track Implementation Protocol sets forth an Intervention Resource Allocation.
- (d) For the Performance Period and for each CRP Track in which the Hospital is participating, the Hospital shall not expend, in the aggregate, more funding on Intervention Resources than the Intervention Resource Allocation set forth in the Hospital’s relevant Approved Track Implementation Protocol.
- (e) Neither the Hospital nor the Care Partner may condition the opportunity to provide or receive Intervention Resources on the volume or value of referrals or business otherwise generated by, between, or among the Hospital, the Care Partner, or any individual or entity affiliated with the Hospital or Care Partner (including a PGP Member in the case of a Care Partner that is a PGP).
- (f) The amount and nature of Intervention Resources provided to a Care Partner must be determined in a manner substantially based on criteria related to quality of care and the performance of Allowable CRP Interventions. The Hospital may take into account –
 - (i) The Care Partner’s need to improve the quality of care it furnishes relative to other Care Partners; and
 - (ii) The Care Partner’s opportunity to perform Allowable CRP Interventions and care management related to Allowable CRP Interventions, relative to other Care Partners.
- (g) The Hospital shall require the Care Partner to use Intervention Resources to perform Allowable CRP Interventions and care management related to Allowable CRP Interventions.

- (h) The Hospital shall maintain records of the following in accordance with section 11.4:
 - (i) The identity of each Care Partner to whom an Intervention Resource was provided;
 - (ii) The date the Intervention Resource was provided, and
 - (A) The date the Hospital ceased to provide the Intervention Resource;
 - (B) The date, if any, on which the Hospital retrieved the Intervention Resource from the Care Partner; and
 - (C) The documentation establishing whether the Care Partner paid for use of Intervention Resources after the effective date of the Hospital's withdrawal from the relevant CRP Track, or the effective date of termination of the Care Partner Arrangement, the relevant CRP Track, or this Agreement;
 - (iii) The nature of the Intervention Resource furnished to each Care Partner; and
 - (iv) The amount actually spent by the Hospital to fund the Intervention Resource; and
 - (v) The CRP Track for which the Intervention Resource was provided.
- (i) The Hospital shall require the Care Partner to maintain records of the information specified in section 6.5(h)(ii), (iii), and (v).

6.6 Incentive Payment Requirements

- (a) To be eligible to receive an Incentive Payment, a Care Partner that is not a PGP Care Partner must:
 - (i) Be identified on the Hospital's Care Partner List for the relevant CRP Track during the Performance Period; and
 - (ii) Have performed at least one Allowable CRP Intervention for the relevant CRP Track during the Performance Period or portion thereof.
- (b) The Hospital may pay a PGP Care Partner an Incentive Payment only if:
 - (i) The PGP Care Partner is identified on the Hospital's Care Partner List for the relevant CRP Track during the Performance Period;
 - (ii) The Incentive Payment is for Allowable CRP Interventions actually performed by the PGP Care Partner or its Downstream Care

Partners, as applicable, during the Performance Period or portion thereof;

- (iii) The Hospital designates the portion of each Incentive Payment that the PGP Care Partner must pay, as a Downstream Incentive Payment, to each Downstream Care Partner; and
 - (iv) The Hospital shall prohibit a PGP Care Partner from retaining any portion of an Incentive Payment that is allocated as a Downstream Incentive Payment to one of its Downstream Care Partners.
- (c) For the Performance Period and for each CRP Track in which the Hospital is participating, the Hospital shall not distribute an Incentive Payment to any Care Partner, unless the Hospital satisfies the PAU Savings and Incentive Payment Pool requirements set forth in section 3.8.
 - (d) For the Performance Period or portion thereof, and for each CRP Track in which the Hospital is participating, an Incentive Payment distributed by the Hospital to a Care Partner must be calculated using the Incentive Payment Methodology set forth in the relevant Approved Track Implementation Protocol.
 - (e) For the Performance Period and for each CRP Track in which the Hospital is participating, the sum of all Incentive Payments distributed by the Hospital to its Care Partners must not exceed the Incentive Payment Pool for that CRP Track, as calculated by the HSCRC, in accordance with section 3.8(b).
 - (f) If the Care Partner is a physician or NPP, the total amount of Incentive Payments distributed to the Care Partner for the Performance Period must not exceed the Physician Incentive Payment Cap. The Physician Incentive Payment Cap is twenty-five percent (25%) of the Average Care Partner PFS Expenditures for the preceding calendar year. The Average Care Partner PFS Expenditures are calculated by CMS by dividing A by B and multiplying the result by .25, where “A” equals the sum of all Medicare PFS payments made during the preceding calendar year for Part B covered services to all of the Hospital’s Downstream Care Partners and Care Partners who are physicians or NPPs, and “B” equals the total number of the Hospital’s Downstream Care Partners and Care Partners who are physicians or NPPs during the Performance Period. For example, if a Hospital has three Care Partners, and the three Care Partners had PFS expenditures the previous year totaling \$100, \$200, and \$300, respectively, then the maximum Physician Incentive Payment for each Care Partner in the Performance Period would be \$50 $((100 + 200 + 300) \div 3 \times .25)$. CMS shall notify the Hospital of the Physician Incentive Payment Cap for the Performance Period by the deadline specified in the CRP Calendar.

- (g) Neither the Hospital nor a Care Partner may condition the opportunity to provide or receive Incentive Payments on the volume or value of referrals or business otherwise generated by, between, or among the Hospital, a Care Partner, a Downstream Care Partner, or any individual or entity affiliated with the Hospital, Care Partner (including a PGP Member), or Downstream Care Partner.
- (h) All Incentive Payments must be made by check, electronic funds transfer, or another traceable cash transaction.
- (i) The Hospital shall maintain records of the following in accordance with section 11.4:
 - (i) The identity of each Care Partner to whom an Incentive Payment was made;
 - (ii) The date the Incentive Payment was made;
 - (iii) The amount of the Incentive Payment made to each Care Partner;
 - (iv) In the case of a PGP Care Partner, the portion of each Incentive Payment designated to be paid to a Downstream Care Partner as a Downstream Incentive Payment; and
 - (v) The CRP Track and Performance Period (or portion thereof) for which the Incentive Payment was calculated.
- (j) The Hospital shall require the Care Partner to maintain records of the information specified in section 6.6(k)(ii)-(v).

ARTICLE VII Downstream Care Partner Arrangements

- 7.1 General.** The requirements of this Article VII survive 150 days after the termination of this Agreement or for such longer period of time as CMS may specify in advance written notice to the Hospital.
- 7.2 Downstream Care Partner Arrangement Requirements.** The Downstream Care Partner Arrangement must comply with the following criteria:
- (a) The arrangement is in writing, legally binds the parties to comply with the terms of the arrangement, and is in existence before Allowable CRP Interventions are performed by the Downstream Care Partner.
 - (b) The arrangement specifies the following:
 - (i) Each CRP Track in which the Downstream Care Partner will participate and the Allowable CRP Interventions, as set forth in the relevant Approved Track Implementation Protocol, that the Downstream Care Partner may perform;

- (ii) The Downstream Care Partner's obligation to report to the PGP Care Partner the number of Allowable CRP Interventions it has performed; and
 - (iii) The financial or economic terms of the Downstream Care Partner Arrangement for each CRP Track in which the Downstream Care Partner is participating, including the frequency and Incentive Payment Methodology for Downstream Incentive Payments.
- (c) The arrangement complies with all relevant laws and regulations, including all applicable fraud and abuse laws and all applicable payment and coverage requirements.
- (d) The arrangement requires the Downstream Care Partner to comply with the applicable terms of this Agreement (including requirements regarding PIPs, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS, the State, or their designees) and all other applicable laws and regulations, including fraud and abuse laws. The Hospital shall require the PGP Care Partner to provide a copy of this Agreement and the Hospital's relevant Approved Track Implementation Protocols to each Downstream Care Partner.
- (e) The arrangement requires the Downstream Care Partner to comply with Article VIII, except that references to "Hospital" are replaced with "Downstream Care Partner."
- (f) The arrangement requires the Downstream Care Partner to be in compliance with all Medicare provider enrollment requirements at 42 CFR 424.400 et seq., including having a valid and active TIN, NPI, or other identifier and reporting all changes to enrollment information to CMS consistent with 42 CFR 424.516.
- (g) The arrangement requires the Downstream Care Partner to use a Certified Electronic Health Record Technology to create a summary record of care formatted according to the standard adopted at 45 CFR 170.205(a)(3) that includes, where applicable, the Common Clinical Data Set as defined by 45 CFR 170.102. The arrangement shall also require the Downstream Care Partner to electronically transmit such summary to a state-designated health information exchange in more than 10 percent of the instances when the Care Partner transitions or refers a patient to another setting of care.
- (h) The Downstream Care Partner's participation in the relevant CRP Track must be voluntary and without penalty for nonparticipation.
- (i) The arrangement does not induce the Hospital or a Care Partner to reduce or limit Medically Necessary services to any Medicare beneficiary.

- (j) The arrangement complies with the requirements set forth in section 7.3 regarding Downstream Incentive Payment requirements.

7.3 Downstream Incentive Payment Requirements.

- (a) To be eligible to receive a Downstream Incentive Payment, the Downstream Care Partner must:
 - (i) Be identified on the Hospital's Care Partner List for the relevant CRP Track during the Performance Period; and
 - (ii) Have performed at least one Allowable CRP Intervention for the relevant CRP Track during the Performance Period.
- (b) The total amount of Downstream Incentive Payments distributed to a Downstream Care Partner for the Performance Period must not exceed the Physician Incentive Payment Cap.
- (c) Neither the PGP Care Partner nor a Downstream Care Partner may condition the opportunity to make or receive Downstream Incentive Payments on the volume or value of referrals or business otherwise generated by, between, or among the Hospital, the PGP Care Partner, the Downstream Care Partner, or any individual or entity affiliated with the Hospital, the PGP Care Partner (including other PGP Members of the PGP Care Partner), or the Downstream Care Partner.
- (d) All Downstream Incentive Payments must be made by check, electronic funds transfer, or another traceable cash transaction.
- (e) The amount of Downstream Incentive Payments designated by the Hospital to be provided to each Downstream Care Partner must be included in the Hospital's CRP Report and reported to CMS and the HSCRC in accordance with Article IX.
- (f) The PGP Care Partner shall maintain records of the following in accordance with section 11.4 of this Agreement:
 - (i) Documentation on a current and historical basis of the identity of its Downstream Care Partners;
 - (ii) The identity of each Downstream Care Partner to whom a Downstream Incentive Payment was made;
 - (iii) The date(s) the Downstream Incentive Payment was made;
 - (iv) The amount of the Downstream Incentive Payment(s) made to each Downstream Care Partner; and
 - (v) The CRP Track and Performance Period (or portion thereof) for which the Downstream Incentive Payment was calculated.

ARTICLE VIII Beneficiary Protections

8.1 Availability of Services

- (a) The Hospital shall make Medically Necessary services available to Maryland Medicare Beneficiaries in accordance with applicable laws, regulations and guidance. Maryland Medicare Beneficiaries and their assignees retain the right to appeal claims determinations in accordance with 42 CFR part 405.
- (b) The Hospital shall not take any action to avoid treating “at risk beneficiaries” (as defined at 42 CFR 425.20) or to target certain beneficiaries for any reason that could compromise the integrity of the CRP, the Maryland All-Payer Model, the Medicare Program or other federal health programs, or the safety of Medicare beneficiaries.
- (c) The Hospital shall not take any action to reduce or limit medically necessary services for Medicare beneficiaries.

8.2 Beneficiary Choice. Consistent with section 1802(a) of the Act, the Hospital shall not commit any act or omission, nor adopt any policy, that inhibits Maryland Medicare Beneficiaries from exercising their freedom to obtain health services from providers and suppliers who are not the Hospital or any of its Care Partners or Downstream Care Partners, or any individual or entity affiliated with the Hospital, any of its Care Partners or Downstream Care Partners. This prohibition shall not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangements with the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if a Maryland Medicare Beneficiary expresses a preference for a different provider or supplier, or the referral is not in the Maryland Medicare Beneficiary's best medical interests in the judgment of the referring party.

ARTICLE IX Reporting Obligations

9.1 CRP Report. The Hospital shall submit the CRP Report to the HSCRC and CMS so that the HSCRC and CMS can determine the Hospital's compliance with the relevant Approved Track Implementation Protocol.

- (a) The Hospital shall submit CRP Reports to the HSCRC and CMS, in a form and manner specified by CMS and by the deadlines specified in the CRP Calendar.
- (b) The CRP Report must include the following information:
 - (i) If applicable, the type and total amount of Intervention Resources provided to each Care Partner for each CRP Track in which it is participating and the amount actually spent by the Hospital to fund

such Intervention Resources, in comparison to the Hospital's Intervention Resource Allocation;

- (ii) The total number of Allowable CRP Interventions performed by each Care Partner and Downstream Care Partner for each CRP Track in which the Hospital is participating;
 - (iii) If applicable, the total amount of Incentive Payments made to each Care Partner for each CRP Track in which the Hospital is participating and for which Incentive Payments may be made at that time, and in the case of a PGP Care Partner, the portions of each Incentive Payment that the Hospital designated pursuant to section 6.6(b)(iii) for distribution as Downstream Incentive Payments;
 - (iv) A summary from the CRP Committee of its monitoring of the Hospital's compliance with this Agreement and each of its Approved Track Implementation Protocols;
 - (v) A qualitative analysis, completed by the CRP Committee, on the status of the Allowable CRP Interventions under each CRP Track in which the Hospital is participating and suggestions from the CRP Committee on how implementing the Allowable CRP Interventions could be improved;
 - (vi) Each IP Failure identified by the State and the status of such IP Failure;
 - (vii) Any PIP or other remedial action taken by CMS or the State and the status of such PIP or action; and
 - (viii) Any obligations on the Hospital, imposed by a Corrective Action Plan issued by CMS under the Model Agreement, and the status of such obligations.
- (c) Upon submission of each CRP Report, the Hospital shall certify the following:
- (i) That the CRP Report is true, accurate and complete; and
 - (ii) That if the Hospital learns that a submitted CRP Report is not true, accurate, or complete, it will promptly submit a revised CRP Report.
- (d) The CRP Report must adhere to the Generally Accepted Accounting Principles and Generally Accepted Government Auditing Standards (the Yellow Book).
- (e) The HSCRC shall review the Hospital's CRP Report in accordance with section 11.3 of this Agreement and the Model Agreement.

- (f) The requirements of this Article IX survive 135 days after the termination of this Agreement, or for such longer period of time as CMS may specify in advance written notice to the Hospital.

ARTICLE X Data Sharing and Reports

10.1 General

- (a) Subject to the limitations discussed in this Agreement, the Hospital's ability to make the assertions provided in Appendix 2 ("Hospital HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet"), and applicable law, CMS will offer the Hospitals an opportunity to request certain individually identifiable data and reports, which are described in Appendix 2 of this Agreement.
- (b) Subject to the limitations discussed in this Agreement, the HSCRC's ability to make the assertions provided in Appendix 3 ("HSCRC HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet"), and applicable law, CMS will offer the HSCRC an opportunity to request certain individually identifiable data and reports, which are described in Appendix 3 of this Agreement.
- (c) Any individually identifiable data and reports that CMS provides to Hospitals and the HSCRC under the preceding paragraphs will omit individually identifiable data for Maryland Medicare Beneficiaries who have opted out of data sharing with the Hospital and the HSCRC, as described in section 10.5 of this Agreement. Furthermore, such data and reports will also omit substance use disorder data for any Maryland Medicare Beneficiaries who have not opted into substance use disorder data sharing, as described in section 10.6 of this Agreement.

10.2 Provision of Certain Data to Hospitals

- (a) CMS believes that the care coordination and quality improvement work of the Hospital and any covered entity ("CE") Care Partners that may seek data from the Hospital because they also treat the Hospital's Maryland Medicare beneficiaries, would benefit from the receipt of certain beneficiary-identifiable claims data. As such, CMS is offering the Hospital the opportunity to request certain claims data on the Maryland Medicare Beneficiaries that have been aligned to the Hospital under the Maryland All-Payer Model, when those individuals are in a treatment relationship with the Hospital. Hospitals that receive such data will be permitted to share such data with their Care Partners in accordance with the terms and conditions of this Agreement and applicable law. Where appropriate, Hospitals may use the Hospital HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet (Appendix 2) to request such data. All such requests will be granted or denied at CMS' sole discretion

based on CMS' available resources, the terms and conditions in this Agreement, and applicable law.

- (b) In offering Appendix 2 as a means for eligible hospitals to request beneficiary-identifiable claims data, CMS does not represent that the Hospital is eligible to make the assertions contained in that document. The assertions in that document are intended to frame the data request as a "health care operations" disclosure under 45 CFR 164.506(c)(4)). The Hospital should consult with its own counsel to confirm its eligibility to make those assertions prior to using Appendix 2 to request data from CMS.
- (c) The beneficiary-identifiable claims data that may be requested using Appendix 2 is described in Appendix 2.
- (d) The parties mutually agree that, except for data covered by section 10.2.(n) below, CMS retains all ownership rights to the data files referred to in Appendix 2, and the Hospital does not obtain any right, title, or interest in any of the data furnished by CMS.
- (e) The Hospital represents, and in furnishing any data files requested in Appendix 2 CMS will have acted in reliance upon such representation, that any data files requested using Appendix 2 will be requested solely for the purposes described in Appendix 2. Furthermore, the Hospital affirms that it will not disclose, use or reuse any of the requested data or any individually identifiable derivative data except as specified in this Agreement, or as CMS may authorize in writing outside of this Agreement, or as required by law. Regardless of what may be permitted by this Agreement or authorized by CMS in writing outside of this Agreement, the Hospital acknowledges that it may only disclose, use and reuse such data in accordance with applicable law, and it further acknowledges that it may not rely on CMS to advise it of such laws. Notwithstanding any other provision in this Agreement, the Hospital further agrees not to sell, rent, or lease data covered by this Agreement without the express written authorization of the subject of such data, and agrees to contractually bind all downstream data recipients to this limitation.
- (f) The Hospital is expected to use the requested data in its efforts to deliver seamless, coordinated care for Maryland Medicare Beneficiaries with whom they have a treatment relationship. CMS believes that such use will promote better care, better health, and lower growth in expenditures. Information derived from the CMS data files specified in Appendix 2 may be used within the legal confines of the Hospital. Such data may also be disclosed to Care Partners in accordance with this Agreement or any writing outside of this Agreement in accordance with applicable law if Hospital contractually binds the Care Partner to limiting its own use and disclosures to the terms and conditions imposed on the Hospital under this Agreement, especially section 10.2. Hospital may also permit Care Partners to further disclose data to additional covered entity or business associate downstream

entities if those downstream entities are contractually bound to these same terms and conditions by the entity providing data to such downstream entities.

- (g) Notwithstanding any other provision of this Agreement, but only in accordance with applicable law, the Hospital may reuse and further disclose original or derivative data received under this Agreement in accordance with applicable law without prior authorization from CMS if such use or disclosure is to enable the provision of clinical treatment, care management and coordination, to enable quality improvement activities, or to design or effectuate provider incentives under the model. Any reuse or disclosure described in this paragraph is further limited to activities that do not result in the disclosure of individually identifiable original or derived information from the data files specified in Appendix 2 to anyone who is not a HIPAA CE or business associate (BA) of a HIPAA CE in a treatment relationship with the subject Maryland Medicare Beneficiary(ies). Furthermore, when using or disclosing protected health information (PHI) or personally identifiable information (PII) obtained from data files specified in Appendix 2, the Hospital must make “reasonable efforts to limit” the information to the “minimum necessary” to accomplish the intended purpose of the use, disclosure or request. The Hospital shall further limit its use and disclosure of such information to the types of disclosures that CMS itself would be permitted to make under the “routine uses” in the applicable systems of records listed in Appendix 2.
- (h) Subject to the limits specified above and elsewhere in this Agreement and applicable law, the Hospital may link individually-identifiable information specified in Appendix 2 (including directly or indirectly identifiable data) or derivative data to other sources of individually-identifiable health information, such as other medical records available to the Hospital. The Hospital may disseminate data obtained through the linking of the data specified in Appendix 2 to other sources of individually identifiable health information if such resulting data has been de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b).
- (i) The Hospital agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the CMS data requested in Appendix 2, and to prevent unauthorized use or disclosure of such data or any individually identifiable derivative data files. The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix I-Responsibilities for Protecting and Managing Federal Information Resources (https://www.whitehouse.gov/omb/circulars_default) as well as Federal Information Processing Standard 200 entitled “Minimum Security Requirements for Federal Information and Information Systems” (<http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>);

and, NIST Special Publication 800-53 “Recommended Security Controls for Federal Information Systems” (nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf).

The Hospital acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Appendix 2 or any such derivative data files is strictly prohibited. Further, the Hospital agrees that the data specified in Appendix 2 must not be physically moved, transmitted or disclosed in any way from or by the site of the custodian indicated in Appendix 2 other than as provided in this Agreement without written approval from CMS, unless such movement, transmission or disclosure is required by a law.

- (j) The Hospital agrees to grant access to the data and/or the facility(ies) in which the data is maintained to the authorized designees of CMS or Health and Human Services (HHS) Office of Inspector General, including at the site of the custodian indicated in Appendix 2, for the purpose of inspecting to confirm compliance with the terms of this Agreement, and to contractually bind downstream data recipients to the same requirements as a condition of receiving such data.
- (k) The Hospital agrees that any publication or dissemination of purportedly “de-identified” data that is derived from the CMS data listed in Appendix 2 must adhere to CMS’ current cell size suppression policy. This policy stipulates that no cell (e.g., admittances, discharges, patients, services) representing 10 or fewer beneficiaries may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer beneficiaries.
- (l) The Hospital agrees to report any breach or potential breach of personal health information (PHI) or personally identifiable information (PII) from or derived from the CMS data files, loss of these data or improper use or disclosure of such data to the CMS Action Desk by telephone at (410) 786-2850 or by email notification at cms_it_service_desk@cms.hhs.gov within one hour of discovery. Furthermore, the Hospital agrees to cooperate fully in any federal incident security process that results from such improper use or disclosure, and to contractually bind downstream data recipients to the same requirements as a condition of receiving such data.
- (m) The Parties mutually agree that the individual named in Appendix 2 is designated as custodian of the CMS data files on behalf of the Hospital and will be responsible for the observance of all conditions of use and disclosure of such data and any derivative data files, and for the establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use or disclosure. The Hospital agrees to notify CMS within 15 days of any change of custodianship. The Parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

- (n) Data disclosed to the Hospital pursuant to Appendix 2 may be retained by the Hospital until the termination of this Agreement. If Hospital elects to share data with its Care Partner under section 10.2, the Hospital may permit retention until the recipients' termination as a Care Partner. The Hospital is permitted to retain any individually identifiable health information from such data files or derivative data files after the termination of this Agreement if the Hospital is a HIPAA CE, and the data has been incorporated into the subject beneficiaries' medical records that are part of a designated record set under HIPAA. Furthermore, any HIPAA CE or BA to whom the Hospital provides such data in the course of carrying out the CRP may also retain such data if the recipient entity is a HIPAA CE or BA and the data is incorporated into the subject beneficiaries' medical records that are part of a designated record set under HIPAA. The Hospital shall destroy all other data, and ensure all other downstream entities' destruction of their copies of the data, and send written certification of the destruction of their and applicable downstream entities' data files and/or any derivative data files to CMS within 30 days following the termination of the Agreement, or, in the case of a Care Partner, the Care Partners' participation in the CRP. These retention and destruction provisions survive termination of this Agreement.

10.3 Provision of Certain Data to the HSCRC

- (a) Based on HSCRC's assertions, CMS understands that the health oversight work of the HSCRC (that is acting on its own behalf as a HIPAA "health oversight agency" pursuant to 45 CFR 164.501) would benefit from the receipt of certain beneficiary-identifiable claims data on Maryland Medicare Beneficiaries. Specifically, CMS understands that HSCRC's receipt of this data will allow it to conduct benchmark and ongoing analysis that will be key aspects of the HSCRC's oversight of the health care system in Maryland, including the Hospital's participation in the Maryland All Payer Model. CMS accepts the HSCRC's assertion that the requested data in [their request] would qualify as a health oversight disclosure under 45 CFR 164.512(d). As such, CMS will offer the HSCRC an opportunity to request certain data and reports about care delivered in Maryland.
- (b) If it meets HSCRC's needs, the HSCRC may use Appendix 3 (the HIPAA-Oversight Disclosure Request Attestation and Data Specification Worksheet) to request such data. All requests for beneficiary-identifiable claims data will be granted or denied at CMS' sole discretion based on CMS' available resources, the limitations in this Agreement, and applicable law. CMS does not represent that the HSCRC is eligible to make the assertions contained in Appendix 3, but notes that Appendix 1 contains assertions from the HSCRC that would lead CMS to believe that it has concluded with the assistance of its counsel that it can do so. If used, CMS will rely upon the assertions in Appendix 3 as the basis for providing data to the HSCRC under 45 CFR 164.512(d)(1).

- (c) The HSCRC is expected to use the requested data in its efforts to monitor and oversee Maryland's health care system as it pertains to the Maryland All-Payer Model. Notwithstanding any other provision of this Agreement, and in accordance with applicable law, the HSCRC may reuse original or derivative data received under this Agreement without prior authorization from CMS if such disclosure is to enable its oversight of the Maryland All-Payer Model, or to enable quality improvement activities, or provider incentive implementation by a Hospital with a treatment relationship to the subject(s). Furthermore, notwithstanding any other provision, the HSCRC may use the data received under this agreement to create patient deidentified data as that term is understood under the regulations implementing the HIPAA statute, as modified, that may be provided to a Hospital.

10.4 De-Identified Reports. CMS will provide the following reports to the Hospital, which will be de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b):

- (a) Monthly Financial Reports. These reports will include monthly and year-to-date information on total Medicare expenditures and expenditures for selected categories of services for Maryland Medicare Beneficiaries. This aggregate information will not include individually identifiable health information and will incorporate de-identified data from Maryland Medicare Beneficiaries who have opted out of data sharing.
- (b) Quarterly Benchmark Reports. CMS will provide quarterly benchmark reports to the Hospital to monitor the Hospital's financial performance throughout the year. The benchmark reports will not contain individually identifiable data.

10.5 Beneficiary Right to Opt Out of Data Sharing

- (a) A Maryland Medicare Beneficiary may express a preference to opt out of the claims data sharing described above via 1-800-MEDICARE. CMS shall exclude such a beneficiary from such data sharing.
- (b) CMS will maintain the data sharing preferences of Maryland Medicare Beneficiaries who elect to decline data sharing in this CRP.
- (c) The Hospital may affirmatively contact a Maryland Medicare Beneficiary who has elected to decline claims data sharing no more than one time in the Performance Period to provide information regarding data sharing. Such contact includes mailings, phone calls, electronic communications, or other methods of communicating with Maryland Medicare Beneficiaries outside of a clinical setting.
- (d) Notwithstanding the foregoing, a Hospital shall receive claims data regarding substance use disorder treatment only if the Maryland Medicare

Beneficiary has not elected to decline data sharing or otherwise been opted out of data sharing and has also submitted a CMS approved form pursuant to section 10.6 of this Agreement.

- (e) CMS will administratively opt a Maryland Medicare Beneficiary back into such claims data sharing if they were administratively opted out of data sharing solely due to the termination of a Hospital. That is, if he or she is in a treatment relationship with the Hospital, unless the Maryland Medicare Beneficiary affirmatively opts out of data sharing according to this section 10.5.

10.6 Beneficiary Substance Use Disorder Data Opt In

- (a) The Hospital may inform each Maryland Medicare Beneficiary, in compliance with applicable law:
 - (i) That he or she may elect to allow the Hospital to receive beneficiary-identifiable data regarding his or her utilization of or treatment for substance use disorder;
 - (ii) Of the mechanism by which the Maryland Medicare Beneficiary can make this election; and
 - (iii) That 1-800-MEDICARE will answer any questions regarding data sharing of substance use disorder.
- (b) A Maryland Medicare Beneficiary may opt in to substance use disorder data sharing under this model by submitting a CMS approved substance use disorder opt in form to the Hospital. The Hospital shall promptly send the opt in form to CMS.

10.7 Certification of Data and Information

- (a) With respect to data and information that are generated or submitted by the Hospital to CMS, the Hospital shall ensure that an individual with the authority to legally bind the Hospital, the individual or entity submitting such data for or on behalf of the Hospital or Downstream User certifies the accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge, information, and belief.
- (b) At the end of the Performance Period, an individual with the legal authority to bind the Hospital must certify to the best of his or her knowledge, information, and belief—
 - (i) That the Hospital is in compliance with CRP requirements; and
 - (ii) That the data and information that are generated or submitted by the Hospital are true, accurate, and complete.

ARTICLE XI Compliance and Monitoring

11.1 Compliance with Law

- (a) The Hospital shall comply with all applicable statutes, regulations, and guidance, including without limitation, federal criminal laws, the federal False Claims Act (31 U.S.C. § 3729 et seq.), the federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)), the federal civil monetary penalties law (42 U.S.C. § 1320a-7a), the federal physician self-referral law (42 U.S.C. § 1395nn), and applicable State laws, as enforced by the State.
- (b) This Agreement does not provide any waivers of laws, and the Hospital, all Care Partners, and all Downstream Care Partners must comply with all applicable laws and regulations, except as explicitly provided in any separate waiver that may be granted pursuant to section 1115A(d)(1) of the Act specifically for the Maryland All-Payer Model and the CRP. Waivers granted under section 1115A(d)(1) may be amended or revoked at any time for any reason without the consent of the State or the Hospital.

11.2 Hospital Compliance and Monitoring Plan

- (a) The Hospital shall have a compliance program that addresses the prevention, detection, and correction of fraud and abuse and noncompliance with this Agreement. The Hospital shall update its compliance program as may be needed as a result of changes in applicable statutes and regulations, and the terms of this Agreement. The Hospital may modify, use and share its existing compliance programs or the compliance programs of its Care Partners to meet the requirements of this section.
- (b) The Hospital shall conduct monitoring activities to ensure that the implementation of the CRP, any of its Approved Track Implementation Protocols, any of its Care Partner Arrangements, complies with this Agreement.

11.3 CMS and State Monitoring Activities

- (a) CMS and the State shall conduct monitoring activities to assess compliance by the Hospital, its Care Partners, and Downstream Care Partners with this Agreement.
- (b) CMS and the State shall conduct monitoring activities to identify evidence of unintended consequences. Such monitoring activities may include without limitation:
 - (i) Examining trends and patterns in the settings of care where beneficiaries receive care;
 - (ii) Examining utilization rates; and
 - (iii) Analyzing resources expended on patient care and cost efficiency.

- (c) The Hospital shall cooperate with, and shall require its CRP Committee, its Care Partners, and its Downstream Care Partners to cooperate with, all State and CMS monitoring requests and activities.
- (d) If the State determines, as a result of its monitoring activities or through other means, that the Hospital has failed to comply with the terms of this Agreement, it shall promptly notify CMS and the other State Party in writing in accordance with section 15.3(a).

11.4 Audits and Record Retention. The Hospital shall comply with, and shall require all of its Care Partners to comply with, the following obligations:

- (a) To give the State and federal government (including CMS, HHS, and the Comptroller General) or their designees, access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Maryland All-Payer Model or CRP, including the Hospital's compliance with this Agreement; the quality of services furnished under the Maryland All-Payer Model; the calculation, administration, allocation, and distribution of any Intervention Resources, Incentive Payments, or Downstream Incentive Payments; Approved Track Implementation Protocols, Care Partner Arrangements, or Downstream Care Partner Arrangements.
- (b) To maintain such books, contracts, records, documents, and other evidence for a period of 10 years after the expiration or termination of this Agreement, or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:
 - (i) The State or CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Hospital at least 30 days before the normal disposition date; or
 - (ii) There has been a termination, dispute, or allegation of fraud or similar fault against the Hospital, its Care Partners, or its Downstream Care Partners, in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

11.5 Reservation of Rights

- (a) Nothing contained in this Agreement shall be construed as:
 - (i) Limiting the authority of the HHS Office of Inspector General or any other federal or state government authority to audit, evaluate, investigate, or inspect the Hospital, its Care Partners, or its Downstream Care Partners;

- (ii) Limiting the right of the federal government to obtain relief under any federal statutes or regulations for noncompliance with the terms of this Agreement or any other provision of law; or
 - (iii) A waiver by CMS, the HHS Office of Inspector General, or any other federal government authority of any right to institute any proceeding or action against the Hospital, any of its Care Partners, or any of its Downstream Care Partners, for violations of any statutes, rules or regulations administered by the federal government.
- (b) This Agreement shall not be construed to bind any federal government agency, except CMS.
- (c) The failure by CMS or the State to require performance of any provision of this Agreement shall not affect CMS's or the State's right to require performance at any time thereafter, nor shall a waiver of any breach or default of this Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

ARTICLE XII Training and Shared Learning Activities

- 12.1 Training Sessions.** The Hospital will make reasonable efforts to participate in CMS-sponsored training sessions related to the implementation and requirements of the CRP. CMS will, wherever possible, offer trainings in virtual or telephonic format, including recorded sessions, and will offer the Hospital access to archived training materials to the extent feasible.
- 12.2 Shared Learning Activities.** The Hospital will make reasonable efforts to regularly participate in CMS-sponsored learning activities designed to strengthen results and share learning that emerges from participation in the CRP. Such learning activities may include periodic conference calls, site visits, virtual or in-person meetings, and other activities by which participants actively share resources, tools, and ideas.

ARTICLE XIII Evaluation

- 13.1 General.** The Hospital shall participate in an independent evaluation conducted by CMS and/or its designees, aimed at assessing the impact of the CRP on the goals of better health, better health care, and lower Medicare per capita costs for Maryland Medicare Beneficiaries. Evaluation activities will include data collection before the Hospital begins participating in the CRP. CMS or its designees shall, to the extent practicable, provide the Hospital with no less than 30 days advance notice of any site visits for purposes of evaluation, learning, and documenting best practices.
- (a) Primary Data. In its evaluation activities, CMS or its designee(s) may collect qualitative and quantitative data from data sources that may include, but are not limited to:

- (i) Site visits with the Hospital;
 - (ii) Interviews or focus groups with Maryland Medicare Beneficiaries and their caregivers;
 - (iii) Interviews or focus groups with the Hospital, its Care Partners, and its Downstream Care Partners;
 - (iv) Direct observation of patient interactions with the Hospital's and Care Partners' staff; and
 - (v) Surveys.
- (b) Secondary Data. In its evaluation activities, CMS or its designee(s) may use data or information submitted by the Hospital for quality and monitoring purposes as well as claims submitted by practitioners, providers and suppliers to CMS for items and services furnished to Maryland Medicare Beneficiaries. These data may include, but are not limited to:
- (i) Claims data;
 - (ii) Survey data;
 - (iii) Medical records including clinical data such as lab values; and
 - (iv) Quality and clinical data submitted via the Hospital's CRP Report.
- (c) Reporting Requirements. CMS may add or modify evaluation-related reporting requirements during the term of this Agreement. CMS will notify the Hospital of any additions or modifications at least 90 days prior to when such additions and modifications will take effect.

ARTICLE XIV Site Visits

- 14.1 Planned Visits.** Except as provided in section 14.2 and 14.3 below, CMS, the State or their designee(s) shall, to the extent practicable, provide the Hospital with no less than 15 days advance notice of a site visit to be conducted as part of compliance and monitoring activities, shared learning activities, or evaluation activities. To the extent practicable, CMS and the State will attempt to accommodate the Hospital's request for particular dates in scheduling site visits, but the Hospital shall not request a date that is more than 30 days after the date of the initial site visit notice from CMS or the State.
- 14.2 Right to Visit.** CMS, the State, or their designee(s) may perform unannounced site visits at any office or physical location of the Hospital or its Care Partners at any time to investigate concerns about the health or safety of Medicare beneficiaries, or other program integrity issues.
- 14.3 Authority to Visit.** Nothing in this Agreement limits the authority of CMS or the State to conduct a site visit permitted by applicable law or regulations.

ARTICLE XV Remedial Action

15.1 Grounds for Remedial Action Against the Hospital.

- (a) CMS or a State Party may impose one or more of the remedial actions described in Section 15.4(a) against the Hospital if CMS makes a determination, including a determination pursuant to section 15.3, that the Hospital:
 - (i) Has an IP Failure, or has otherwise failed to comply with any provision of this Agreement, one or more of its Approved Track Implementation Protocols, one or more Care Partner Arrangements, one or more Downstream Care Partner Arrangements, any requirement under the Maryland All-Payer Model, or any applicable Medicare program requirement, rule or regulation;
 - (ii) Has failed to demonstrate improved performance following any remedial action, including a PIP, or has failed to address an IP Failure by the deadlines specified in a PIP;
 - (iii) Has taken any action that threatens the health or safety of a beneficiary or other patient;
 - (iv) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the CRP, the Maryland All-Payer Model, or any requirement of the Medicare Program;
 - (v) Is subject to sanctions or other actions of an accrediting organization or a federal, state or local government agency, including revocation of Medicare billing privileges, Medicare or Medicaid program exclusion, or debarment;
 - (vi) Except as specified in section 18.6, assign, or purport to assign, any of the rights or obligations under this Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS; or
 - (vii) Has past or present program integrity issues.
- (b) CMS may impose one or more of the remedial actions described in section 15.4(b) against the Hospital if CMS makes a determination, including a determination pursuant to section 15.3, that a Care Partner or Downstream Care Partner:
 - (i) Has taken any action that threatens the health or safety of a beneficiary or other patient;

- (ii) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the CRP, the Maryland All-Payer Model, or any requirement of the Medicare Program;
- (iii) Is subject to sanctions or other actions of an accrediting organization or a federal, state or local government agency, including revocation of Medicare billing privileges, Medicare or Medicaid program exclusion, or debarment; or
- (iv) Has any past or present program integrity issues.

15.2 Grounds for Remedial Action Against the State. CMS may impose remedial action against a State Party for noncompliance with this Agreement, in accordance with the Model Agreement.

15.3 Remedial Action Procedure

- (a) If a State Party determines, as a result of its monitoring activities or through other means, that grounds for remedial action against the Hospital exist, it shall promptly notify CMS and the other State Party in writing. Such notice shall specify the grounds for remedial action, the relevant facts, whether it recommends that any remedial action should be imposed, and if applicable, the type of remedial action that should be imposed. CMS shall promptly review the notice and determine the appropriate response. CMS shall promptly inform the State of its determination in writing and shall specify the party or parties to this Agreement that will be responsible for imposing and monitoring the remedial action.
- (b) If CMS has not received a notice under paragraph (a) of this section 15.3, and it determines both that grounds for remedial action against the Hospital exist and that remedial action should be imposed, it shall promptly notify each State Party in writing. Such notice shall specify the grounds for remedial action, the relevant facts, the plan for remedial action, and the party or parties to this Agreement that will be responsible for imposing and monitoring the remedial action.

15.4 Types of Remedial Action

- (a) If CMS determines that remedial action is warranted pursuant to sections 3.4(g), 3.12, or 15.1(a), one or more of the actions set forth in the following paragraphs (i) – (xii) may be taken by CMS or a State Party, and CMS may take either or both of the actions set forth in the following paragraphs (xiii) and (xiv).
 - (i) Notify the Hospital and, if appropriate, its Care Partner and its Downstream Care Partners, of the violation;

- (ii) Require the Hospital to provide additional information to CMS, the State or their designees;
 - (iii) Conduct on-site visits, interview the Hospital's and Care Partner's personnel and staff, or interview beneficiaries and patients to gather information;
 - (iv) Subject the Hospital to additional monitoring, auditing, or both;
 - (v) Remove one or more individuals or entities from the Hospital's Care Partner List;
 - (vi) Require the Hospital to terminate one or more of its Care Partner Arrangements;
 - (vii) Prohibit or suspend the Hospital's distribution of Incentive Payments or Intervention Resources to any of its Care Partners;
 - (viii) Require the Hospital to recalculate an Incentive Payment based on a prohibition or suspension of a PGP Care Partner's distribution of a Downstream Incentive Payment to any of its Downstream Care Partners;
 - (ix) Require the Hospital to amend one or more of its Approved Track Implementation Protocols;
 - (x) Terminate the Hospital's participation in one or more CRP Tracks;
 - (xi) Require the Hospital to enter into a PIP, in accordance with section 15.6;
 - (xii) Require the Hospital to comply with any applicable requirements under a Corrective Action Plan that CMS imposes upon the State, under the terms of the Model Agreement;
 - (xiii) Amend this Agreement without the consent of the Hospital to limit or deny the applicability of any or all waivers of existing law made pursuant to section 1115A(d)(1) of the Act; or
 - (xiv) Discontinue the provision of data sharing and reports to the Hospital, under section 10.2.
- (b) If CMS determines that remedial action is warranted pursuant to section 15.1(b), CMS may take one or more of the following actions:
- (i) Remove the Care Partner or Downstream Care Partner from the Hospital's Care Partner List;
 - (ii) Require the Hospital to terminate its Care Partner Arrangements with the Care Partner;

- (iii) If the Care Partner remains on the Care Partner List, prohibit or suspend the Hospital's distribution of Incentive Payments or Intervention Resources to that Care Partner; or
- (iv) Require the Hospital to recalculate an Incentive Payment based on a prohibition or suspension of a PGP Care Partner's distribution of a Downstream Incentive Payment to the Downstream Care Partner.

15.5 IP Failure. If the HSCRC, after consultation with the Hospital, determines the Hospital has caused or suffered an IP Failure, the HSCRC must provide written notice (an "**IP Failure Notice**") to the Hospital and CMS. The IP Failure Notice must identify and explain how the Hospital failed to comply with the relevant Approved Track Implementation Protocol and may require the Hospital to –

- (a) Implement a PIP, in accordance with section 15.6; or
- (b) Amend one or more Approved Track Implementation Protocols in accordance with section 3.6. If the HSCRC rejects the amended Approved Track Implementation Protocol in accordance with section 3.6(b)(ii), the HSCRC may require the Hospital to implement a PIP.

15.6 Performance Improvement Plans

- (a) If the Hospital is required to implement a PIP, the Hospital must, as instructed by CMS or the HSCRC, either:
 - (i) Submit to CMS or the HSCRC, as applicable, a proposed PIP for review by a deadline specified by CMS or the HSCRC as applicable; or
 - (ii) Cooperate with CMS or the HSCRC, as applicable, in developing a PIP.
- (b) The PIP must outline the actions the Hospital will take within a specified time period to ensure that the IP Failure will be corrected and that the Hospital will come into and remain in compliance with this Agreement and all relevant Approved Track Implementation Protocols.
- (c) If applicable, the HSCRC will promptly review the proposed PIP. If the HSCRC determines the proposed PIP will adequately address the IP Failure, the HSCRC will submit the PIP to CMS for review.
- (d) CMS will promptly review the proposed PIP and will provide revisions to the proposed PIP, if any, to the HSCRC within 30 days of receipt. The HSCRC will incorporate CMS' revisions, if any, into the proposed PIP and will provide the Hospital with the final PIP it must implement.
- (e) If the HSCRC or CMS determines the proposed PIP will not address the IP Failure, the HSCRC or CMS may terminate the Hospital's Approved Track Implementation Protocols for the relevant CRP Track(s) and, upon written

notice to the Hospital, the HSCRC or CMS may terminate any of the Hospital's other Approved Track Implementation Protocols, or this Agreement, in accordance with section 16.3. If, as a result of terminating one or more Approved Track Implementation Protocols, the Hospital is no longer participating in a CRP Track, this Agreement will terminate in accordance with section 16.1(b).

- (f) If the Hospital does not comply with the PIP within the specified timeframe, CMS or the HSCRC may take one or more of the actions set forth in section 15.4.
- (g) The Hospital must ensure that all Care Partners and Downstream Care Partners comply with the terms of the PIP, if applicable.
- (h) The Hospital shall not distribute any Incentive Payments or distribute any new Intervention Resources after the receipt of an IP Failure Notice until:
 - (i) The Hospital has implemented the PIP or the amended Approved Track Implementation Protocol, as required by the State; and
 - (ii) The State has provided the Hospital with written notice that the IP Failure is resolved and that the Hospital may distribute Incentive Payments or new Intervention Resources to its Care Partners.

ARTICLE XVI Termination

16.1 Automatic Termination

- (a) This Agreement will terminate upon the effective date of termination of the following:
 - (i) The Model Agreement; or
 - (ii) The CRP pursuant to the Model Agreement.
- (b) If the State updates and removes the Hospital from Appendix 1 of the Model Agreement, this Agreement will terminate upon the effective date of such removal.
- (c) If the Hospital is participating in only one CRP Track, this Agreement terminates upon the effective date of the Hospital's withdrawal from the CRP Track or CMS' or the State's termination of the CRP Track or termination of the Hospital's participation in the CRP Track.

16.2 Termination by the Hospital. The Hospital may terminate this Agreement for any reason by providing written notice to CMS and each State Party at least 90 days prior to the effective date of termination.

16.3 Termination by CMS.

- (a) Except as set forth in paragraph (b) of this section, CMS may immediately or with advance notice terminate this Agreement if CMS determines that any of the grounds for remedial action set forth in sections 15.1 or 15.2 continue to exist after remedial action has been taken.
- (b) CMS may immediately or with advance notice terminate this Agreement if the Hospital –
 - (i) Is subject to investigation or action by HHS (including HHS Office of Inspector General and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the federal government; or
 - (ii) Has past or present program integrity issues.

16.4 Termination by the State

- (a) A State Party must obtain prior written consent from CMS to any termination of this Agreement for the Hospital's failure to comply with the terms of this Agreement. If a State Party so wishes to terminate this Agreement, it shall provide written notice to CMS specifying the grounds for termination, the proposed effective date of termination, whether the other State Party consents to the termination, and if applicable, the reasons why the other State Party does not consent to the termination. CMS shall promptly review the notice and either approve or reject the proposed termination.
- (b) The State may terminate this Agreement if either State Party notifies CMS in writing at least 90 days before the effective date.

16.5 Notice of Termination

- (a) To Parties. A party that terminates this Agreement pursuant to sections 16.2, 16.3, or 16.4 must provide written notice of termination to each of the other parties. Such notice shall specify the reason for termination, the effective date of such termination, and if applicable, whether the Hospital will be prohibited after such effective date from distributing Incentive Payments.
- (b) To Care Partners. The Hospital must provide written notice of termination to each of its Care Partners upon either receiving a notice of termination from the State or CMS, or providing a notice of termination to the State and CMS. Such notice shall specify the effective date of such termination and if applicable, whether the Hospital is prohibited after such effective date from distributing Incentive Payments.

16.6 Consequences of Termination

- (a) The Hospital shall distribute any Incentive Payments owed to a Care Partner for Allowable CRP Interventions performed by the Care Partner prior to the effective date of termination of this Agreement, unless this Agreement is terminated pursuant to sections 16.3 or 16.4(a) and CMS or the State prohibits the Hospital from distributing an Incentive Payment to one or more Care Partners.
- (b) The Hospital shall not distribute any new Intervention Resources to its Care Partners after issuing or receiving notice of termination of this Agreement.
- (c) If after the effective date of termination, the Hospital continues to make available any Intervention Resource already distributed to its Care Partners, the Hospital shall charge the Care Partner fair market value for the use of the Intervention Resource after the effective date of termination.

ARTICLE XVII Limitations on Review and Dispute Resolution

17.1 Limitations on Review. Notwithstanding any other provision of this Agreement, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

- (a) The selection of models for testing or expansion under section 1115A of the Act;
- (b) The selection of organizations, sites, or participants to test the selected models, including the decision by CMS to terminate this Agreement, or to require the Hospital to terminate any Care Partner Arrangement or Downstream Care Partner Arrangement;
- (c) The elements, parameters, scope, and duration of such models for testing or dissemination, including the addition or removal of a CRP Track and the methodologies used to calculate PAU Savings, and the Incentive Payment Pool;
- (d) Determinations regarding budget neutrality under subsection 1115A(b)(3) of the Act;
- (e) The termination or modification of the design and implementation of a model under subsection 1115A(b)(3)(B) of the Act; or
- (f) Decisions about expansion of the duration and scope of a model under subsection 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

17.2 Dispute Resolution Process. The State will consider disputes by the Hospital that are not precluded from review (“**Permitted Dispute**”), as determined by CMS, including determinations made in accordance with section 3.8(f). The State will only consider a dispute of PAU Savings and Incentive Payment Pool calculations

if it has received a timely notice of error as specified in section 3.8(f). The Hospital must copy CMS on any such Permitted Dispute correspondence and send to CMS at the address listed in section 18.1. If the State and the Hospital are unable to resolve a Permitted Dispute to mutual satisfaction, the Permitted Dispute will be subject to the following dispute resolution process, which process is limited solely to Permitted Disputes:

- (a) The Hospital must submit a request for reconsideration to a designee of CMS (“**Reconsideration Official**”) who is authorized to receive such requests and did not participate in the determination that is the subject of the reconsideration request. The request must contain a detailed, written explanation of the basis for the dispute, including supporting documentation. The request must be made within 30 days after the date of the determination for which reconsideration is being requested, and it must be submitted by email to CMS at the address specified in section 18.1 or such other address as may be specified by CMS. Requests that do not meet these requirements will be denied by the reconsideration official.
- (b) The reconsideration request must contain a detailed, written explanation of the basis for the Permitted Dispute, including supporting documentation sufficient for CMS to evaluate the dispute.
- (c) The Hospital must submit the reconsideration request within 30 days of the date of its receipt of the calculation related to the Permitted Dispute, via email to CMS at the address specified in section 18.1 or such other address as may be specified in writing by CMS.
- (d) Within 15 days of receiving a reconsideration request satisfying the requirements under paragraph (b) of this section 17.2, the Reconsideration Official will send to the Hospital, CMS and the State a written acknowledgement of receipt of the Reconsideration Request, which must set forth:
 - (i) The procedures under which the Reconsideration Official will review the reconsideration request (the “**Reconsideration Review**”), consistent with the procedures outlined in this section 17.2; and
 - (ii) A briefing schedule that permits each party to submit only one written brief, including any evidence, for consideration by the Reconsideration Official in support of the party’s position. The submission of any additional briefs or supplemental evidence will be at the sole discretion of the Reconsideration Official.
- (e) The Reconsideration Review will consist of a review of documentation that is submitted timely and in accordance with the procedures described in the Reconsideration Official’s acknowledgment under paragraph (d) of this section 17.2.

- (f) The burden of proof is on the Hospital to demonstrate with clear and convincing evidence that the calculation is inconsistent with the terms of this Agreement and any Approved Track Implementation Protocol.
- (g) The Reconsideration Official will base its final determination (the “**Reconsideration Determination**”) only upon:
 - (i) Position papers and supporting documentation that are timely submitted to the Reconsideration Official in accordance with the procedures described in the Reconsideration Official’s acknowledgment under paragraph (d) of this section 17.2; and
 - (ii) Documents and data that the State or its designee considered prior to making the calculation related to the Permitted Dispute.
- (h) The Reconsideration Determination is not subject to review under the terms of this Agreement.
- (i) The Reconsideration Official will send its written Reconsideration Determination to CMS, the State and the Hospital within 60 days of receipt of timely filed position papers and supporting documentation.
- (j) The Reconsideration Determination is final and binding.
- (k) The Reconsideration Review process under this Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by government agencies, including HSCRC determinations made in accordance with its agreement with the Hospital.

ARTICLE XVIII Miscellaneous

18.1 Notifications and Communications Unless otherwise stated in writing after the Effective Date, all notifications and information required under this Agreement shall be submitted to the parties at the addresses set forth below:

If to CMS:

**Maryland All-Payer Model
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop: WB-06-05
Baltimore, MD 21244
Email: marylandmodel@cms.hhs.gov**

If to the State:

**Health Services Cost Review Commission
Care Redesign Program**

**4160 Patterson Avenue
Baltimore, MD 21215**

Email: hsrcrc.care-redesign@maryland.gov

If to Hospital:

Email: _____

18.2 Notice of Bankruptcy. In the event the Hospital enters into proceedings relating to bankruptcy, whether voluntary or involuntary, the Hospital shall furnish, by certified mail, written notification of the bankruptcy to CMS and the local U.S. Attorney Office. The Hospital shall furnish the notice within five days after the initiation of the proceedings relating to bankruptcy filing. The notice must include the date of the bankruptcy filing and the identity of the court in which the bankruptcy petition was filed. This obligation remains in effect until this Agreement has terminated and all administrative and judicial review proceedings relating to any payments under this Agreement have been fully and finally resolved.

18.3 Severability. If any provision of this Agreement is held to be unenforceable:

- (a) The provision will be modified to the minimum extent necessary to make it enforceable, unless that modification is not permitted by law, in which case that provision will be disregarded;
- (b) The rest of this Agreement will remain in effect as written; and
- (c) Any unenforceable provision will remain as written in any circumstances other than those in which the provision is held to be unenforceable.

18.4 Entire Agreement; Amendment. This Agreement, including all appendices, constitutes the entire agreement between the parties. The parties may amend this Agreement or any appendix hereto at any time by mutual written agreement; provided, however, that CMS may unilaterally amend this Agreement or any appendix hereto, as specified in this Agreement, or for good cause or as necessary to comply with applicable federal or state law, regulatory requirements, accreditation standards or licensing guidelines or rules. To the extent practicable, CMS shall provide the Hospital and the State with at least 30 days advance written notice of any such unilateral amendment, which notice will specify the amendment's effective date.

18.5 Survival. Termination of this Agreement by any party will not affect the rights and obligations of the parties accrued prior to the effective date of the termination of this Agreement, except as provided in this Agreement. The data privacy and security requirements articulated in this Agreement survive for the duration that CMS data remains in the possession of a Care Partner, the Hospital, or any entities with which the Hospital shared such data.

18.6 Prohibition on Assignment; Change in Control

- (a) Except in accordance with prior written consent of CMS, the Hospital shall not assign or transfer, including by merger (whether the Hospital is the surviving or disappearing entity), consolidation, dissolution, or otherwise:
 - (i) Any discretion granted it under this Agreement;
 - (ii) Any right that it has to satisfy a condition under this Agreement;
 - (iii) Any remedy that it has under this Agreement; or
 - (iv) Any obligation imposed on it under this Agreement.
- (b) The Hospital shall request prior written consent from CMS at least 90 days in advance of any proposed assignment or transfer. This obligation remains in effect until the termination of this Agreement and final payment under this Agreement has been made and all administrative and judicial review proceedings relating to any payments under this Agreement have been fully and finally resolved. CMS may condition its consent to such transfer on the Hospital's immediate payment of all amounts owed to CMS under this Agreement. Any purported transfer in violation of this section is void.

18.7 Execution in Counterpart. If the parties sign this Agreement and any amendments to it in counterparts, each counterpart will be deemed to be an original, but all counterparts taken together will constitute one instrument. If any signature is delivered by email or a “.pdf” data file, such signature will create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such “.pdf” signature page were an original.

[Signature Page Follows]

Each party is signing this Agreement on the date stated next to that party's signature. If a party signs but fails to date a signature, the date that the other parties receive the signing party's signature will be deemed the date that the signing party signed this Agreement.

HOSPITAL

Date: _____ By: _____

Name of Authorized Signatory

Title

CENTERS FOR MEDICARE & MEDICAID SERVICES

Date: _____

By: _____

Adam Boehler, Director, Center for Medicare and Medicaid Innovation

MARYLAND DEPARTMENT OF HEALTH

Date: _____

By: _____

Robert Neall, Secretary

HEALTH SERVICES COST REVIEW COMMISSION

Date: _____

By: _____

Nelson Sabatini, Chair