



Centers for Medicare & Medicaid Services

Center for Medicare & Medicaid Innovation

Prevention and Population Health Group

2810 Lord Baltimore Drive, Suite 130

Baltimore, MD 21244



Emergency Triage, Treat, and Transport Model

Participation Agreement

Last Updated: September 30, 2020

# **Table of Contents**

PARTICIP	ATION AGREEMENT	1
Article I.	Agreement Term; Model Performance Period; Performance Years	1
1.1	Effective Date	1
1.2	Agreement Term	1
1.3	Model Performance Period	2
Article II.	Definitions	2
Article III	. Participant Requirements	6
3.1	General Requirements	6
3.2	Participant Changes	7
3.3	State and Local Requirements	7
3.4	Non-Duplication of Participation	8
Article IV	ET3 Partners	8
4.1	General Requirements	8
4.2	ET3 List	9
4.3	ET3 Partner Arrangement	12
4.4	Notification of Termination and Other Changes	15
4.5	Limitations	15
Article V.	Implementation of ET3 Model Interventions	16
5.1	Implementation Plan	16
5.2	Payer Strategy	19
5.3	Access Plan	19
5.4	Transport to Covered Destinations	20
5.5	Clinical Protocols	20
Article VI	. ET3 Model Interventions	20
6.1	General	20
6.2	Transport to an Alternative Destination Intervention	21
6.3	Optional Treatment in Place Intervention	22
Article VI	I. Payment to Participant	24
7.1	General	24
7.2	Payment for Transport to an Alternative Destination	25
7.3	Payment for Initiation and Facilitation of Treatment in Place	26

Performance-Based Payments	27
II. Payment to ET3 Partners or their Billing Parties	28
Payment to Qualified Health Care Partners and their Billing Parties for Covered Services ned as part of a Treatment in Place Intervention	28
Payment to Alternative Destination Partners or their Billing Parties for Covered Services and after Transport to an Alternative Destination	29
Payment to CMS	29
Payment in Error	29
Medicare Payment Waivers	30
General	30
Transport to an Alternative Destination	30
In-Person Treatment in Place	30
Telehealth Treatment in Place	30
Beneficiary Protections	30
Beneficiary Notifications	30
Availability of Services	31
Beneficiary Freedom of Choice	31
Prohibition of Promotion and Inducements	31
Beneficiary Privacy and Patient Data Sharing	32
I. Participation in Evaluation; Shared Learning Activities; and Site Visits	32
Evaluation Requirements	32
Shared Learning Activities	33
Site Visits	34
Rights in Data and Intellectual Property	35
II. Participant Release of Information	35
CMS Prior Approval	35
Required Disclaimer	36
V. Compliance and Oversight	36
Participant Compliance Plan	36
Compliance with Monitoring and Oversight Activities	37
/. Data Sharing and Reports	41
General	41
Provision of Certain De-Identified Data for Quality Improvement and Safety	41
Provision of De-Identified Dashboard and Summary Information	41
	Rayment to ET3 Partners or their Billing Parties.  Payment to Qualified Health Care Partners and their Billing Parties for Covered Services and as part of a Treatment in Place Intervention.  Payment to Alternative Destination Partners or their Billing Parties for Covered Services after Transport to an Alternative Destination.  Payment to CMS  Payment in Error  Medicare Payment Waivers  General  Transport to an Alternative Destination  In-Person Treatment in Place  Beneficiary Protections  Beneficiary Protections and Inducements  Beneficiary Privacy and Patient Data Sharing  Participation in Evaluation; Shared Learning Activities; and Site Visits  Evaluation Requirements  Shared Learning Activities  Site Visits  Rights in Data and Intellectual Property  In. Participant Release of Information  CMS Prior Approval  Required Disclaimer  V. Compliance and Oversight  Participant Compliance Plan  Compliance with Monitoring and Oversight Activities  General  Provision of Certain De-Identified Data for Quality Improvement and Safety

Article X	VI. Submission of Required Data	42
16.1	General	42
16.2	Submission Timing and Contents	42
16.3	Required Data	42
16.4	CMS Quality Reporting Initiatives	42
Article X\	VII. Certification of Data and Information	43
17.1	General	43
17.2	Annual Certification	43
Article X	VIII. Audits and Record Retention	43
18.1	Right to Audit and Correction	43
18.2	Maintenance of Records	44
Article XI	X. Remedial Action and Termination	44
19.1	Remedial Action	44
19.2	Termination of the Agreement by the Participant	45
19.3	Termination of the Agreement by CMS	46
19.4	Notification of ET3 Partners, Downstream Practitioners and Billing Parties	46
Article XX	K. Limitations on Review and Dispute Resolution	47
20.1	Limitations on Review	47
20.2	Dispute Resolution	47
Article XX	Kl. Miscellaneous	48
21.1	Agency Notifications and Submission Reports	48
21.2	Notice of Bankruptcy	48
21.3	Severability	49
21.4	Entire Agreement: Amendment	49
21.5	Survival	49
21.6	Precedence	49
21.7	Prohibition on Assignment	50
21.8	Change of Control	50
21.9	Certification	50
21.10	Interpretation of the Agreement	50
21.11	Execution in Counterpart	51
21.12	Autopen or Electronic Signature	51
APPENDI	X A: PROPRIETARY INFORMATION DISCLOSURE TEMPLATE	53

APPENDIX B: IN-PERSON TREATMENT IN PLACE INTERVENTION WAIVER	
I. Election of the In-Person Treatment in Place Intervention	54
II. Waiver and Terms	54
III. Responsibility for Denied Claims	55
IV. Compliance and Enforcement	56
APPENDIX C: TELEHEALTH TREATMENT IN PLACE INTERVENTION WAIVER	57
I. Election of the Telehealth Treatment in Place Intervention Waiver	57
II. Waiver and Terms	57
III. Responsibility for Denied Claims	58
IV. Compliance and Enforcement	59
APPENDIX D: DESTINATION REQUIREMENTS FOR AMBULANCE SERVICES WAIVER	60
I. Applicability of Waiver	60
II. Waiver and Terms	60
III. Responsibility for Denied Claims	60
IV. Compliance and Enforcement	61

#### **PARTICIPATION AGREEMENT**

This Participation Agreement ("Agreement")	is between the Centers for Medicare & Medicaid
Services ("CMS") and	("Participant") (each a "Party" and
collectively the "Parties").	

CMS is the agency within the U.S. Department of Health and Human Services ("HHS") that is charged with administering the Medicare and Medicaid programs.

The Participant is an entity that is enrolled in Medicare as an ambulance service supplier or ambulance provider.

CMS is implementing the Emergency Triage, Treat, and Transport Model ("ET3 Model" or "Model") under Section 1115A of the Social Security Act ("Act"), which authorizes CMS, through its Center for Medicare and Medicaid Innovation, to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program ("CHIP") expenditures while maintaining or improving the quality of care for Medicare, Medicaid, or CHIP beneficiaries.

The purpose of the ET3 Model is to test whether paying for (1) Transport to an Alternative Destination and (2) Treatment in Place, each furnished to low-acuity Medicare FFS beneficiaries following a 9-1-1 call, will reduce avoidable transports of Medicare FFS beneficiaries to emergency departments and/or utilization of other Covered Services.

The Participant submitted an application to participate in the ET3 Model ("Application"), and CMS has approved the Participant for participation in the ET3 Model.

The Parties, intending to be legally bound, therefore agree as follows:

Article I. Agreement Term; Model Performance Period; Performance Years

### 1.1 Effective Date

The effective date of this Agreement ("Effective Date") is the date this Agreement is signed by the last Party to sign it (as indicated by the date associated with that Party's signature).

## 1.2 Agreement Term

The term of this Agreement ("Agreement Term") begins on the Effective Date and expires two years after the last Day of the Model Performance Period, unless this Agreement is sooner terminated by either Party in accordance with Article 19, in which case the Agreement shall expire either on the effective date of termination or, if the Agreement is terminated by CMS pursuant to Article 19.3(a), on the effective date of the new agreement described in Article 19.3(a).

### 1.3 <u>Model Performance Period</u>

The performance period for this Agreement ("Model Performance Period") begins on January 1, 2021 ("Start Date") and ends on December 31, 2025, unless the Agreement is sooner terminated by either Party in accordance with Article 19, in which case the Model Performance Period terminates immediately upon the effective date of such termination. The Model Performance Period includes the following five performance years (each a "Performance Year"):

Performance Year 1: January 1, 2021 through December 31, 2021

Performance Year 2: January 1, 2022 through December 31, 2022

Performance Year 3: January 1, 2023 through December 31, 2023

Performance Year 4: January 1, 2024 through December 31, 2024

Performance Year 5: January 1, 2025 through December 31, 2025

#### Article II. Definitions

In this Agreement, the following definitions apply:

"After Hours" means the hours between 8:00pm and 8:00am local time at the ET3 Model Beneficiary's location.

"After Hours Service" means a Covered Service, which may include a Telehealth Service, that is (1) furnished as part of a Treatment in Place intervention to an ET3 Model Beneficiary; (2) by a Medicare-Enrolled Qualified Health Care Partner or Downstream Practitioner of a Qualified Health Care Partner; and (3) initiated or completed After Hours.

"After Hours Payment" means the allowed amount for an After Hours Service plus the After Hours Upward Payment Adjustment.

"After Hours Upward Payment Adjustment" means a 15% upward adjustment to the allowed amount for an After Hours Service.

"Alternative Destination Partner" means an individual or entity that has agreed to furnish Covered Services, or to arrange for a Downstream Practitioner to furnish Covered Services, to an ET3 Model Beneficiary at an Alternative Destination owned or operated by the individual or entity following a Transport to an Alternative Destination intervention.

"Alternative Destination" means a destination that (1) is not a Medicare-covered destination as identified in 42 C.F.R. § 410.40(f)(1); and (2) is owned or operated by an Alternative Destination Partner.

"Available Interventions" means (1) ET3 Model Interventions; and (2) Medicare-Covered Ground Ambulance Transport. For the duration of the PHE, the term Available Interventions also refers to medically necessary unscheduled ground ambulance transport to a Medicare covered destination as identified in 42 C.F.R. § 410.40(f)(5) that is not also identified in 42 C.F.R. § 410.40(f)(1).

"Billing Party" means any individual or entity, including, but not limited to, a Downstream Practitioner that (1) is Medicare-Enrolled; (2) is not an ET3 Partner; (3) is listed as the "billing provider" on a claim submitted to Medicare for Covered Services furnished by an ET3 Partner or its Downstream Practitioner to an ET3 Model Beneficiary during a Treatment in Place intervention or at an Alternative Destination following a Transport to an Alternative Destination intervention, and (4) bills for the Covered Services in their own name or pursuant to a valid reassignment of the right to receive Medicare payment.

"C.F.R." means the Code of Federal Regulations, as may be amended from time to time.

"Change of Control" means any of the following: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of an entity representing more than 50 percent of the entity's outstanding voting securities or rights to acquire such securities; (2) the acquisition of an entity by any other individual or entity; (3) any merger, division, or expansion of an entity (including satellite offices); or (4) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of an entity, or an agreement for the sale or liquidation of the entity.

"Clinical Protocols" means pre-determined protocols developed by the Participant in accordance with Article 5.5.

"County or Equivalent Entity" means a county that is the primary legal subdivision of a state, or any of the following equivalent entities:

- a. The District of Columbia.
- b. Parishes in Louisiana.
- c. Boroughs, cities, municipalities, and census areas in Alaska.
- d. Municipios in Puerto Rico.
- e. A city in Maryland, Missouri, Nevada or Virginia that is independent of any county and considered a primary legal subdivision of that state.

"Covered Services" means the scope of health care benefits described in Sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

"Days" means calendar days unless otherwise specified.

"Distant Site" means "distant site" as defined in 42 C.F.R. § 410.78(a)(2).

"Downstream Practitioner" means an individual who (1) is a Medicare-Enrolled Physician or Non-Physician Practitioner who furnishes Covered Services to ET3 Model Beneficiaries following a Transport to an Alternative Destination intervention or as part of a Treatment in Place intervention; (2) has a written arrangement with an ET3 Partner that meets all applicable requirements of Article 4.3, under which the Downstream Practitioner agrees to participate in

the Model and comply with all applicable terms and conditions under this Agreement; and (3) bills Medicare for such services directly or pursuant to a valid reassignment with a Billing Party in accordance with applicable regulations

**"Encounter"** means an encounter with a Patient that begins when the Participant arrives on the scene of a 9-1-1 emergency response in the Model Region following a 9-1-1 call, and ends when the Patient for whom the 9-1-1 call was placed is no longer in the physical care of the Participant, or, in the case of a Treatment in Place intervention, the Participant's Qualified Health Care Partner or a Qualified Health Care Partner's Downstream Practitioner.

**"ET3 Model Beneficiary"** means an individual who is (1) entitled to benefits under Medicare Part A and enrolled under Medicare Part B; (2) is suffering from a complaint for which a 9-1-1 call is placed and Participant is dispatched; and (3) is located in the Model Region when the Participant arrives on the scene of the 9-1-1 emergency response.

**"ET3 Model Intervention"** means either of the following interventions made available to an ET3 Model Beneficiary during an Encounter: (1) Transport to an Alternative Destination; or (2) Treatment in Place.

**"ET3 Partner"** means an Alternative Destination Partner or a Qualified Health Care Partner that (1) is identified by a TIN; (2) has a written arrangement with the Participant that meets the requirements of Article 4.3; and (3) is identified as an ET3 Partner on the ET3 List.

**"ET3 List"** means the list of the Participant's ET3 Partners, any Alternative Destinations identified by an NPI that is not shared with its associated Alternative Destination Partner, and any Billing Parties that bill Medicare for Covered Services as part of a Treatment in Place intervention, as established and updated in accordance with Article 4.2 and Article 4.4(b).

"Implementation Plan" means a complete description of the Participant's plan to implement the ET3 Model Intervention(s) by making such interventions available to ET3 Model Beneficiaries in the Model Region established pursuant to Article 5.1.

"In-Person Treatment in Place Intervention" means Covered Services furnished in person at the scene of a 9-1-1 emergency response to an ET3 Model Beneficiary during an Encounter, including Covered Services furnished by a Medicare-Enrolled Qualified Health Care Partner or a Downstream Practitioner as part of the In-Person Treatment in Place Intervention, and the initiation and facilitation of such Covered Services by the Participant.

"Learning System" means a structured approach to sharing, integrating, and actively applying quality improvement concepts, tactics, and lessons learned in order to create an environment that will maximize the likelihood of success of the Model.

"Medically Necessary" means reasonable and necessary as determined in accordance with Section 1862(a) of the Act.

"Medicare-Covered Ground Ambulance Transport" means a medically necessary unscheduled ground ambulance transport to a Medicare-covered destination as identified in 42 C.F.R. § 410.40(f)(1).

"Medicare-Enrolled" means the state of being enrolled in the Medicare program and thereby being eligible to bill and receive payment from Medicare for Medically Necessary Covered Services furnished to Medicare beneficiaries.

"Medicare Fee-for-Service" or "Medicare FFS" means Medicare Part A and Part B. As used in this Agreement, the term Medicare FFS does not include Medicare Part C (Medicare Advantage) or Medicare Part D (Prescription Drug Benefit).

"Model Participant" means an entity that has executed an agreement with CMS to participate in the Model.

"Model Region" means the Counties or Equivalent Entities where the Participant offers Medicare-Covered Ground Ambulance Transport, ET3 Model Interventions, and during the PHE, PHE Alternative Transports to ET3 Model Beneficiaries during the Model Performance Period in accordance with the Implementation Plan.

"Originating Site" means "originating site" as defined in 42 C.F.R. § 410.78(a)(4).

"Patient" means an individual, regardless of health insurance status, who is suffering from a complaint for which a 9-1-1 call is placed and Participant is dispatched and who is located in the Model Region when the Participant arrives on the scene of the 9-1-1 emergency response.

"Patient Care Report Data" or "PCR Data" means patient care information that is collected, most often in the National EMS Information System (NEMSIS) standard, following a 9-1-1 call for assistance.

"PHE" means "public health emergency" as defined in 42 C.F.R. § 400.200.

"PHE Alternative Transport" means a medically necessary unscheduled emergency ground ambulance transport of an ET3 Model Beneficiary from the scene of a 9-1-1 emergency response to a Medicare-covered destination identified in 42 C.F.R. § 410.40(f)(5) that is not also identified in 42 C.F.R. § 410.40(f)(1).

"Physician or Non-Physician Practitioner" means a physician or non-physician practitioner who meets all State and local laws, regulatory requirements, accreditation standards, and licensing guidelines or rules to render the particular Covered Service furnished to an ET3 Model Beneficiary as part of a Treatment in Place intervention or following a Transport to an Alternative Destination intervention.

"Program Integrity Screening" means a review of an individual's or entity's program integrity history, which may include a review of the individual's or entity's history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or CHIP; history of failure to pay Medicare debts in a timely manner; 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.

"Protected Health Information (PHI)" means protected health information as defined in 45 C.F.R § 160.103.

"Provider" means a "provider of services" defined under section 1861(u) of the Act and codified in the definition of "provider" at 42 C.F.R. § 400.202, as may be amended from time to time.

"Qualified Health Care Partner" means an individual or entity that has agreed to furnish a Treatment in Place intervention, or to arrange for a Downstream Practitioner to furnish a Treatment in Place intervention, to an ET3 Model Beneficiary.

"Supplier" means a supplier as defined in section 1861(d) of the Act and codified at 42 C.F.R. § 400.202, as may be amended from time to time.

"Telehealth Services" means Covered Services that are furnished as telehealth services under section 1834(m) of the Act and 42 C.F.R. § 410.78.

"Telehealth Treatment in Place Intervention" means Telehealth Services furnished to an ET3 Model Beneficiary located at the scene of a 9-1-1 emergency response during an Encounter, including Covered Services furnished by a Medicare-Enrolled Qualified Health Care Partner or a Downstream Practitioner as part of the Telehealth Treatment in Place Intervention, as well as the initiation and facilitation of such Covered Services by the Participant.

**"TIN"** means a federal Taxpayer Identification Number, which in some cases may be a Social Security Number.

"Transport to an Alternative Destination" means medically necessary (as described in 42 C.F.R. § 410.40(e)(1)) unscheduled emergency ground ambulance transport, other than PHE Alternative Transport, of an ET3 Model Beneficiary by the Participant from the scene of a 9-1-1 emergency response to an Alternative Destination during an Encounter.

"Treatment in Place" means (1) a Telehealth Treatment in Place Intervention; or (2) an In-Person Treatment in Place Intervention.

"Triage Decision" means the Participant's procedures to (1) use its' Clinical Protocols to assess a Patient's condition after the Participant arrives on the scene of a 9-1-1 emergency response; (2) determine which Available Intervention (if any) is most clinically appropriate; and (3) use the information from steps (1) through (2), together with the Participant's determination as to whether the Patient is an ET3 Model Beneficiary in accordance with the Eligibility Plan developed pursuant to Article 5.2(a)(ii), to make the offer (if any) of an Available Intervention to the Patient.

## Article III. Participant Requirements

### 3.1 General Requirements

- (a) The Participant must be a legal entity identified by a TIN formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates.
- (b) The Participant must be a Medicare-Enrolled ambulance service supplier or ambulance provider that meets the applicable vehicle, staff, billing and reporting requirements of 42 C.F.R. § 410.41, is authorized to respond to 9-1-1 emergency medical requests, is subject to community-wide emergency medical services ("EMS") protocols and state or local laws governing EMS. The Participant must notify CMS of any administrative or other action that

- may affect the Participant's Medicare enrollment status within 30 Days of the Participant's receipt of notice of such action.
- (c) The Participant must notify CMS in writing of any noncompliance or deficiencies in regards to this Agreement within 15 Days of discovery, unless a different timeframe for notification is specified in this Agreement.
- (d) The Participant must ensure that all ET3 Partners, Downstream Practitioners, Billing Parties, and other entities and individuals performing functions or services related to the ET3 Model Interventions are obligated to comply with the applicable terms and conditions of this Agreement, and must ensure that the Participant has sufficient access to all necessary records, data, and information of and pertaining to the ET3 Partners, Downstream Practitioners, Billing Parties, and other entities and individuals performing functions or services related to the ET3 Model Interventions, as applicable, to enable the Participant to carry out this responsibility.

## 3.2 <u>Participant Changes</u>

#### (a) Legal Name Change

The Participant must provide written notice to CMS at least 60 Days before any change in the Participant's legal name. The notice of legal name change must include a copy of any legal document effecting the name change, authenticated by the appropriate state official (if applicable), and the Parties must execute an agreement reflecting the change of the Participant's legal name.

#### (b) Change of Control

The Participant must provide written notice to CMS at least 90 Days before the effective date of any Change of Control of the Participant. This obligation remains in effect throughout the Agreement Term and until final payment by or to the Participant has been made in accordance with this Agreement. After review of such notice, CMS may terminate this Agreement, demand immediate payment of any amount owed by the Participant to CMS under this Agreement, or may take any other actions consistent with the terms of this Agreement, to include Article 21.7.

### (c) Identifier Change

The Participant must provide written notice to CMS as soon as practicable, but no later than 30 Days after any change in TIN, NPI, or other identifier specified by CMS with respect to the Participant. After review of such notice, CMS may terminate this Agreement, demand immediate payment of any amount owed by the Participant to CMS under this Agreement, or may take any other actions consistent with the terms of this Agreement.

## 3.3 <u>State and Local Requirements</u>

(a) For the duration of the Model Performance Period, the Participant must meet all applicable requirements to operate as a 9-1-1 emergency ambulance service supplier or ambulance provider in each state that is included (in whole or in part) in the Model Region, including,

- but not limited to, adherence to state-wide EMS protocols, agency license, medical director license, personnel certifications, and vehicle licenses and requirements.
- (b) For the duration of the Model Performance Period, the Participant must meet all applicable requirements to operate as a 9-1-1 emergency ambulance service supplier or ambulance provider in each County or Equivalent Entity that is included (in whole or in part) in the Model Region, including, but not limited to, adherence to community-wide EMS protocols, business license, or other local authorizations and licenses.

#### 3.4 Non-Duplication of Participation

- (a) The Participant may concurrently participate in the ET3 Model and other CMS initiatives, including, but not limited to: shared savings initiatives; total cost of care initiatives; the Medicare Prior Authorization of Repetitive, Scheduled Non-Emergent Ambulance Transport Model; and medical home initiatives.
- (b) The Participant must give written notice to CMS if the Participant is selected to participate in any CMS initiative after the Participant submitted its Application. Such notice must be given within 30 Days of the Effective Date if the Participant was selected after submitting the Application but prior to the Effective Date or, if the Participant is selected on or after the Effective Date, within 30 Days of receiving notification that the Participant has been selected to participate in the initiative.
- (c) Where the Participant concurrently participates in the Model and any other CMS initiative, CMS reserves the right to amend this Agreement without the consent of the Participant to include additional requirements, revise ET3 Model parameters, or ultimately prohibit simultaneous participation in multiple initiatives, in order to avoid counting savings twice in interacting initiatives and to enable CMS to conduct a robust evaluation of each such initiative.

#### Article IV. ET3 Partners

### 4.1 <u>General Requirements</u>

- (a) The Participant must notify and educate each individual and entity who is a potential ET3 Partner about the Model to enable them to make an informed decision about whether to participate in the Model as an ET3 Partner. The provision of information to a potential ET3 Partner for purposes of satisfying this requirement is not considered promotion, marketing, or advertising under Article 11.4(b).
- (b) The Participant must provide a copy of this Agreement and any amendments hereto to each potential ET3 Partner prior to obtaining their consent to participate in the Model as an ET3 Partner and must obligate each ET3 Partner to provide such documents to each potential Downstream Practitioner and Billing Party.
- (c) If the requirements of Article 4.1(a) and Article 4.1(b) are not satisfied prior to the Participant's execution of an arrangement with an ET3 Partner pursuant to Article 4.3, the requirements of this Article 4.1 are not satisfied.

#### 4.2 ET3 List

#### (a) General

- (i) The Participant must ensure that all proposed ET3 Partners, Alternative Destinations identified by an NPI that is not shared with its associated Alternative Destination Partner, and any Billing Parties, including Downstream Practitioners, that will bill Medicare for Covered Services furnished as part of a Treatment in Place intervention are approved by CMS to be added to the ET3 List pursuant to this Article 4.2 prior to furnishing ET3 Model Interventions under the terms of this Agreement to an ET3 Model Beneficiary.
- (ii) An individual or entity will be included on the ET3 List only upon written approval of CMS.
- (iii) CMS will maintain the ET3 List in a manner that permits the Participant to review the list. The Participant must periodically review its ET3 List to ensure that the list is true, accurate, and complete, and must make any updates to the ET3 List in accordance with Article 4.2(c).
- (iv) The Participant must maintain documentation of all ET3 Lists, both current and historical, in accordance with Article 18.2.
- (v) CMS may periodically conduct a Program Integrity Screening of each individual and entity listed on the ET3 List. The presence of an individual or entity on the ET3 List does not imply or constitute a determination that the individual or entity has no program integrity issues, nor does it preclude CMS or any other federal government agency from enforcing any and all applicable laws, rules and regulations, or from initiating or continuing any audit or investigation of an individual or entity listed on the ET3 List.

#### (b) Initial ET3 List

- (i) If the Participant intends to implement ET3 Model Interventions as of the Start Date, the Parties acknowledge that the Participant submitted to CMS a proposed list of individuals and entities for inclusion on the ET3 List that satisfied the requirements of this Article 4.2(b).
- (ii) If the Participant intends to implement ET3 Model Interventions at some point after the Start Date, the Participant shall submit a proposed list of individuals for inclusion on the ET3 List at least 45 days prior to the first day on which the Participant intends to implement ET3 Model Interventions.
- (iii) The Participant must include all information necessary for CMS to perform a Program Integrity Screening of the individual or entity proposed for inclusion on the ET3 List, to include without limitation:

- 1) Medicare-Enrolled individuals and entities proposed for inclusion on the ET3 List must be identified by legal business name (or, in the case of an individual, legal name), correspondence address, NPI, Medicare Provider Identification Number(s) (if issued), and CMS Certification Number (if applicable).
- Those individuals and entities who are not Medicare-Enrolled must be identified by legal business name (or, in the case of an individual, legal name), correspondence address, type of entity, TIN, NPI, existing and/or past state license number (if any) and state that issued license; and for any board member or individual with managing control, partnership interest, or a 10% or greater direct or indirect ownership in the ET3 Partner, the individual's name, date of birth, NPI (if applicable), and social security number.
- (iv) For each individual or entity proposed for inclusion on the ET3 List, the Participant must indicate whether the individual or entity is proposed as an ET3 Partner, Alternative Destination identified by an NPI that is not shared with its associated Alternative Destination Partner, or Billing Party. In the case of an Alternative Destination or Billing Party, the Participant must indicate the ET3 Partner associated with the Alternative Destination or Billing Party.
- (v) CMS will review the list of individuals and entities proposed for inclusion on the ET3 List and conduct a Program Integrity Screening of those individuals and entities for which CMS received all information necessary to conduct a Program Integrity Screening.
- (vi) CMS will submit to the Participant a list of individuals and entities that it approved for inclusion on the ET3 List. The Participant shall review this list and make any necessary corrections to it, including the removal of any individuals or entities proposed as ET3 Partners or any proposed Downstream Practitioners identified as Billing Parties that have not agreed to participate in the Model pursuant to a written arrangement meeting the requirements of Article 4.3.
- (vii) The Participant shall submit to CMS an initial ET3 List that the Participant has certified is a true, accurate, and complete list of all of the Participant's ET3 Partners, as well as those Alternative Destinations and Billing Parties that must be included on the ET3 List pursuant to Article 4.2(a)(i).
- (viii) Once the initial ET3 List has been certified by the Participant and submitted to CMS, that list shall be deemed the final ET3 List and the Participant must update the ET3 List in accordance with Article 4.2(c).
- (c) Updates to ET3 List
  - (i) Removals from the ET3 List
    - 1) In a form and manner specified by CMS, the Participant must notify CMS no later than 30 Days after an individual or entity on the ET3 List has ceased to be an ET3 Partner, Alternative Destination, or Billing Party for any reason other than termination by CMS, and must include in the notice the date on which the individual or entity ceased to be an ET3 Partner, Alternative Destination, or Billing Party. The removal of the individual or entity from the ET3 List will be effective on

- the date the individual or entity ceased to be an ET3 Partner, Alternative Destination, or Billing Party.
- 2) CMS may terminate an individual or entity and update the ET3 List to reflect this termination or subject the Participant to additional monitoring pursuant to Article 14.2(f)(i) on the basis of the results of a periodic Program Integrity Screening or information obtained regarding an individual's or entity's history of program integrity issues. CMS will notify the Participant if CMS chooses to terminate an individual or entity and remove them from the ET3 List. Such notice will specify the effective date of termination.

#### (ii) Additions to the ET3 List

- 1) If, after the initial ET3 List has been deemed final, the Participant wishes to add an individual or entity to the ET3 List as an ET3 Partner, Alternative Destination identified by an NPI that is not shared with its associated Alternative Destination Partner, or Billing Party, it must submit a request to CMS, in a form and manner and by a deadline specified by CMS, that meets the following requirements:
  - a) The Participant must include all information necessary for CMS to perform a Program Integrity Screening of the individual or entity proposed for inclusion on the ET3 List, including without limitation the information specified in paragraphs (1) and (2) of Article 4.2(b)(iii).
  - b) For each individual or entity proposed for inclusion on the ET3 List, the Participant must indicate whether the individual or entity is proposed as an ET3 Partner, Alternative Destination identified by an NPI that is not shared with its associated Alternative Destination Partner, or Billing Party. In the case of an Alternative Destination or Billing Party, the Participant must indicate the ET3 Partner associated with the Alternative Destination or Billing Party.
  - c) The Participant must ensure that it has a written arrangement that meets the requirements of Article 4.3 with any proposed ET3 Partner and that any proposed Alternative Destination or Billing Party is associated with an approved ET3 Partner.
- 2) CMS will conduct a Program Integrity Screening of each individual or entity proposed for inclusion on the ET3 List by the Participant.
- 3) CMS will notify the Participant regarding whether the proposed individual or entity has been approved or rejected for inclusion on the ET3 List on the basis that the individual or entity fails to satisfy the definition of an "ET3 Partner," "Alternative Destination," or "Billing Party", or on the basis of a Program Integrity Screening. If CMS approves the request, the individual or entity will be added to the ET3 List, effective on the date the addition is approved by CMS.

## 4.3 <u>ET3 Partner Arrangement</u>

- (a) The Participant must have an arrangement with each ET3 Partner that complies with the following requirements:
  - (i) The arrangement is in writing, and the only parties to the arrangement are the Participant and ET3 Partner.
  - (ii) **Arrangements with Alternative Destination Partners.** For an arrangement between the Participant and an ET3 Partner that is an Alternative Destination Partner:
    - The arrangement requires the Alternative Destination Partner to participate in the Model and furnish Covered Services, or arrange for Covered Services to be furnished by a Downstream Practitioner, to ET3 Model Beneficiaries following Transport to an Alternative Destination.
    - The arrangement requires the Alternative Destination Partner to ensure it has the ability to (1) assess the real-time capacity of an Alternative Destination of the Alternative Destination Partner to furnish the required level and type of care for the illness or injury of any ET3 Model Beneficiary prior to accepting transport of the ET3 Model Beneficiary by the Participant to the Alternative Destination pursuant to Article 6.2; (2) meet the needs of any ET3 Model Beneficiary accepted for transport to an Alternative Destination of the Alternative Destination Partner; and (3) bill Medicare for Covered Services furnished to ET3 Model Beneficiaries at an Alternative Destination of the Alternative Destination Partner or, if the Alternative Destination Partner cannot or does not intend to bill Medicare for such Covered Services, has arranged for such Covered Services to be billed by a Billing Party that has the ability to bill Medicare for such Covered Services.
    - 3) If the Alternative Destination Partner is not Medicare-Enrolled, the arrangement requires the Alternative Destination Partner to contract or employ at least one Downstream Practitioner who is Medicare-Enrolled and has the ability to furnish Covered Services described in Article 6.2 that are furnished at an Alternative Destination of the Alternative Destination Partner, and if the Downstream Practitioner cannot or does not intend to bill Medicare for such Covered Services, has arranged for such Covered Services to be billed by a Billing Party that has the ability to bill Medicare for such Covered Services furnished by the Downstream Practitioner.
  - (iii) Arrangements with Qualified Health Care Partners. For an arrangement between the Participant and an ET3 Partner who is a Qualified Health Care Partner:
    - The arrangement requires the Qualified Health Care Partner to participate in the Model and furnish Covered Services to ET3 Model Beneficiaries as part of a Treatment in Place intervention, or to arrange for Covered Services to be furnished by a Downstream Practitioner to ET3 Model Beneficiaries as part of a Treatment in Place intervention.
    - 2) The arrangement requires the Qualified Health Care Partner to ensure it has the capacity to meet the needs of ET3 Model Beneficiaries who receive Covered

Services during a Treatment in Place intervention, as well as the ability to bill Medicare for Covered Services furnished to ET3 Model Beneficiaries during a Treatment in Place intervention or, if the Qualified Health Care Partner cannot or does not intend to bill Medicare for such Covered Services, has arranged for such Covered Services to be billed by a Billing Party that has the ability to bill Medicare for such Covered Services.

- 3) If the Qualified Health Care Partner is not Medicare-Enrolled, the arrangement requires the Qualified Health Care Partner to contract or employ at least one Downstream Practitioner who is Medicare-Enrolled and has the capacity to furnish Covered Services that satisfy the requirements of Article 6.3, and if the Downstream Practitioner cannot or does not plan to bill Medicare for such Covered Service, has arranged for such Covered Services to be billed by a Billing Party that has the ability to bill Medicare for such Covered Services furnished by the Downstream Practitioner.
- 4) The arrangement requires the Qualified Health Care Partner to collect and report to the Participant data on an Encounter, as necessary and appropriate, to ensure that the Participant makes data submissions to CMS in accordance with Article 16 and requires the Qualified Health Care Partner to impose this requirement on its Downstream Practitioners and Billing Parties.
- 5) The arrangement requires the Qualified Health Care Partner to collect and report to the Participant data on an Encounter, as necessary and appropriate, to ensure that the Participant makes data submissions to CMS in accordance with Article 16 and requires the Qualified Health Care Partner to impose this requirement on its Downstream Practitioners and Billing Parties.
- 6) The arrangement includes written confirmation of the Qualified Health Care Partner's consent to bill and receive payment for Covered Services furnished as part of a Treatment in Place intervention as described in Article 8.1 and, if applicable, also requires the Qualified Health Care Partner to ensure that its Billing Parties provide written confirmation of the Billing Parties' consent to bill and receive payment for such Covered Services as described in Article 8.1.
- (iv) The arrangement expressly sets forth the ET3 Partner's obligation to comply with the applicable terms and conditions of the Model as set forth in this Agreement, including, but not limited to, compliance with ET3 Model evaluation, monitoring, and oversight activities and also requires the ET3 Partner to ensure that its Downstream Practitioners and Billing Parties are obligated to comply with the applicable terms and conditions of the Model as set forth in this Agreement.
- (v) The arrangement expressly requires the ET3 Partner to comply with all applicable laws and regulations including, but not limited to, those specified in Article 14.2(b), and also requires the ET3 Partner to ensure that its Downstream Practitioners and Billing Parties are obligated to comply with all such laws and regulations.

- (vi) The arrangement expressly requires the ET3 Partner to promptly submit to the Participant a true, accurate, and complete list of all the ET3 Partner's Alternative Destinations, Downstream Practitioners, and Billing Parties upon request by the Participant. Such list must include the legal name and NPI of each Billing Party and Downstream Practitioner. Billing Parties that are Downstream Practitioners need not be listed twice.
- (vii) If Covered Services furnished to an ET3 Model Beneficiary during a Treatment in Place intervention or following Transport to an Alternative Destination are furnished by a Downstream Practitioner and the Billing Party is not the Downstream Practitioner who furnished the Covered Services, the arrangement obligates the ET3 Partner to ensure that the Downstream Practitioner who furnished the Covered Services has reassigned his or her right to bill the Medicare program and receive Medicare payments for the Covered Services to the Billing Party.
- (viii) The arrangement requires the ET3 Partner to require its Downstream Practitioners and Billing Parties to update their Medicare enrollment information on a timely basis in accordance with Medicare program requirements and, if the ET3 Partner is Medicare enrolled, also requires the ET3 Partner to do the same.
- (ix) If the ET3 Partner is Medicare-Enrolled, the arrangement requires the ET3 Partner to notify the Participant of any changes to its Medicare enrollment information, legal name, NPI or other identifier specified by CMS with respect to the individual or entity, and a Change of Control within 30 Days after becoming aware of the change, and also requires the ET3 Partner to ensure that its Alternative Destinations, Downstream Practitioners and other Billing Parties are obligated to do the same if they are on the ET3 List, or if the change meaningfully affects the Downstream Practitioner's capacity to furnish Covered Services to ET3 Model Beneficiaries as part of an ET3 Model Intervention.
- (x) The arrangement requires the ET3 Partner to notify the Participant within 7 Days of becoming aware that it or any of its Downstream Practitioners or Billing Parties is under investigation or has been sanctioned (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, loss of medical license or equivalent, corrective action plans, and revocation of Medicare billing privileges) by the federal, state, or local government, or any licensing authority, and requires the ET3 Partner to ensure that its Downstream Practitioners and Billing Parties provide such notice to the ET3 Partner if the Downstream Practitioner or Billing Party is the subject of such investigations or sanctions.
- (xi) The arrangement permits the Participant to take remedial action against the ET3
  Partner, including termination of the Participant's arrangement with the ET3 Partner,
  to address noncompliance with the terms of the Model as set forth in this Agreement
  or program integrity issues identified by CMS, and also requires the ET3 Partner to
  ensure that the ET3 Partner's arrangements with its Downstream Practitioners and
  Billing Parties permit the ET3 Partner to take such actions against a Downstream

- Practitioner or Billing Party to address noncompliance with the applicable terms of this Model as set forth in this Agreement or program integrity issues identified by CMS.
- (xii) The arrangement permits early termination if CMS removes the ET3 Partner from the ET3 List and, if the ET3 Partner is a Qualified Health Care Partner, requires the Qualified Health Care Partner to ensure it has the ability to terminate its arrangement with any of its Billing Parties who are removed from the ET3 List by CMS.
- (b) CMS provides no opinion on the legality of any contractual or other arrangement that the Participant, ET3 Partner, a Downstream Practitioner, Billing Party, or other individual or entity involved in the Participant's implementation of ET3 Model Interventions has proposed, implemented, or documented. The receipt by CMS of any such documents in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules or regulations, and will not preclude CMS, HHS or its Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules and regulations.

### 4.4 Notification of Termination and Other Changes

- (a) The Participant must provide written notice to CMS of the following:
  - (i) The Participant must provide written notice to CMS within 30 Days before the termination of a written arrangement described in Article 4.3.
  - (ii) The Participant must provide written notice to CMS within 30 Days after becoming aware of any change in the legal name of any individual or entity listed on the ET3 List.
  - (iii) The Participant must provide written notice to CMS within 30 Days after becoming aware of any Change of Control of any entity listed on the ET3 List.
  - (iv) The Participant must provide written notice to CMS as soon as practicable, but no later than 30 Days after becoming aware of any change in Medicare enrollment status or change in NPI or other identifier specified by CMS with respect to any Medicare-Enrolled individual or entity listed on the ET3 List.
  - (v) The Participant must provide written notice to CMS within 30 Days after becoming aware that any individual or entity listed on the ET3 List is under investigation or has been sanctioned (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, loss of medical license or equivalent, corrective action plans, and revocation of Medicare billing privileges) by the federal, state, or local government or any licensing authority.
- (b) After review of a notice described under Article 4.4(a), CMS may conduct a Program Integrity Screening with respect to such individual or entity listed on the ET3 List, terminate such individual or entity on the ET3 List, or take any of the actions set forth in Article 19.

## 4.5 <u>Limitations</u>

The Participant must not take any action to limit the ability of an ET3 Partner or Downstream Practitioner to make decisions in the best interest of an ET3 Model Beneficiary, including the selection of care or services furnished to an ET3 Model

Beneficiary under the Model, or to offer an ET3 Model Beneficiary an Available Intervention that differs from the Available Intervention identified by the Participant's Triage Decision.

#### Article V. Implementation of ET3 Model Interventions

#### 5.1 Implementation Plan

- (a) Submission and Acceptance
  - (i) The Parties acknowledge that the Participant submitted to CMS an Implementation Plan that includes, at a minimum, all the information described in Article 5.1(b), subject to CMS review and approval pursuant to Article 5.1(d).
  - (ii) The Participant shall update the Implementation Plan throughout the Model Performance Period in accordance with Article 5.1(c).
  - (iii) CMS's acceptance of the Participant's Implementation Plan or any updates thereto does not imply or constitute a determination that the Participant's Implementation Plan complies with federal statutes or regulations or relieve the Participant, ET3 Partners, Downstream Practitioners, Billing Parties, or other individuals or entities included in the Implementation Plan, such as payers included in the Participant's Multi-Payer Strategy described in Article 5.2 (if applicable), of the obligation to comply with the applicable terms of this Agreement or all applicable laws, rules, and regulations. Such acceptance does not preclude CMS or any other federal government agency from enforcing any and all applicable laws, rules, and regulations.
  - (iv) The Participant shall adhere to the CMS-accepted Implementation Plan and must obligate its ET3 Partners to adhere to the applicable requirements of the Implementation Plan and to obligate their Downstream Practitioners and Billing Parties to do the same. If CMS determines that the Participant is materially unable to implement its Implementation Plan during the Model Performance Period, CMS reserves the right to take remedial action pursuant to Article 19.

#### (b) Required Implementation Plan Content

The Participant's Implementation Plan submitted pursuant to Article 5.1(a) and updated in accordance with Article 5.1(c) must include, in a form and manner specified by CMS, all of the following information:

- (i) A description of the Model Region.
- (ii) A description of how the Participant will implement the Transport to an Alternative Destination intervention during the Model Performance Period in accordance with the requirements of this Agreement, including all of the following:
  - 1) The date by which the Participant proposes to make the Transport to an Alternative Destination intervention available to ET3 Model Beneficiaries.
  - 2) A description of how the Participant will meet each of the requirements of Article 6.2.

- 3) A description of any Alternative Destination Partners approved by CMS for inclusion on the ET3 List in accordance with Article 4.2 and/or any individuals or entities the Participant intends to add to the ET3 List as an Alternative Destination Partner, subject to CMS review and approval, including a description of the Alternative Destination Partner's capacity to serve ET3 Model Beneficiaries at one or more Alternative Destinations.
- (iii) If the Participant intends to perform PHE Alternative Transports during the Model Performance Period concurrent with its implementation of the Transport to an Alternative Destination intervention, the Participant must describe its plan to simultaneously comply with both ET3 Model requirements and the requirements of 42 C.F.R. §410.40(f)(5) for PHE Alternative Transports, including, but not limited to, its plan to identify whether a given transport is a PHE Alternative Transport or a Transport to an Alternative Destination and to avoid the submission of inaccurate or duplicative claims.
- (iv) A statement indicating whether the Participant has elected to implement the optional Treatment in Place intervention in accordance with Article 6.3(b).
- (v) If the Participant has elected to implement the Treatment in Place intervention, the Implementation Plan must also contain the following information:
  - A description of how the Participant will implement the Treatment in Place intervention during the Model Performance Period in accordance with the requirements of this Agreement, including:
    - a) a statement indicating whether the Participant will make the In-Person Treatment in Place Intervention, the Telehealth Treatment in Place Intervention, or both interventions available to ET3 Model Beneficiaries,
    - b) if the Participant has elected to implement the Treatment in Place intervention during Performance Year 1, a statement indicating whether the Participant will implement the Treatment in Place intervention pursuant to Article 6.3(a)(i) or the exception specified in Article 6.3(a)(ii), and
    - c) a description of how the Participant will meet the requirements of Article6.3.
  - 2) The date by which the Participant proposes to make the Treatment in Place intervention available to ET3 Model Beneficiaries; and
  - 3) If the Participant has elected to implement the optional Treatment in Place intervention during Performance Year 1 pursuant to the exception specified in Article 6.3(a)(ii):
    - a) a description of each destination to which the Participant has made the necessary arrangements to make PHE Alternative Transports available to

- ET3 Model Beneficiaries including, legal business name and type of facility, and
- b) a description of the Participant's operational plan to respond to a loss of eligibility to implement the optional Treatment in Place intervention pursuant to the exception specified in Article 6.3(a)(ii) due to a termination the PHE determination without a subsequent renewal.
- (vi) The Participant's Payer Strategy developed in accordance with Article 5.2.
- (vii) The Participant's Access Plan developed in accordance with Article 5.3.
- (c) Updates to Implementation Plan
  - (i) The Participant shall update all Implementation Plan content on an annual basis in a form and manner and by a date specified by CMS.
  - (ii) The Participant also must promptly update its Implementation Plan prior to the next annual update to reflect:
    - 1) Material changes in how the Participant will implement the Transport to an Alternative Destination intervention. Such material changes include, but are not limited to, changes to the date Participant proposed to make the Transport to an Alternative Destination intervention available to ET3 Model Beneficiaries and any interruptions in the Participant's ability to make the Transport to an Alternative Destination intervention available, such as gaps or anticipated gaps in the Participant's ability to make available the Transport to an Alternative Destination intervention.
    - 2) Material changes in how the Participant will implement the optional Treatment in Place intervention. Such material changes include, but are not limited to, the Participant's decision to no longer make the optional Treatment in Place intervention available to ET3 Model Beneficiaries, changes to the date Participant proposed to make the Treatment in Place intervention available, changes to Participant's eligibility to implement the Treatment in Place intervention, and changes in the type of Treatment in Place intervention (In-Person Treatment in Place Intervention, Telehealth Treatment in Place Intervention, or both) that the Participant will make available to ET3 Model Beneficiaries.
    - 3) Material changes to the Participant's Payer Strategy. Such material changes include, but are not limited to, a change in the Participant's election to implement either a Medicare FFS Strategy or Multi-Payer Strategy, any significant changes to the Participant's Eligibility Plan, and any significant changes to the proposed timeline or partnerships associated with the Payer Strategy.
    - 4) Material changes to the Participant's Access Plan. Such material changes include, but are not limited to, changes to the timeline to achieve 24/7 access, any changes that will materially limit the Participant's ability to achieve 24/7 access, or any changes that will lead to material interruptions in the Participant's ability to meet the 24/7 access requirement.
  - (iii) If the Participant updates its Implementation Plan to elect to implement the optional

Treatment in Place intervention, the Participant must submit the updated Implementation Plan to CMS no less than 45 Days prior to the date by which the Participant proposes to make the Treatment in Place intervention available to ET3 Model Beneficiaries.

#### (d) CMS Review and Acceptance

- (i) CMS will review the Implementation Plan, including any updates thereto, and will make reasonable efforts to accept the Implementation Plan, reject the Implementation Plan, or provide notice to the Participant of an extension of CMS's period of review of the Implementation Plan, within 30 Days of CMS's receipt thereof.
- (ii) CMS may require the Participant to make changes to the Implementation Plan before acceptance and may reject the Implementation Plan if the Participant does not make satisfactory changes. If CMS rejects the Participant's Implementation Plan, CMS may take remedial action in accordance with Article 19.

## 5.2 Payer Strategy

- (a) The Participant must implement a "Payer Strategy" that includes:
  - (i) Either a strategy for how the Participant will operationalize its proposed ET3 Model Interventions in Medicare FFS only ("Medicare FFS Strategy") or a strategy for how the Participant will work with multiple payers such as Medicaid managed care, Medicare Advantage, commercial insurance, or others, in addition to Medicare FFS, to implement coverage of an ET3 Model-like intervention that provides coverage for unscheduled ground ambulance transport to a site not currently covered by the payer and/or provides coverage for services furnished in-person or through telehealth at the scene of a 9-1-1 emergency response ("Multi-Payer Strategy"); and
  - (ii) A plan to identify whether a Patient is an ET3 Model Beneficiary prior to offering an ET3 Model Intervention ("Eligibility Plan").
  - (iii) Information provided to a potential payer partner for the purposes of developing or implementing the Participant's Multi-Payer Strategy is not considered promotion, advertising, or marketing under Article 11.4(b).

## 5.3 Access Plan

(a) Except as provided in Article 5.3(b), after the Participant makes the Transport to an Alternative Destination intervention available pursuant to Article 6.2, the Participant must ensure that ET3 Model Beneficiaries have access to at least one ET3 Model Intervention 24 hours per Day, 7 Days per week during the Model Performance Period. The Participant shall achieve such access based on the availability of one or more Alternative Destinations or, if the Participant has elected to implement the optional Treatment in Place intervention, on the availability of a combination of Alternative Destinations and Qualified Health Care Partners. (b) If the Participant has elected to implement the optional Treatment in Place intervention during Performance Year 1 pursuant to the exception specified in Article 6.3(a)(ii), the Participant must ensure that ET3 Model Beneficiaries have access to either PHE Alternative Transports or Treatment in Place 24 hours per Day, 7 Days per week for any period during Performance Year 1 that the Participant implements the optional Treatment in Place intervention pursuant to the exception specified in Article 6.3(a)(ii). The Participant shall achieve such access based on a combination of the availability of Qualified Health Care Partners or their Downstream Practitioners to furnish Covered Services during a Treatment in Place intervention and the availability of any destination with which the Participant has made any necessary arrangements to make PHE Alternative Transports available to ET3 Model Beneficiaries.

#### 5.4 Transport to Covered Destinations

The Participant must continue to offer Medically Necessary Medicare-Covered Ground Ambulance Transport for ET3 Model Beneficiaries within the Model Region for the duration of the Model Performance Period.

#### 5.5 Clinical Protocols

- (a) With oversight from the Participant's medical director or equivalent, the Participant must develop, implement, and maintain appropriate Clinical Protocols and other operational guidelines relevant to the Model, which are compliant with state and local requirements and clinical best practices, and are subject to internal quality improvement processes to ensure that quality and safety practices are implemented and tracked.
- (b) During an Encounter, the Participant must use its Clinical Protocols to make a Triage Decision for any Patient identified as an ET3 Model Beneficiary before the Participant may offer an ET3 Intervention available to the ET3 Model Beneficiary.

### Article VI. ET3 Model Interventions

#### 6.1 General

- (a) Notwithstanding any requirements of this Agreement, the Participant may offer PHE Alternative Transports at any time during the Model Performance Period that overlaps with the PHE, including any period during which the Participant is also implementing the Transport to an Alternative Destination intervention.
- (b) No earlier than the Start Date, and no later than January 1, 2022 or such later date as specified by CMS, the Participant must make the Transport to an Alternative Destination intervention available to ET3 Model Beneficiaries in accordance with the Implementation Plan and Article 6.2, and must thereafter continue to make the Transport to an Alternative Destination intervention available to ET3 Model Beneficiaries for the remaining duration of the Model Performance Period.
- (c) In accordance with Article 6.3(b), the Participant may elect to make the optional Treatment in Place intervention available to ET3 Model Beneficiaries during the Model Performance Period.

- (d) The Participant must ensure that Covered Services furnished to an ET3 Model Beneficiary following Transport to an Alternative Destination or as part of a Treatment in Place intervention are furnished by a Medicare-Enrolled ET3 Partner or a Downstream Practitioner.
- (e) Subject to the requirements of Article 6.2 and Article 6.3, the Participant may furnish or, if applicable, initiate and facilitate an ET3 Model Intervention for a Patient only after the Participant has:
  - (i) made a Triage Decision that identified an ET3 Model Intervention as the most appropriate Available Intervention,
  - (ii) identified the Patient as an ET3 Model Beneficiary in accordance with the Eligibility Plan developed pursuant to Article 5.2(a)(ii),
  - (iii) offered the ET3 Model Intervention to the ET3 Model Beneficiary in accordance with Article 11.1 and subject to the requirements of Article 5.3,
  - (iv) obtained and documented the ET3 Model Beneficiary's consent to receive the ET3 Model Intervention in accordance with Article 11.1, and
  - (v) if furnishing the Transport to an Alternative Destination intervention, the Participant must confirm the real-time capacity of the Alternative Destination to furnish the required level and type of care for the ET3 Model Beneficiary's illness or injury pursuant to the method described in Article 6.2(a)(ii).

### 6.2 <u>Transport to an Alternative Destination Intervention</u>

- (a) The Participant must make the Transport to an Alternative Destination intervention available to ET3 Model Beneficiaries in accordance with a CMS-accepted Implementation Plan, the Participant's Clinical Protocols, and this Article 6.2.
- (b) The Participant must, prior to making the Transport to an Alternative Destination intervention available to ET3 Model Beneficiaries:
  - (i) Update its ET3 List in accordance with Article 4.2(c)(ii) to include:
    - at least one Alternative Destination Partner that has agreed to furnish Medically Necessary Covered Services, or has arranged for Medically Necessary Covered Services to be furnished by a Downstream Practitioner of the Alternative Destination Partner, to ET3 Model Beneficiaries following Transport to an Alternative Destination, and
    - 2) if the Alternative Destination Partner cannot or does not intend to bill Medicare for such Covered Services, at least one Billing Party that has the capacity to bill Medicare for such Covered Services furnished by the Alternative Destination Partner or a Downstream Practitioner of the Alternative Destination Partner to ET3 Model Beneficiaries at an Alternative Destination of the Alternative Destination Partner following Transport to an Alternative Destination.

- (ii) Develop a method to ensure that an Alternative Destination has the real-time capacity to furnish the required level and type of care for an ET3 Model Beneficiary's illness or injury prior to transporting the ET3 Model Beneficiary to the Alternative Destination.
- (iii) Be capable of meeting the requirements of Article 6.1(e).
- (c) The Participant must ensure that each Transport to an Alternative Destination intervention furnished to an ET3 Model Beneficiary:
  - (i) is, in whole or in part, for the purpose of facilitating the ET3 Model Beneficiary's receipt of a Medically Necessary Covered Service by the Alternative Destination Partner or its Downstream Practitioner at an Alternative Destination, and
  - (ii) is made to the nearest appropriate Alternative Destination that has the real-time capacity to furnish the required level and type of care for the ET3 Model Beneficiary's illness or injury.

### 6.3 Optional Treatment in Place Intervention

#### (a) Eligibility

- (i) Except as specified in Article 6.3(a)(ii), the Participant may elect to implement the optional Treatment in Place intervention pursuant to Article 6.3(b) only if the Participant is implementing the Transport to an Alternative Destination intervention in accordance with Article 6.2.
- (ii) For Performance Year 1, the Participant may elect to implement the optional Treatment in Place intervention pursuant to Article 6.3(b) during any period of the Performance Year during which the PHE exists if:
  - 1) The Participant is not eligible to elect to implement the optional Treatment in Place intervention pursuant to Article 6.3(a)(i), and
  - 2) The Participant has made the necessary arrangements to make PHE Alternative Transports available to ET3 Model Beneficiaries during such period.

#### (b) Election

If eligible pursuant to Article 6.3(a)(i) or, for Performance Year 1, Article 6.3(a)(ii), the Participant may elect to implement the optional Treatment in Place intervention by stating so in the Implementation Plan in accordance with Article 5.1(b)(iv).

### (c) Implementation

- (i) If the Participant has elected to implement the optional Treatment in Place intervention, the Participant must make the Treatment in Place intervention available to ET3 Model Beneficiaries in accordance with a CMS-accepted Implementation Plan, the Participant's Clinical Protocols, and this Article 6.4(c).
- (ii) Prior to making the Treatment in Place intervention available to ET3 Model Beneficiaries and on an ongoing basis thereafter, the Participant must:
  - 1) Update its ET3 List in accordance with Article 4.2(c)(ii) to include:

- a) at least one Qualified Health Care Partner that has agreed to furnish Medically Necessary Covered Services, or has arranged for Medically Necessary Covered Services to be furnished by a Downstream Practitioner of the Qualified Health Care Partner, to ET3 Model Beneficiaries as part of a Treatment in Place intervention, and
- b) if the Qualified Health Care Partner cannot or does not intend to bill Medicare for such Covered Services, at least one Billing Party that has the capacity to bill Medicare for such Covered Services furnished by the Qualified Health Care Partner or a Downstream Practitioner of the Qualified Health Care Partner to ET3 Model Beneficiaries as part of a Treatment in Place intervention.
- 2) Obtain written consent in accordance with Article 6.3(d) and Article 6.3(e), and
- 3) Be capable of meeting the requirements of Article 6.1(e).
- (iii) The Participant must ensure that the Participant, a Medicare-Enrolled Qualified Health Care Partner, or a Downstream Practitioner is physically present at all times at the scene of the 9-1-1 emergency response where the Treatment in Place intervention is furnished.
- (d) Consent to Payment Terms for Services Furnished as part of a Treatment in Place intervention
  - (i) The Participant shall obtain written confirmation of consent to bill and receive payment for Covered Services furnished as part of a Treatment in Place intervention under the terms specified in Article 8.1, and Appendices B and C of this Agreement from each Medicare-Enrolled Qualified Health Care Partner that has agreed to furnish Covered Services as part of the Treatment in Place intervention to ET3 Model Beneficiaries and, if applicable, require each Qualified Health Care Partner that has agreed to arrange for Covered Services to be furnished to ET3 Model Beneficiaries as part of a Treatment in Place intervention by one or more Downstream Practitioners to obtain such consent from each of its Downstream Practitioners who have agreed to furnish Covered Services as part of the Treatment in Place intervention to ET3 Model Beneficiaries, as well as from any Billing Parties that have agreed to submit claims to Medicare for such Covered Services. Any such agreement must be signed by an individual legally authorized to act for the individual or entity through whose TIN the Qualified Health Care Partner, Downstream Practitioner, or Billing Party bills Medicare.
  - (ii) As part of the written confirmation of consent described in Article 6.3(d)(i), the individual legally authorized to act for the individual or entity through whose TIN the Medicare-Enrolled Qualified Health Care Partner, Downstream Practitioner, or Billing Party bills Medicare must verify the accuracy of the list of Medicare-Enrolled Qualified Health Care Partners, Downstream Practitioners, and Billing Parties billing under that TIN that have affirmatively consented to receive payment for Covered Services under the terms specified in Article 8.1 and Appendices B and C of this Agreement.

- (iii) The written confirmation of consent described in this Article 6.3(d) must be renewed annually in advance of the subsequent Performance Year in order for those Qualified Health Care Partners, Downstream Practitioners, and Billing Parties to continue to participate in the ET3 Model as a Qualified Health Care Partner, Downstream Practitioner, or Billing Party for that Performance Year.
- (e) Consent to After Hours Upward Payment Adjustment
  - (i) The Participant shall obtain written confirmation of consent to the After Hours Upward Payment Adjustment from each Medicare-Enrolled Qualified Health Care Partner that has agreed to furnish Covered Services to ET3 Model Beneficiaries as part of a Treatment in Place intervention and, if applicable, require each Qualified Health Care Partner that has agreed to arrange for Covered Services to be furnished to ET3 Model Beneficiaries as part of a Treatment in Place intervention by one or more Downstream Practitioners to obtain such consent from each of its Downstream Practitioners who have agreed to furnish Covered Services to ET3 Model Beneficiaries as part of a Treatment in Place intervention, as well as from any Billing Parties who have agreed to submit claims to Medicare for such Covered Services. Any such agreement must be signed by an individual legally authorized to act for the individual or entity through whose TIN the Qualified Health Care Partner, Downstream Practitioner, or Billing Party bills Medicare.
  - (ii) The individual who signs the consent to receive the After Hours Upward Payment Adjustment must verify the accuracy of the list of Medicare-Enrolled Qualified Health Care Partners, Downstream Practitioners, and Billing Parties billing under that TIN that have affirmatively consented to receive the After Hours Upward Payment Adjustment.
  - (iii) Consent to receive the After Hours Upward Payment Adjustment provided by a Medicare-Enrolled Qualified Health Care Partner, Downstream Practitioner, or Billing Party must be renewed annually in order for those Qualified Health Care Partners, Downstream Practitioners, or Billing Parties to continue to participate in the ET3 Model as a Qualified Health Care Partner, Downstream Practitioner, or Billing Party for that Performance Year.

### Article VII. Payment to Participant

### 7.1 General

(a) The Participant may receive payment for Transport to an Alternative Destination furnished to an ET3 Model Beneficiary as set forth in this Article VII and Appendix D of this Agreement. If the Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to implement the In-Person Treatment in Place Intervention, the Participant may receive payment for Covered Services furnished as part of initiating and facilitating an In-Person Treatment in Place Intervention as set forth in this Article VII and Appendix B of this Agreement. If the Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to implement the Telehealth Treatment in Place Intervention, the Participant may receive payment for Covered Services furnished

- as part of initiating and facilitating a Telehealth Treatment in Place Intervention as set forth in this Article VII and Appendix C of this Agreement.
- (b) The Participant may receive payment for only one Available Intervention per Encounter with an ET3 Model Beneficiary. If the Participant furnishes more than one Available Intervention to an ET3 Model Beneficiary during a single Encounter, the Participant may receive payment only for the Available Intervention furnished to the ET3 Model Beneficiary last in time during that Encounter.
- (c) If the Participant offers an ET3 Model Intervention to an ET3 Model Beneficiary and the ET3 Model Beneficiary chooses to decline the offer, the Participant must include a non-payable code specified by CMS to document the refusal on any claim submitted to CMS for an item or service furnished during the Encounter.
- (d) CMS will provide the Participant with billing guidelines for ET3 Model Interventions, including the applicable non-payable codes to document the refusal of an ET3 Model Intervention, as well as the appropriate claims modifiers and HCPCS-codes that are required for the Participant to receive payment for an ET3 Model Intervention.
- (e) CMS will pay the Participant for Medicare-Covered Ground Ambulance Transport and PHE Alternative Transport services furnished to an ET3 Model Beneficiary at the applicable Medicare FFS rates, pursuant to Medicare FFS rules and billing guidelines, including the applicable rules regarding debt collection.

### 7.2 Payment for Transport to an Alternative Destination

### (a) Eligibility

- (i) The Participant may receive payment for Transport to an Alternative Destination only if:
  - 1) The Participant has a CMS-accepted Implementation Plan;
  - 2) The Alternative Destination Partner is listed on the ET3 List in accordance with Article 4.2 and complies with the applicable terms and conditions of the Model as set forth in this Agreement;
  - The transport is to an Alternative Destination and is medically necessary as described in 42 C.F.R. § 410.40(e)(1); and
  - 4) The Participant submits the claim for payment to CMS and such claim includes the modifiers and HCPCS codes specified by CMS.

#### (b) Payment Rate

- (i) If the requirements of Article 7.2(a) are met, CMS will pay the Participant for Transport to an Alternative Destination at a rate equivalent to:
  - 1) The Medicare Part B Ambulance Fee Schedule (AFS) base rate, as calculated under 42 C.F.R. § 414.610, for emergency Basic Life Support (BLS-E) ground ambulance or emergency Advanced Life Support, Level 1 (ALS1-E) ground ambulance based on the level of service provided under the definitions of Basic life support (BLS),

- Advanced life support, level 1 (ALS1), and Emergency response at 42 C.F.R. § 414.605; and
- 2) Mileage rates and adjustments applicable to BLS-E or ALS1-E transports to a Medicare-covered destination as identified in 42 C.F.R. § 410.40(f)(1), including, but not limited to, the geographic adjustment factor at § 414.610(c)(4), the rural adjustment factors at 42 C.F.R. § 414.610(c)(5)(i) and (ii), rural and urban add-ons at 42 C.F.R. § 414.610(c)(1)(ii), the multiple patient rule, if applicable, at 42 C.F.R. § 414.610(c)(6), and the payment reduction for failure to report data at 42 C.F.R. § 414.610(c)(9).
- (ii) In order to bill and receive payment at the ALS1-E base rate, the Participant must provide Medically Necessary Covered Services and either an ALS assessment by ALS personnel or at least one ALS intervention as defined in 42 C.F.R. § 414.605.
- (iii) CMS will update the base payment rates annually to match the BLS-E and ALS1-E base rates in the Medicare Part B Ambulance Fee Schedule.

#### 7.3 Payment for Initiation and Facilitation of Treatment in Place

- (a) In-Person Treatment in Place Intervention
  - (i) Eligibility

The Participant may receive payment for initiating and facilitating an In-Person Treatment in Place Intervention in accordance with this Agreement only if:

- The Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to implement the In-Person Treatment in Place Intervention;
- 2) The Covered Service initiated and facilitated by the Participant as part of the In-Person Treatment in Place Intervention is Medically Necessary; and
- 3) The Participant submits the claim for payment to CMS and such claim includes the modifiers and HCPCS-codes specified by CMS.

#### (ii) Payment Rate

- 1) If the requirements of Article 7.3(a)(i) are met, CMS will pay the Participant for the initiation and facilitation of an In-Person Treatment in Place Intervention at a rate equivalent to the Medicare Part B AFS base rate, as calculated under 42 C.F.R. § 414.610, for BLS-E ground ambulance service or ALS1-E ground ambulance service based on the level of service provided under the definitions of Basic life support (BLS), Advanced life support, level 1 (ALS1), and Emergency response at 42 C.F.R. § 414.605.
- 2) In order to bill and receive payment at the ALS1-E base rate, the Participant must provide Medically Necessary supplies and services and either an ALS assessment by ALS personnel or at least one ALS intervention as defined in 42 C.F.R. §414.605.
- 3) CMS will update the base payment rates annually to match the BLS-E and ALS1-E base rates in the Medicare Part B Ambulance Fee Schedule.

#### (b) Telehealth Treatment in Place Intervention

#### (i) Eligibility

The Participant may receive payment for initiating and facilitating a Telehealth Treatment in Place Intervention in accordance with this Agreement only if:

- The Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to implement the Telehealth Treatment in Place Intervention;
- 2) The Covered Services initiated and facilitated by the Participant as part of the Telehealth Treatment in Place Intervention are Medically Necessary; and
- 3) The Participant submits the claim for payment to CMS and such claim includes the modifiers and HCPCS codes specified by CMS.

#### (ii) Payment Rate

- 1) If the requirements of Article 7.3(b)(i) are met, the Participant may receive payment from CMS for a Telehealth Treatment in Place Intervention at a base payment rate equivalent to the Medicare Part B AFS base rate, as calculated under 42 C.F.R. § 414.610, for BLS-E ground ambulance service or ALS1-E ground ambulance service based on the level of service provided under the definitions of Basic life support (BLS), Advanced life support, level 1 (ALS1), and Emergency response at 42 C.F.R. § 414.605.
- 2) In order to bill and receive payment at the ALS1-E base rate, the Participant must provide medically necessary supplies and services and either an ALS assessment by ALS personnel or at least one ALS intervention as defined in 42 C.F.R. § 414.605.
- 3) The base payment rate for a Telehealth Treatment in Place Intervention will be updated annually to match the BLS-E and ALS1-E base rates in the Medicare Part B Ambulance Fee Schedule for the year.

### 7.4 Performance-Based Payments

- (a) CMS will, in its sole discretion, determine the availability of performance-based upward payment adjustments for Model Participants, and the availability of such upward payment adjustments is not guaranteed. Prior to the start of Performance Year 3 of the Model Performance Period, CMS will notify the Participant whether performance-based payment adjustments will be made.
- (b) If CMS, in its sole and absolute discretion, offers performance-based payment adjustments to Model Participants, CMS may unilaterally amend this Agreement or any Appendix hereto as may be necessary to make such payments available to the Participant under this Agreement. CMS shall provide the Participant with 60 Days advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

#### Article VIII. Payment to ET3 Partners or their Billing Parties

8.1 Payment to Qualified Health Care Partners and their Billing Parties for Covered Services
Furnished as part of a Treatment in Place Intervention

#### (a) General

- (i) If the Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to implement the In-Person Treatment in Place intervention, CMS shall pay Qualified Health Care Partners and their Billing Parties for Covered Services furnished in accordance with this Agreement as part an In-Person Treatment in Place Intervention as set forth in this Article 8.1 and Appendix B of this Agreement. If the Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to implement the Telehealth Treatment in Place Intervention, CMS shall pay, Qualified Health Care Partners and their Billing Parties for Covered Services furnished in accordance with this Agreement as part of a Telehealth Treatment in Place Intervention as set forth in this Article 8.1 and Appendix C of this Agreement.
- (ii) CMS will provide the Participant with billing guidelines for ET3 Model Interventions, including appropriate claims modifiers and G-codes that are required for Qualified Health Care Partners and their Billing Parties to receive payment for a Treatment in Place intervention.

### (b) Eligibility

CMS shall pay a Qualified Health Care Partner or their Billing Party for Covered Services furnished in accordance with this Agreement as part of a Treatment in Place intervention as set forth in this Article 8.1 and Appendix C of this Agreement only if:

- (i) The Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to implement the Treatment in Place intervention in a manner that includes the type of Covered Service furnished by the Qualified Health Care Partner or their Downstream Practitioner;
- (ii) The Qualified Health Care Partner or their Billing Party is listed on the ET3 List in accordance with Article 4.2;
- (iii) The claim for the Covered Service includes the modifiers and codes specified by CMS; and
- (iv) The Covered Service is Medically Necessary.

#### (c) Payment Rate

Except as specified in Article 8.1(d), CMS shall pay a Medicare-Enrolled Qualified Health Care Partner or their Billing Party for Covered Services furnished as part of a Treatment in Place intervention at the applicable Medicare FFS rates, pursuant to Medicare FFS rules and billing guidelines, including the applicable rules regarding debt collection.

- (d) After Hours Upward Payment Adjustment
  - If the requirements of Article 8.1(b) and Article 6.3 are met, CMS shall pay a Qualified Health Care Partner or their Billing Party, the After Hours Payment for After Hours Services.
- (e) Loss of Telehealth Technology Connection during a Telehealth Treatment in Place Intervention
  - (i) If a Telehealth Service being furnished to an ET3 Model Beneficiary as part of a Telehealth Treatment in Place Intervention is interrupted due to poor connectivity and the Telehealth Service cannot be completed, a Medicare-enrolled Qualified Health Care Partner or Billing Party may bill and receive payment for the Telehealth Service only if the Telehealth Service is substantially completed when the disruption occurs and the requirements of Article 8.1(b) and Article 6.3 are met.
  - (ii) If the Participant, a Qualified Health Care Partner, or a Downstream Practitioner offers an ET3 Model Beneficiary an Available Intervention during an Encounter in which a Telehealth Service was initiated as part of a Telehealth Treatment in Place Intervention, but could not be completed due to an interruption in connectivity, the Telehealth Service initiated during the failed Telehealth Treatment in Place Intervention is not substantially completed.
- 8.2 <u>Payment to Alternative Destination Partners or their Billing Parties for Covered Services</u> <u>furnished after Transport to an Alternative Destination</u>

CMS shall pay for Covered Services furnished to an ET3 Model Beneficiary by an Alternative Destination Partner or their Downstream Practitioner following Transport to an Alternative Destination at the applicable Medicare FFS rates, pursuant to Medicare FFS rules and billing guidelines, including the applicable rules regarding debt collection.

## Article IX. Payment to CMS

#### 9.1 Payment in Error

- (a) If CMS determines that a payment made by CMS pursuant to Article 7 or Article 8 was made in error, CMS shall send the Participant, Qualified Health Care Partner, or Billing Party a demand letter for the amount of such payment, and may take a remedial action as described in Article 19. The Participant, Qualified Health Care Partner, or Billing Party, as applicable, shall pay any such amount within 30 Days of the date of the demand letter.
- (b) If CMS does not receive payment of the full amount owed by the date specified in the demand letter, CMS may assess interest at the rate applicable to other Medicare debts pursuant to 42 C.F.R. §405.378 on any outstanding unpaid amounts. Interest will be calculated in 30-day periods and assessed for each 30-day period that payment is not made in full.
- (c) If the Participant, a Qualified Health Care Partner, or Billing Party fails to pay CMS the full amount owed by the date specified in the demand letter, CMS will recoup monies owed from present and future Medicare payments otherwise owed to the Participant, Qualified Health Care Partner, or Billing Party, as applicable. If CMS is unable to recoup the full amount owed via Medicare payments, CMS will invoke all legal means to collect the debt,

including referral of the remaining debt to the United States Department of Treasury, pursuant to 31 U.S.C. 3711(g).

### Article X. Medicare Payment Waivers

#### 10.1 General

CMS finds it necessary solely for purposes of testing the Model to waive the requirements of Title XVIII of the Act set forth in this Agreement pursuant to Section 1115A(d)(1) of the Act. CMS reserves the right to reconsider these waivers and, where the public interest requires, to amend this Agreement without the consent of the Participant to modify or terminate these waivers at any time. CMS may also amend this Agreement without the consent of the Participant if CMS determines, in CMS's sole discretion, that it is necessary to waive additional Medicare payment requirements solely for purposes of testing the Model.

## 10.2 <u>Transport to an Alternative Destination</u>

Appendix D specifies the waivers necessary solely for purposes of testing the Transport to an Alternative Destination intervention and shall remain in effect for the duration of the Model Performance Period, unless this Agreement is sooner terminated or CMS sooner modifies or terminates such waivers.

#### 10.3 In-Person Treatment in Place

Appendix B specifies the waivers necessary solely for purposes of testing the In-Person Treatment in Place Intervention and shall apply to this Agreement only for those periods of the Model Performance Period during which the Participant implements the In-Person Treatment in Place Intervention to ET3 Model Beneficiaries in accordance with a CMS-accepted Implementation Plan.

#### 10.4 Telehealth Treatment in Place

Appendix C specifies the waivers necessary solely for purposes of testing the Telehealth Treatment in Place Intervention and shall apply to this Agreement only for those periods during the Model Performance Period during which the Participant implements the Telehealth Treatment in Place Intervention to ET3 Model Beneficiaries in accordance with a CMS-accepted Implementation Plan.

### Article XI. Beneficiary Protections

#### 11.1 Beneficiary Notifications

(a) The Participant must develop, maintain, and implement written processes to obtain and document ET3 Model Beneficiary consent and/or refusal of an offer by the Participant, an ET3 Partner, or Downstream Practitioner to furnish Covered Services related to an ET3 Model Intervention during an Encounter, consistent with all applicable federal, state, and local laws and requirements. Documentation of such processes, both current and historical, must be maintained in accordance with Article 18.2.

- (b) Information and education provided to beneficiaries for purposes of obtaining their consent or refusal for Covered Services in compliance with this Article 11.1 is not considered promotion, marketing, or advertising for the purposes of Article 11.4.
- (c) The Participant must ensure that ET3 Model Beneficiaries are entitled to the same notifications as all other Medicare beneficiaries, including Advance Beneficiary Notices, if applicable. The Participant may reference the Medicare Claims Processing Manual, Chapter 30, Sections 40.3, 40.4, 50.15.2 for guidance on applicable policies on Emergencies or Urgent Situations / Ambulance Transport.
- (d) The Participant must ensure that any notice furnished to an ET3 Model Beneficiary for purposes of complying with this Article 11.1 is provided in such a way that it addresses the needs of the ET3 Model Beneficiary and their families and/or caregivers with limited English proficiency or low or limited health literacy.

#### 11.2 Availability of Services

The Participant must not restrict, and must require ET3 Partners and Downstream Practitioners not to restrict an ET3 Model Beneficiary's access to Medically Necessary Covered Services. The Participant must make, and must require ET3 Partners and Downstream Practitioners to make, Medically Necessary Covered Services available to ET3 Model Beneficiaries in accordance with all applicable laws and regulations, as well as the Participant's Clinical Protocols. ET3 Model Beneficiaries and their appointed representatives and assignees retain their right to appeal claims determinations in accordance with 42 C.F.R. Part 405, Subpart I.

### 11.3 <u>Beneficiary Freedom of Choice</u>

- (a) Consistent with Section 1802(a) of the Act, the Participant, ET3 Partners, Downstream Practitioners, or other individuals or entities performing functions or services related to ET3 Model Interventions shall not commit any act or omission, nor adopt any policy, that inhibits beneficiaries from exercising their freedom to receive Medicare-Covered Ground Ambulance Transport or PHE Alternative Transport, to decline such transport, or to decline an ET3 Model Intervention offered to the beneficiary, including transport to a specific Alternative Destination, subject to state and local EMS protocols, Medicare program requirements, and any applicable licensing guidelines or rules.
- (b) Notwithstanding the foregoing, during an Encounter, the Participant may communicate to ET3 Model Beneficiaries the benefits of receiving ET3 Model Interventions from the Participant, ET3 Partners, or Downstream Practitioners.
- (c) Subject to Medicare program requirements, the Participant must furnish Medicare-Covered Ground Ambulance Transport or PHE Alternative Transport to an ET3 Model Beneficiary if, at any time prior to the conclusion of the Encounter, an ET3 Model Beneficiary chooses to access treatment via Medicare-Covered Ground Ambulance Transport.

#### 11.4 <u>Prohibition of Promotion and Inducements</u>

(a) The Participant is prohibited, and shall prohibit its ET3 Partners, Downstream Practitioners, and Billing Parties from providing gifts or other remuneration to ET3 Model Beneficiaries to

- induce them to receive ET3 Model Interventions from the Participant, an ET3 Partner, or a Downstream Practitioner.
- (b) The Participant shall not, and shall require that its ET3 Partners, Downstream Practitioners, and Billing Parties do not, promote, market, or advertise the availability of ET3 Model Interventions, including, but not limited to, encouraging Patients to utilize 9-1-1 to access ET3 Model Interventions.

# 11.5 Beneficiary Privacy and Patient Data Sharing

- (a) Health Insurance Portability and Accountability Act (HIPAA) Requirements
  - (i) The Participant acknowledges that it is a covered entity or a business associate, as those terms are defined in 45 C.F.R. §160.103.
  - (ii) The Participant shall have all appropriate administrative, technical, and physical safeguards in place before the start of the Model Performance Period to protect the privacy and security of PHI in accordance with 45 C.F.R. §164.530(c).
  - (iii) The Participant shall maintain the privacy and security of all Model-related information that identifies individual beneficiaries in accordance with the HIPAA Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and business associates, including 42 C.F.R. Part 2, as well as applicable state laws and regulations, for as long as the Participant retains the data, which may extend beyond the Model Performance Period.

# Article XII. Participation in Evaluation; Shared Learning Activities; and Site Visits

## 12.1 <u>Evaluation Requirements</u>

- (a) General
  - (i) CMS will contract with an independent evaluator to evaluate the Model in accordance with Section 1115A(b)(4) of the Act.
  - (ii) Consistent with the requirements of 42 C.F.R. § 403.1110, the Participant shall participate and cooperate in the evaluation activities described in Article 12.1(a)(iii) during the Model Performance Period and for six months thereafter to enable CMS and/or its designees to track and obtain any and all relevant data as may be needed for the Model evaluations, and shall require its ET3 Partners and Downstream Practitioners to participate and cooperate in the same.
  - (iii) Evaluation activities may include, but are not limited to:
    - 1) Supplying data to measure quality of care;
    - 2) Participating in surveys, interviews, and site visits; and
    - 3) Participating in other activities deemed necessary by CMS to conduct a comprehensive formative and summative Model evaluation.

(iv) The Participant shall ensure that it has written arrangements and/or legal relationships with any individuals or entities performing functions and services related to the Model that are necessary to ensure the Participant can participate and cooperate in the evaluation activities described in Article 12.1(a)(iii).

# (b) 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,
- (ii) surveys,
- (iii) interviews with Patients and their caregivers,
- (iv) focus groups of Patients and their caregivers,
- (v) interviews with the Participant, its ET3 Partners and Downstream Practitioners, Billing Parties, and/or their staff,
- (vi) focus groups with the Participant, its ET3 Partners and Downstream Practitioners, Billing Parties, and/or their staff,
- (vii) direct observation of ET3 Model Beneficiary interactions with the Participant, ET3
  Partner, and Downstream Practitioner staff and other activities related to the
  Participant's participation in the Model, and
- (viii) PCR Data.

## (c) Secondary Data

In its evaluation activities, CMS or its designee(s) may use data or information submitted by or made available by the Participant as well as claims submitted to CMS for items and services furnished to beneficiaries. These data may include, but are not limited to:

- (i) claims data,
- (ii) survey data,
- (iii) clinical data such as lab values,
- (iv) medical records, and
- (v) Clinical Protocols, Implementation Plan, or other Model implementation documents.

## 12.2 Shared Learning Activities

- (a) The Participant shall actively participate in the Learning System designed by CMS to strengthen results and share learning that emerges from participation in the Model. Specifically, the Participant shall:
  - (i) Participate in Learning System activities throughout the term of this Agreement, including during the period after the Effective Date but prior to the Start Date. By the end of the second quarter following the Start Date, the Participant shall develop and submit to CMS, in a form and manner specified by CMS, a visual display of what drives

- achievement of Participant's implementation aim ("Driver Diagram") designed to drive toward the achievement of project aim as well as the inclusion of objectives and key results ("OKRs"). CMS will work with the Participant to provide sufficient instruction on Driver Diagram and OKR development. The Participant shall annually update the Driver Diagram and OKRs and submit to CMS;
- (ii) Respond to surveys, interviews, or other assessment mechanisms from CMS or its designees in order to assist CMS in identifying Participant learning needs;
- (iii) Participate in the identification and dissemination of promising practices, challenges, and other opportunities useful for learning, peer-to-peer sharing, and overall improvement across Model Participants (e.g., presenting on webinars, spotlights, etc.);
- (iv) Participate in required ET3 Model Learning System activities during the Model Performance Period, including up to one virtual Learning System activity every quarter. Repeated failure to actively participate in required Learning System activities and related events could result in remedial action and/or termination of this Agreement pursuant to Article 19;
- (v) Develop, track, and report to CMS on quality improvement efforts, activities, and program measures, at regular intervals; and
- (vi) Participate in at least one in-person Learning System event during the Model Performance Period. The location of each in-person event will be made at CMS's sole discretion. In-person events may be held in the Baltimore/District of Columbia area or another location. These events will focus on Model Participant learning, collaboration, dissemination of ET3 Model promising practices, and other Model Participant needs. This event may be conducted virtually, subject to CMS discretion.
- (b) The Participant shall ensure ET3 Partners, Downstream Practitioners, and any non-Medicare payers with which the Participant has partnered with as part of the Participant's Payer Strategy described in Article 5.2. are informed of the opportunity to participate in the ET3 Model's Learning System activities. CMS will aim to design Learning System events relevant to ET3 Partners, Downstream Practitioners, and non-Medicare payers.

# 12.3 Site Visits

- (a) The Participant shall cooperate in periodic site visits by CMS and/or its designees in order to facilitate evaluation, Learning System activities, monitoring, or the fulfilment of the terms of this Agreement, and shall require ET3 Partners, Downstream Practitioners, and Billing Parties to participate and cooperate in the same. Site visits may involve virtual or inperson interviews with executive leadership, staff, and individuals or entities performing functions related to the Model. The duration of a site visit will depend on the size and complexity of the Participant, ET3 Partner, Downstream Practitioner, or Billing Party.
- (b) CMS or its designees shall provide the Participant with no less than 3 Days advance notice of site visits. To the extent practicable, CMS will attempt to accommodate the Participant's request for particular dates in scheduling site visits. However, the Participant may not request a date that is more than 60 Days after the date of the initial site visit notice from CMS.

- (c) Notwithstanding the foregoing, and to the extent feasible, CMS may perform unannounced site visits at the office of any Model Participant, ET3 Partner, Downstream Practitioner, or Billing Party at any time to investigate concerns about the health or safety of beneficiaries or other program integrity issues.
- (d) The Participant shall ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during site visits.
- (e) Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

# 12.4 Rights in Data and Intellectual Property

- (a) CMS may use any data obtained pursuant to the Model to evaluate and monitor the Model and to disseminate quantitative and qualitative results, including factors associated with successful approaches to ET3 Model implementation and multi-payer participation, to Model Participants and the public. Data to be disseminated may include measures based upon claims, medical records, and other data sources.
- (b) The Participant may be permitted to comment on evaluation reports for factual accuracy but may not edit conclusions or control the dissemination of reports.
- (c) Notwithstanding any other provision in this Agreement, all proprietary trade secret information and technology of the Participant, an ET3 Partner, a Downstream Practitioner, or a Billing Party is and shall remain the sole property of the Participant, ET3 Partner, Downstream Practitioner, or Billing Party and, except as required by Federal law, shall not be released by CMS or its designee(s) without the express written consent of the Participant. The regulation at 48 C.F.R. § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into this Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the proprietary information or technology of the Participant, ET3 Partners, Downstream Practitioners, or Billing Parties.
- (d) The Participant shall submit to CMS a form identifying any specific examples of what the Participant considers proprietary and confidential information currently contained in its program that should not be publicly disclosed. The template for this form is attached as Appendix A of this Agreement. In a form and manner established by CMS, the Participant may resubmit the form to CMS as may be necessary to identify additional examples of what the Participant considers proprietary and confidential information during the Agreement Term.

# Article XIII. Participant Release of Information

# 13.1 CMS Prior Approval

The Participant shall, and shall require its ET3 Partners, Downstream Practitioners, and Billing Parties to, obtain prior approval from CMS during the Model Performance Period and for six months thereafter for the publication or release of any press release, beneficiary education materials, external report or statistical/analytical material that materially and substantially references the participation of the Participant, an ET3 Partner, a Downstream Practitioner, or a

Billing Party in the Model or the financial arrangement between the Participant and CMS. External reports and statistical/analytical material may include, but are not limited to, papers, articles, professional publications, speeches, and testimony.

### 13.2 Required Disclaimer

All external reports and statistical/analytical material that are subject to the requirements of Article 13.1 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

# Article XIV. Compliance and Oversight

## 14.1 Participant Compliance Plan

- (a) Throughout the Model Performance Period, the Participant must implement and maintain a plan for compliance with the terms of the Agreement and with all applicable laws and regulations ("Compliance Plan") and must update the Compliance Plan periodically to reflect any amendments to this Agreement, any changes due to local, state or federal emergency declarations and any changes in applicable laws and regulations.
- (b) The Compliance Plan must include:
  - (i) The basic elements of a compliance program for ambulance suppliers identified in the HHS Office of Inspector General's Compliance Program Guidance for Ambulance Suppliers<sup>1</sup>, including but not limited to:
    - Development and distribution of written standards of conduct, as well as written
      policies and procedures that reflect the Participant's commitment to compliance
      and address specific areas of potential fraud or abuse;
    - 2) Designation of a compliance officer who is not legal counsel and appropriate bodies (e.g., a compliance committee) that report directly to the organization's upper management and are charged with responsibility for operating and monitoring the Participant's compliance program;
    - 3) Regular compliance training and education for the Participant, including Model-related compliance training and education for ET3 Partners, Downstream Practitioners, Billing Parties, and other individuals or entities performing functions or services related to ET3 Model Interventions;
    - 4) Mechanisms for identifying and appropriately addressing compliance problems related to the Participant's operations and performance, including activities related to the Model that are performed by ET3 Partners, and Downstream

<sup>&</sup>lt;sup>1</sup> The HHS Office of Inspector General's Compliance Program Guidance for Ambulance Suppliers uses the term "ambulance suppliers" to refer to both ambulance suppliers and ambulance providers. *See* 68 Fed. Reg. 14245, 14246 (March 24, 2003).

- Practitioners, Billing Parties, and other individuals or entities performing functions or services related to ET3 Model Interventions;
- 5) A method for employees or contractors of the Participant, ET3 Partners, Downstream Practitioners, Billing Parties, and other individuals or entities performing functions or services related to ET3 Model Interventions to anonymously report to the compliance official suspected problems related to the Participant, including an ET3 Partner's, Downstream Practitioner's, Billing Parties', or other individual's or entity's noncompliance with obligations set forth in an arrangement entered into pursuant to the terms of this Agreement; and
- A requirement for the Participant to report probable violations of law to an appropriate law enforcement agency.
- (ii) A plan for avoiding inappropriate utilization of ET3 Model Interventions, including overutilization of such interventions and under-triaging of ET3 Model Beneficiaries who are transported to an Alternative Destination and, if applicable, receive a Treatment in Place intervention. This includes ensuring that any Transport to an Alternative Destination does not duplicate a Medicare-Covered Ground Ambulance Transport or PHE Alternative Transport.
- (iii) A plan for successfully implementing the ET3 Model Interventions within the context of applicable federal, state, and County or Equivalent Entity EMS laws, regulations, and policies, including the Emergency Medical Treatment & Labor Act (EMTALA); applicable laws and scope of practice rules governing the provision of emergency medical services by ambulance suppliers and providers, ET3 Partners, and Downstream Practitioners; and policies of the Participant, ET3 Partners, and Downstream Practitioners.
- (iv) Identification of a governing body or other organizational mechanisms that will make and execute decisions related to the Model; develop, implement, and monitor Clinical Protocols, including quality and safety practices; and develop and oversee compliance with federal fraud and abuse requirements.
- (c) In a form and manner determined by CMS, the Participant must notify CMS of any material changes to the Compliance Plan within 30 days of the change including, but not limited to, any changes to the Participant's ability to implement the Model in compliance with state, local, or federal laws, regulations, protocols, or other requirements including EMTALA and any failure to gain or maintain approval for Clinical Protocols or to meet requirements to operate as a 9-1-1 emergency ambulance supplier or provider within any state located (in whole or in part) in the Model Region that are necessary for implementation of the Model.

#### 14.2 Compliance with Monitoring and Oversight Activities

## (a) General

(i) Consistent with the requirements of 42 C.F.R. § 403.1110, the Participant shall comply fully with, and shall require ET3 Partners and Downstream Practitioners to comply fully with, all CMS monitoring and oversight requests and activities, including:

- 1) Providing data related to the Participant, ET3 Partners, Downstream Practitioners, Billing Parties, and Patients in accordance with applicable law;
- Promptly submitting a list of all the Downstream Practitioners and Billing Parties
  of one or more of the Participant's ET3 Partners to CMS and its designees, upon
  request;
- 3) Being available for site visits by CMS and its designees at their respective facilities in accordance with the terms of the Agreement;
- 4) Providing all information and documentation related to desk and in-person audits as required and requested by CMS staff and its designees;
- 5) Participating in surveys and interviews as requested by CMS and its designees; and
- 6) Tracking ongoing monitoring information, including operational metrics and measures related to performance improvement efforts and providing such information to CMS and its designees, upon request.

# (b) Agreement to Comply

- (i) The Participant shall comply with, and shall require all ET3 Partners, Downstream Practitioners, and Billing Parties to comply with, all applicable statutes, rules, and regulations, including, without limitation: (a) federal criminal laws; (b) the False Claims Act (31 U.S.C. 3729 et seq.); (c) the anti-kickback statutes (42 U.S.C. 1320a-7b(b)); and (d) the civil monetary penalties law (42 U.S.C. 1395nn).
- (ii) This Agreement does not waive any obligation of the Participant, ET3 Partners, Downstream Practitioners, or Billing Parties to comply with the terms of any other CMS contract, agreement, Model, or demonstration.
- (c) Office of Inspector General of the Department of Health and Human Services (OIG)
  Authority

None of the provisions of this Agreement limit or restrict the OIG's authority to audit, evaluate, investigate, or inspect the Participant, ET3 Partners, Downstream Practitioners, or Billing Parties.

## (d) Reservation of Rights

(i) Nothing contained in this Agreement or in the application process for the Model is intended or shall be construed as a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of Inspector General, or CMS of any right to institute any proceeding or action against defendants for violations of any statutes, rules or regulations administered by a federal agency, or to prevent or limit the rights of the federal government to obtain relief under any other federal statutes or regulations, or on account of any violation of this Agreement or any other provision of law. This Agreement shall not be construed to bind any federal agency except CMS, and this Agreement binds CMS only to the extent provided herein.

- (ii) The submission of any information, Clinical Protocols, plans, strategies or documents during the Model application process or otherwise does not imply that CMS has reviewed or approved the information, Clinical Protocols, plans, strategies, or documents.
- (iii) CMS provides no opinion on the legality of any information, Clinical Protocols, plans, strategies, or documents that the Participant has proposed, implemented, or documented. The receipt by CMS of any such items in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules or regulations, and will not preclude CMS, HHS or its Office of Inspector General, a law enforcement agency, or any other federal, state, or local agency from enforcing any and all applicable laws, rules, and regulations.
- (iv) The failure by CMS to require performance of any provision of this Agreement does not affect CMS's right to require performance at any time thereafter, nor does 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.

# (e) Other Authority

None of the provisions of this Agreement limit or restrict any other government authority that is permitted by law to audit, evaluate, investigate, or inspect the Participant, ET3 Partners, Downstream Practitioners, or Billing Parties.

- (f) Monitoring for Participant Compliance
  - (i) CMS shall screen and continuously monitor the Participant, ET3 Partners, Downstream Practitioners, and Billing Parties throughout the Model Performance Period to prevent, identify, and respond to potential fraud, waste, and abuse related to the Model. At CMS's discretion, the Participant, ET3 Partners, Downstream Practitioners, and Billing Parties will be subject to periodic Program Integrity Screenings.
  - (ii) CMS shall conduct monitoring activities to evaluate compliance by the Participant with the terms of this Agreement. Such monitoring activities may include, without limitation:
    - 1) collection and analysis of the Participant's data submitted pursuant to this Agreement, including data submitted as required under Article 16;
    - 2) interviews with any individual or entity involved in ET3 Model Interventions such as members of the Participant's leadership and management or the leadership and management of an ET3 Partner, a Downstream Practitioner, or a Billing Party;
    - monitoring for inappropriate provision of care, including, but not limited to, unsafe Patient care practices and overutilization of services associated with the Model;
    - obtaining information regarding any financial arrangements between the Participant and its ET3 Partners, Downstream Practitioners, and Billing Parties;

- 5) audits of charts, medical records, and other data from the Participant, ET3 Partners, Downstream Practitioners, and Billing Parties;
- 6) site visits (including on-site visits and desk audits) to the Participant, ET3 Partners, Downstream Practitioners, and Billing Parties;
- 7) requests sent to the Participant, ET3 Partners, Downstream Practitioners, and Billing Parties including surveys and questionnaires; and
- analysis of supporting documentation submitted by the Participant as part the Application (e.g., any letters of intent or arrangements between the Participant and an ET3 Partner; documents about the Participant's sanctions, or other actions; past or current investigation information; financial arrangement documents) or submitted pursuant to this Agreement, including initial and updated information.
- (iii) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including, without limitation, service utilization and referral patterns by the Participant, ET3 Partners, Downstream Practitioners, and Billing Parties, as well as Medicare claims submitted for items or services furnished to ET3 Model Beneficiaries.
- (iv) CMS will assess metrics that measure the Participant's implementation activities (implementation efficacy, Patient safety, billing behaviors, and overall impact on Model aims) throughout the entirety of the Model Performance Period. These performance metrics will be compared against the Participant's own data, including, but not limited to, PCR Data and CMS claims data from before and after the Start Date that is collected by CMS in accordance with Article 16, and compared to multiple groupings of Model Participants, to identify outlier behavior, unintended consequences, and other instances that suggest the Participant is struggling to implement Model requirements or may be engaging in potentially fraudulent activity.

## (g) Monitoring for Model Impact

Using claims and other data reported by the Participant, CMS and its designees may monitor the Model's impact on quality of care and the broader EMS system in the Model Region to determine whether the Model transforms care delivery appropriately, without resulting in negative unintended consequences. Such monitoring efforts may include, but are not limited to, measurements of:

- (i) Proportion of dispatches that result in transport;
- (ii) Adherence to Clinical Protocols;
- (iii) EMS response time from dispatch to arrival on scene for critical illness;
- (iv) Patterns of frequent utilization of services by beneficiaries, the Participant, ET3
  Partners, and Downstream Practitioners, including multiple Encounters for the same
  ET3 Model Beneficiary in the same Day and overutilization of ET3 Model
  Interventions including services associated with Treatment in Place; and

(v) Diagnostic codes for services furnished by ET3 Partners and Downstream Practitioners as part of a Treatment in Place intervention or at Alternative Destinations.

## Article XV. Data Sharing and Reports

#### 15.1 General

- (a) CMS may elect to provide, and Participant retains the right to request, aggregate data from CMS regarding the Participant's progress in the Model, which may be used to facilitate the Participant's learning, and certain other data as described in Article 16.2 and Article 16.3 of this Agreement. CMS retains the right to accept, reject, or defer the Participant's requests for data due to availability of data dashboards, analysis time and frequencies, level of effort to retrieve the data, quantity of data, or other reasons. If such a request is accepted, the Participant may view the aggregate data in a form and manner and at a time determined by CMS.
- (b) Data provided to the Participant will be aggregate data that have been fully de-identified in accordance with the HIPAA Privacy Rule, 45 C.F.R. § 164.514(b)(2).

# 15.2 Provision of Certain De-Identified Data for Quality Improvement and Safety

- (a) Upon request by the Participant or as indicated by monitoring data, CMS and its designees may provide de-identified, aggregate data to the Participant for the purpose of supporting the Participant's efforts to comply with Article 5.5(a), which requires the Participant to continuously implement and track quality improvement and safety practices.
- (b) The Parties mutually agree that CMS retains all ownership rights to all data furnished to the Participant by CMS. The Participant does not obtain any right, title, or interest in any of the data furnished by CMS.
- (c) The Participant represents and warrants that the use of data provided by CMS under this Article 15.2 will be used solely to develop and implement improvements in the quality and efficacy of care provided under the Model to Patients, including the quality of the Participant's own Clinical Protocols and Triage Decisions or to implement the Multi-Payer Strategy, as applicable.

# 15.3 Provision of De-Identified Dashboard and Summary Information

When provided by CMS to all Model Participants or as the result of the Participant's data request, the following data will be provided at the aggregate level and will be de-identified in accordance with 45 C.F.R. § 164.514(b)(2):

- (a) Dashboards comparing the Participant performance on quality metrics to a baseline comparison developed by CMS; and
- (b) Summary tables with the Participant's aggregate performance data over the course of the Model Performance Period.

## Article XVI. Submission of Required Data

# 16.1 General

For the duration of the Model Performance Period, the Participant must periodically submit all required data specified in Article 16.3 ("Required Data") to CMS for the purposes of Model monitoring and evaluation.

# 16.2 Submission Timing and Contents

## (a) Initial Data Submission

- (i) No later than 60 Days prior to the date of the initial submission of Required Data to CMS ("Initial Data Submission"), CMS will notify the Participant of the deadline and form and manner for the Initial Data Submission and each of the subsequent data submissions. The date of the Initial Data Submission will be no earlier than February of 2021.
- (ii) By the deadline for the Initial Data Submission, the Participant must submit:
  - all Required Data for all Patients seen by the Participant in an interval of time which begins on the Start Date and ends on a date prior to the Initial Data Submission that will be specified by CMS, and
  - 2) required Data for dates of service for a period of time specified by CMS, which will be up to two calendar years prior to the Start Date.

## (b) Subsequent Data Submissions

- (i) After the Initial Data Submission, by a deadline and in a form and manner specified by CMS, the Participant must submit all Required Data for Patients no less frequently than once per calendar month.
- (ii) The final data submission will include all dates of service up to the last Day of the Model Performance Period and will be submitted no later than 90 Days after the end of the Model Performance Period.

## 16.3 Required Data

- (a) The Required Data for Performance Year 1 include those PCR Data specified by CMS no later than 60 Days prior to the Initial Submission Date.
- (b) On an annual basis, CMS may provide an updated list of PCR Data that the Participant must submit to CMS.
- (c) If CMS updates the Required Data list in accordance with Article 16.3(b) to include additional PCR Data, the Participant may be required to submit those new data for dates of service up to one calendar year prior to the Start Date.
- (d) Failure to submit all Required Data in the form and manner and by the deadline specified by CMS may result in CMS taking remedial action under Article 19.

# 16.4 CMS Quality Reporting Initiatives

The Participant, ET3 Partners, Downstream Practitioners, and Billing Parties must continue to participate in all applicable CMS quality reporting initiatives for the duration of the Model.

## Article XVII. Certification of Data and Information

### 17.1 General

With respect to data and information that are generated or submitted by the Participant, ET3 Partners, Downstream Practitioners, or Billing Parties related to implementation of the Model, the Participant shall ensure that an individual with the authority to legally bind the individual or entity submitting such data or information certifies the accuracy, completeness, and truthfulness of the data and information to the best of their knowledge, information, and belief.

## 17.2 Annual Certification

- (a) At the end of each Performance Year, an individual with the legal authority to bind the Participant must certify to the best of their knowledge, information, and belief:
  - (i) that the Participant, ET3 Partners, Downstream Practitioners, Billing Parties, and other individuals and entities performing functions or services related to ET3 Model Interventions are in compliance with the applicable Model requirements, and
  - (ii) that all data and information related to ET3 Model Interventions that are generated or submitted by the Participant, ET3 Partners, and, if applicable, Downstream Practitioners and Billing Parties are accurate, complete, and truthful.

## Article XVIII. Audits and Record Retention

## 18.1 Right to Audit and Correction

- (a) The Participant agrees, and must require all ET3 Partners, Downstream Practitioners, Billing Parties, and other individuals and entities performing functions or services related to ET3 Model Interventions to agree that the federal government, including CMS, HHS, and the Comptroller General or their designees, has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents, and other evidence of the Participant, ET3 Partners, Downstream Practitioners, Billing Parties, and other individuals and entities performing functions or services related to ET3 Model Interventions that pertain to the following:
  - (i) The Participant's compliance with this Agreement, including provisions that require the Participant to impose duties or requirements on ET3 Partners, Downstream Practitioners, and Billing Parties;
  - (ii) Whether ET3 Partners, Downstream Practitioners, and Billing Parties complied with the duties and requirements imposed on them by the Participant pursuant to the terms of this Agreement;
  - (iii) Patient complaints and appeals;
  - (iv) The quality of the services performed under this Agreement; and
  - (v) ET3 Model Beneficiary medical records.

### 18.2 Maintenance of Records

- (a) The Participant agrees, and must require all ET3 Partners, Downstream Practitioners, and Billing Parties to agree, to the following:
  - (i) To maintain and give the 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 other financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Participant's compliance with this Agreement, including provisions that require the Participant to impose duties or requirements on ET3 Partners, Downstream Practitioners, and Billing Parties; whether ET3 Partners, Downstream Practitioners, or Billing Parties complied with the duties and requirements imposed on them by the Participant pursuant to the terms of this Agreement; the quality of services furnished to ET3 Model Beneficiaries under the Model; and the Participant's obligation and ability to repay any monies owed to CMS.
  - (ii) To maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:
    - CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Participant at least 30 Days before the normal disposition date; or
    - There has been a termination, dispute, or allegation of fraud or similar fault against the Participant, ET3 Partners, Downstream Practitioners, or Billing Party related to the ET3 Model, 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.

## Article XIX. Remedial Action and Termination

# 19.1 Remedial Action

If CMS determines through monitoring or otherwise that the Participant, an ET3 Partner, a Downstream Practitioner, or Billing Party is not in compliance with the applicable terms of this Agreement, CMS may take one or more of the following actions:

- (a) Notify the Participant and, if appropriate, ET3 Partner, Downstream Practitioner, and/or Billing Party of the violation by warning letter, email, or otherwise;
- (b) Require the Participant to provide additional information to CMS or its designees;
- (c) Conduct on-site visits and/or desk audits, interview Patients after receipt of an ET3 Model Intervention, or take other actions to gather information;
- (d) Place the Participant on a monitoring and/or auditing plan developed by CMS;

- (e) Require the Participant to cease transportation of ET3 Model Beneficiaries to an Alternative Destination and/or to terminate the Participant's arrangement, immediately or within a timeframe specified by CMS, with an Alternative Destination Partner with respect to this Model;
- (f) Require the Participant to cease utilization of a Qualified Health Care Partner and/or to modify or terminate the Participant's arrangement, immediately or within a timeframe specified by CMS, with such Qualified Health Care Partner with respect to this Model or require the Participant to require the Qualified Health Care Partner to cease utilization of a Downstream Practitioner and/or to modify or terminate the Qualified Health Care Partner's arrangement, immediately or within a timeframe specified by CMS, with such Downstream Practitioner with respect to this Model;
- (g) Require the Participant to terminate its relationship with any other individual or entity performing functions or services related to the ET3 Model;
- (h) Terminate or temporarily suspend the ability of the Participant, Qualified Health Care Partners, or Billing Parties to receive payment under any or all waivers of existing law made pursuant to Section 1115A(d)(1) of the Act and established in Appendices B, C, or D of this Agreement;
- (i) Request a corrective action plan ("CAP") from the Participant that is acceptable to CMS, with respect to which the following requirements:
  - (i) The Participant shall submit a CAP for CMS approval by a deadline established by CMS;
  - (ii) The CAP must address what actions the Participant will take, or will require any ET3
    Partners, Billing Parties, or any Downstream Practitioners to take, within a specified
    time period to ensure that all deficiencies will be corrected and that the Participant will
    be in compliance with the terms of this Agreement; and
  - (iii) The CAP must also indicate how the Participant will measure, track, and report implementation of the CAP, which must be deemed useful to CMS to determine whether changes proposed in the Participant's CAP were made.
- (j) Demand repayment of any amounts paid under the Agreement pursuant to Articles 7 and 8.

## 19.2 Termination of the Agreement by the Participant

The Participant may terminate this Agreement at any time for any reason upon 30 Days advance written notice to CMS in a manner prescribed by CMS. At CMS's request, the Participant shall provide feedback regarding its decision to terminate the Agreement and its experience as it relates to the provision of ET3 Model Interventions and compliance with other Model requirements outlined in this Agreement.

### 19.3 Termination of the Agreement by CMS

CMS may immediately or with advance notice terminate this Agreement by promptly notifying the Participant, in writing, of the effective date of the termination and the reason for such termination. CMS may terminate this Agreement for any of the following reasons:

- (a) CMS offers an updated version of this Agreement to take effect at the start of a subsequent Performance Year or such other time specified by CMS;
- (b) CMS determines in its sole discretion that CMS no longer has the funds to support the Model or that continuing the Model is no longer in the public interest;
- (c) CMS modifies or terminates the Model pursuant to Section 1115A(b)(3)(B) of the Act; or
- (d) CMS determines that the Participant, an ET3 Partner, a Downstream Practitioner, or a Billing Party:
  - (i) Has failed to comply with any term of this Agreement, identified by CMS through monitoring of the Model or otherwise, including restricting access to Medically Necessary care;
  - (ii) Has failed to demonstrate improved performance following any remedial action;
  - (iii) Has taken any action that threatens the health or safety of an ET3 Model Beneficiary or other Patient;
  - (iv) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model under the terms of this Agreement;
  - (v) Is subject to sanctions or other actions of an accrediting organization or a federal, state or local government agency;
  - (vi) Is subject to investigation or action by HHS (including HHS-OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including violation of antitrust laws, the federal anti-kickback statute, the federal civil monetary penalties law, the federal physician self-referral law or any other applicable Medicare laws, rules or regulations that are relevant to this Model, or being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, or being named as a defendant in a False Claims Act qui tam matter in which the government has intervened;
  - (vii) No longer provides Medicare-Covered Ground Ambulance Transport services to Medicare FFS beneficiaries within every County or Equivalent Entity in the Participant's Model Region; or
  - (viii) Is unable to implement the Model due to state or local laws or scope of practice barriers.

# 19.4 <u>Notification of ET3 Partners, Downstream Practitioners and Billing Parties</u>

If this Agreement is terminated under Article 19.2 or Article 19.3, the Participant shall provide written notice of the termination to all ET3 Partners, Downstream Practitioners, and Billing Parties. The Participant shall deliver such written notice of the termination to all ET3 Partners, Downstream Practitioners, and Billing Parties. The Participant shall deliver such notice in a manner determined by CMS and no later than 30 Days before the effective date of the

termination unless a later date is specified by CMS. The Participant shall include in such notices any content specified by CMS.

# Article XX. Limitations on Review and Dispute Resolution

#### 20.1 Limitations on Review

There is no administrative or judicial review under Sections 1869 or 1878 of the Act or otherwise for the following:

- (a) The Section of models for testing or expansion under Section 1115A of the Act;
- (b) The selection of organizations, sites, or Model Participants to test the selected models, including the decision by CMS to terminate this Agreement or to require the termination of any individual's or entity's status as the Participant, ET3 Partner, Downstream Practitioner, or Billing Party;
- (c) The elements, parameters, scope, and duration of such Models for testing or dissemination;
- (d) Determinations regarding budget neutrality under Section 1115A(b)(3) of the Act;
- (e) The termination or modification of the design and implementation of a model under Section 1115A(b)(3)(B) of the Act; and
- (f) Decisions about expansion of the duration and scope of a model under Subsection 1115A(c), including the determination that a Model is not expected to meet criteria described in paragraph (1) or (2) of such Subsection.

# 20.2 <u>Dispute Resolution</u>

- (a) The Parties agree to the following procedures for any dispute that is not subject to preclusion of administrative or judicial review as set forth in Article 20.1.
- (b) The Participant shall notify CMS of any such dispute in writing within 30 Days of the date on which the Participant becomes aware, or should have become aware, of the determination giving rise to the dispute. This written notification must provide a detailed explanation of the basis for the dispute and supporting documentation.
- (c) If the Parties cannot resolve any such dispute within 90 Days after CMS receives written notice of the dispute, then the Participant shall submit within 30 subsequent Days an informal hearing request to a CMS hearing officer, or a CMS designee, including the detailed explanation of the basis for the dispute and supporting documentation.
- (d) After receiving the Participant's informal hearing request, the CMS hearing officer shall issue a notice within 30 Days to the Participant and CMS for a hearing scheduled no fewer than 30 Days after the date of the notice. This notice will specify the date, time and location of the hearing, and the issues in dispute.
- (e) Within 30 Days of the hearing, the CMS hearing officer shall issue a written notice to the Participant containing its final determination on the issue, and announcing the effective date of the determination, if applicable.

- (f) CMS's determination under Article 20.2(e) shall be final and binding.
- (g) The Parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.

#### Article XXI. Miscellaneous

#### 21.1 **Agency Notifications and Submission Reports**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this Agreement shall be submitted to the Parties at the addresses set forth below:

CMS: Emergency Triage, Treat, and Transport Model Centers for Medicare & Medicaid Services Center for Medicare and Medicaid Innovation Emergency Triage, Treat, and Transport Model 7500 Security Boulevard Mailstop: WB-06-05 Baltimore, MD 21244 Email: ET3Model@cms.hhs.gov

Participant:

Organization Name:

Address:

Email:

## Phone Number:

#### 21.2 Notice of Bankruptcy

In the event the Participant enters into proceedings relating to bankruptcy, whether voluntary or involuntary, the Participant agrees to furnish, by certified mail, written notification of the bankruptcy to CMS. This notification shall be furnished within 5 Days of the initiation of the proceedings relating to bankruptcy filing. This notification shall include the date on which the bankruptcy petition was filed, the identity of the court in which the bankruptcy petition was filed, and a listing of all federal government contracts, project agreements, contract officers, and project officers for all government contracts and project agreements against which final

payment has not been made. This obligation remains in effect until the expiration or termination of this Agreement and final payment under this Agreement has been made.

# 21.3 <u>Severability</u>

In the event that any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, but this Agreement shall be construed as if such invalid, illegal or unenforceable provisions had never been contained herein, unless the deletion of such provision or provisions would result in such a material change so as to cause completion of the transactions contemplated herein to be unreasonable.

## 21.4 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 including its Appendices, 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 Participant with 30 Days advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

# 21.5 Survival

Termination or expiration of this Agreement by any party shall not affect the rights and obligations of the Parties accrued prior to the effective date of the termination or expiration 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 the Participant. The rights and duties under the following Sections of this Agreement shall also survive termination of this Agreement and apply thereafter:

- (a) Article 11.5 [Beneficiary Privacy and Patient Data Sharing]
- (b) Article 12.1 [Evaluation Requirements];
- (c) Article 14 [Compliance and Oversight];
- (d) Article 15[Data Sharing and Reports];
- (e) Article 18 [Audits and Record Retention];
- (f) Article 19.4 [Notification of ET3 Partners, Downstream Practitioners and Billing Parties]; and
- (g) Article 21.2 [Notice of Bankruptcy].

## 21.6 Precedence

If any provision of this Agreement conflicts with a provision of any document incorporated herein by reference, the provision of this Agreement shall prevail.

# 21.7 Prohibition on Assignment

Except with the prior written consent of CMS, the Participant shall not transfer, including by merger (whether the Participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under this Agreement; (2) any right that it has to satisfy a condition under this Agreement; (3) any remedy that it has under this Agreement; or (4) any obligation imposed on it under this Agreement. The Participant shall provide CMS 90 Days advance written notice of any such transfer. This obligation remains in effect until the expiration or termination of this Agreement and final payment by the Participant under this Agreement has been made. CMS may condition its consent to such transfer on full or partial payment of any monies owed to CMS under the terms of this Agreement. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

# 21.8 Change of Control

CMS may terminate this Agreement or require immediate payment of any monies owed under this Agreement if the Participant undergoes a Change of Control. For purposes of this paragraph, a "Change of Control" shall mean: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the Participant representing more than 50% of the Participant's outstanding voting securities or rights to acquire such securities; (2) upon any sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the Participant; or (3) a plan of liquidation of the Participant or an agreement for the sale or liquidation of the Participant is approved and completed. The Participant shall provide CMS 90 Days advance written notice of a Change of Control. This obligation remains in effect until the expiration or termination of this Agreement and final payment by the Participant under this Agreement has been made.

# 21.9 <u>Certification</u>

The individual signing this Agreement on behalf of the Participant certifies to the best of their knowledge, information, and belief that the information contained in this Agreement (inclusive of Appendices), is accurate, complete, and truthful and that he or she is authorized by the Participant to execute this Agreement and to legally bind the Participant on whose behalf he or she is executing this Agreement to its terms and conditions.

## 21.10 Interpretation of the Agreement

The Participant has been represented (or has had the opportunity to be represented) by their attorneys throughout the transactions contemplated by this Agreement in connection with the execution of this Agreement and any agreements and instruments executed in connection herewith. As a consequence, the Parties do not intend that the presumptions of laws or rules relating to the interpretation of contracts against the drafter of any particular clause should be applied to this Agreement or any document or instrument executed in connection herewith, and therefore waive their effects.

# 21.11 Execution in Counterpart

This Agreement and any amendments thereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same Agreement. In the event that any signature is delivered by facsimile transmission or by email delivery of a ".pdf" format data file, such signature shall 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 facsimile or ".pdf" signature page were an original thereof.

# 21.12 <u>Autopen or Electronic Signature</u>

This Agreement and any amendments hereto may be signed by autopen or electronic signature (e.g., DocuSign or similar electronic signature technology) and may be transmitted by electronic means. Copies of this Agreement and any amendments hereto that are so executed and delivered have the same force and effect as if executed with handwritten signatures and physically delivered.

[SIGNATURE PAGE FOLLOWS]

Each Party is signing this Agreement on the date stated opposite that Party's signature. If a Party signs but fails to date a signature, the date that the other Party receives the signing Party's signature will be deemed to be the date that the signing Party signed this Agreement.

PARTICIPANT:	
Date:	
Ву:	
Name of authorized signatory	-
Title	-
NPI:	
Application ID:	
CMS:	
Date:	
Ву:	
Name of authorized signatory	-
 Title	-

# APPENDIX A: PROPRIETARY INFORMATION DISCLOSURE TEMPLATE

The following are specific examples, without limitation, of what the Participant considers proprietary and confidential information currently contained in its program that should not be publicly disclosed:

1)

2)

3)

In accordance with Article 12.4 of this Agreement, this information shall remain the sole property of the Participant and, except as required by federal law, shall not be released by CMS without the express written consent of the Participant.

#### APPENDIX B: IN-PERSON TREATMENT IN PLACE INTERVENTION WAIVER

## I. Election of the In-Person Treatment in Place Intervention

If the Participant wishes to implement the In-Person Treatment in Place Intervention during the Model Performance Period it must submit an Implementation Plan in accordance with Article 5.1 of the Agreement for CMS review and acceptance, which states the Participant's intention to implement the In-Person Treatment in Place Intervention. The waivers described in Section II of this Appendix B shall apply only if CMS accepts such Implementation Plan and the In-Person Treatment in Place Intervention is furnished in accordance with the applicable requirements of this Agreement.

## II. Waiver and Terms

Under the authority of Section 1115A(d)(1) of the Act, CMS finds it necessary solely for purposes of testing the Model to waive the following requirements:

# (a) Waiver of Transport Requirement:

CMS waives the transportation requirement in the definitions of Advanced Life Support, Level 1 (ALS1) and Basic Life Support (BLS) in 42 C.F.R. §414.605 to allow payment to the Participant that is equivalent to the BLS-E or ALS1-E rate for the initiation and facilitation of an In-Person Treatment in Place Intervention furnished in accordance with this Agreement without requiring the Participant to transport the ET3 Model Beneficiary from the scene of a 9-1-1 emergency response.

# (b) Waiver of Outpatient Setting Requirement:

CMS waives the requirements of Sections 1832(a)(2)(B) and 1861(s)(2)(B) of the Act, which establish the Part B coverage for medical and other health services and limit medical and other health services that are hospital services to those rendered in the outpatient setting to allow medical and other health services that otherwise would be furnished in an outpatient setting to be furnished by, and payment made to, the Participant when furnished in accordance with this Agreement at the scene of a 9-1-1 emergency response as part of the initiation and facilitation of an In-Person Treatment in Place Intervention.

## (c) Waiver of Physician Fee Schedule Payment Requirement for After Hours Services:

CMS waives the requirement of Section 1848(a)(1) of the Act that payment amounts for physicians' services (as defined in Section 1848(j)(3) of the Act) be determined under the Physician Fee Schedule (PFS), to allow the After Hours Payment to be made to ET3 Partners or their Billing Parties, for an In-Person Treatment in Place Intervention furnished After Hours.

## III. Responsibility for Denied Claims

- (a) If CMS denies a claim for services furnished by the Participant as part of initiating and facilitating an In-Person Treatment in Place Intervention, or by a Qualified Health Care Partner or Downstream Practitioner, as part of an In-Person Treatment in Place Intervention, and CMS later determines that such services were furnished in accordance with the terms of this Agreement:
  - (i) CMS shall, notwithstanding such denial, pay for the services under the waiver in Section II of this Appendix B as though the denial had not occurred;
  - (ii) the Participant shall not charge the beneficiary for the expenses incurred by such services and shall ensure that its Qualified Health Care Partners and their Billing Parties do not charge the beneficiary for the expenses incurred by such services; and
  - (iii) the Participant shall return to the beneficiary any monies collected from the beneficiary for such services and shall ensure that its Qualified Health Care Partners and their Billing Parties return to the beneficiary any monies collected from the beneficiary for such services.
- (b) If CMS denies a claim for services furnished by the Participant as part of initiating and facilitating an In-Person Treatment in Place Intervention, or by a Qualified Health Care Partner or Downstream Practitioner as part of an In-Person Treatment in Place Intervention, and CMS later determines that such services were not furnished in accordance with the terms of this Agreement:
  - (i) CMS shall not make payment to the Participant, the Qualified Health Care Partner, or the Qualified Health Care Partner's Billing Party, for such services;
  - (ii) the Participant shall not charge the beneficiary for the expenses incurred by such services and shall ensure that its Qualified Health Care Partners and their Billing Parties do not charge the beneficiary for the expenses incurred for such services; and
  - (iii) the Participant shall return to the beneficiary any monies collected from the beneficiary for such services and shall ensure that its Qualified Health Care Partners and their Billing Parties return to the beneficiary any monies collected from the beneficiary for such services.
- (c) If CMS pays a claim for services furnished by the Participant to initiate and facilitate an In-Person Treatment in Place Intervention, or by a Qualified Health Care Partner or Downstream Practitioner as part of an In-Person Treatment in Place Intervention, and CMS later determines that such services were not furnished in accordance with the terms of this Agreement:
  - (i) CMS shall recoup any payment made to the Participant for such services in accordance with Article 9 of this Agreement, or from the Qualified Health Care Partner or their Billing Party for such services in accordance with applicable Medicare debt collection requirements;

- (ii) the Participant shall not charge the beneficiary for the expenses incurred for such services and shall ensure that its Qualified Health Care Partners and their Billing Parties do not charge the beneficiary for the expenses incurred for such services; and
- (iii) the Participant shall return to the beneficiary any monies collected from the beneficiary for such services and shall ensure that its Qualified Health Care Partners and their Billing Parties return to the beneficiary any monies collected from the beneficiary for such services.

# IV. Compliance and Enforcement

- (a) The Participant shall submit and shall require its Qualified Health Care Partners and their Billing Parties to submit information to CMS, by a time and in a manner determined by CMS, upon request regarding the Participant, Qualified Health Care Partner, or the Qualified Health Care Partner's Billing Party use of the In-Person Treatment in Place Intervention Waiver.
- (b) In accordance with Article 19.1 of the Agreement, CMS may suspend or terminate the Participant, Qualified Health Care Partner, Downstream Practitioner, or Billing Party's ability to utilize the waiver in Section II of this Appendix B, as appropriate, for failure to comply with the terms and conditions of the Agreement including this Appendix B.

#### APPENDIX C: TELEHEALTH TREATMENT IN PLACE INTERVENTION WAIVER

## I. Election of the Telehealth Treatment in Place Intervention Waiver

If the Participant wishes to implement the Telehealth Treatment in Place Intervention during the Model Performance Period, it must submit an Implementation Plan in accordance with Article 5.1 of the Agreement for CMS review and approval which states the Participant's intention to implement the Telehealth Treatment in Place Intervention to ET3 Model Beneficiaries. The waivers described in Section II of this Appendix C shall apply only if CMS accepts such Implementation Plan and the Telehealth Treatment in Place Intervention is furnished in accordance with the applicable requirements of this Agreement.

## II. Waiver and Terms

Under the authority of Section 1115A(d)(1) of the Act, CMS finds it necessary solely for purposes of testing the Model to waive the following requirements:

(a) Waiver of Originating Site Facility Fee Requirement:

CMS waives the requirements of Section 1834(m)(2)(B) of the Act, which establishes the telehealth Originating Site facility fee, to allow payment of a modified Originating Site facility fee equal to either the BLS-E or ALS1-E rate payment to the Participant for the initiation and facilitation of a Telehealth Treatment in Place Intervention furnished at the scene of a 911 emergency response.

(b) Waiver of Originating Site Location Requirement:

CMS waives the requirements of Section 1834(m)(2)(B) and 1834(m)(4)(C) of the Act and 42 C.F.R. §410.78(b)(3) and (b)(4), which limit Medicare telehealth services to those furnished in specific types of Originating Sites located in certain areas, to allow:

- (i) payment to the Participant for the initiation and facilitation of a Telehealth Treatment in Place Intervention furnished at the scene of a 911 emergency response, and
- (ii) payment to Qualified Health Care Partners and their Billing Parties for Covered Services furnished at a Distant Site during a Telehealth Treatment in Place Intervention.
- (c) Waiver of Outpatient Setting Requirement:

CMS waives the requirements of Sections 1832(a)(2)(B) and 1861(s)(2)(B) of the Act, which establish the Part B coverage for medical and other health services and limit medical and other health services that are hospital services to those rendered in the outpatient setting to allow medical and other health services that otherwise would be furnished in an outpatient setting to be provided by, and paid to, the Participant when furnished at the scene of a 9-1-1 emergency response as part of the initiation and facilitation of a Telehealth Treatment in Place Intervention furnished in accordance with this Agreement.

(d) Waiver of Telehealth Service Payment Requirement:

CMS waives the requirements of Section 1834(m)(2)(A) of the Act, which requires that a physician or practitioner located at a Distant Site that furnishes a Telehealth Service to an eligible telehealth individual be paid an amount equal to the amount that such physician or

practitioner would have been paid had such service been furnished without the use of a telecommunications system, to allow the After Hours Payment to be made to Qualified Health Care Partners and their Billing Parties for a Telehealth Treatment in Place Intervention furnished After Hours.

### III. Responsibility for Denied Claims

- (a) If CMS denies a claim for services furnished by the Participant as part of initiating and facilitating a Telehealth Treatment in Place Intervention, or by a Qualified Health Care Partner or their Downstream Practitioner, as part of a Telehealth Treatment in Place Intervention, and CMS later determines that such services were furnished in accordance with the terms of this Agreement:
  - (i) CMS shall, notwithstanding such denial, pay for the service under the waiver in Section II of this Appendix C as though the denial had not occurred,
  - (ii) the Participant shall not charge the beneficiary for the expenses incurred by such services and shall ensure that its Qualified Health Care Partners and their Billing Parties do not charge the beneficiary for the expenses incurred by such services, and
  - (iii) The Participant shall return to the beneficiary any monies collected from the beneficiary for such services and shall ensure that its Qualified Health Care Partners and their Billing Parties, return to the beneficiary any monies collected from the beneficiary for such services.
- (b) If CMS denies a claim for services furnished by the Participant as part of initiating and facilitating a Telehealth Treatment in Place Intervention, or by a Qualified Health Care Partner, or their Downstream Practitioner as part of a Telehealth Treatment in Place Intervention, and CMS later determines that such services were not furnished in accordance with the terms of this Agreement:
  - (i) CMS shall not make payment to the Participant, Qualified Health Care Partner, and/or their Billing Parties for such services,
  - (ii) the Participant shall not charge the beneficiary for the expenses incurred by such services and shall ensure that its Qualified Health Care Partners and their Billing Parties, do not charge the beneficiary for the expenses incurred for such services, and
  - (iii) the Participant shall return to the beneficiary any monies collected from the beneficiary for such services and shall ensure that its Qualified Health Care Partners and their Billing Parties return to the beneficiary any monies collected from the beneficiary for such services.
- (c) If CMS pays a claim for services furnished by the Participant as part of initiating and facilitating a Telehealth Treatment in Place Intervention, or by a Qualified Health Care Partner or Downstream Practitioner as part of a Telehealth Treatment in Place Intervention, and CMS later determines that such services were not furnished in accordance with the terms of this Agreement:
  - (i) CMS shall recoup any payment made to the Participant for such services in accordance with Article 9 of this Agreement, or from the Qualified Health Care Partner

- or their Billing Parties for such services in accordance with applicable Medicare debt collection requirements,
- (ii) the Participant shall not charge the beneficiary for the expenses incurred for such services and shall ensure that its Qualified Health Care Partners and their Billing Parties do not charge the beneficiary for the expenses incurred for such services, and
- (iii) the Participant shall return to the beneficiary any monies collected from the beneficiary for such services and shall ensure that its Qualified Health Care Partners and their Billing Parties return to the beneficiary any monies collected from the beneficiary for such services.

# IV. Compliance and Enforcement

- (a) The Participant shall submit and shall require its Qualified Health Care Partners and their Billing Parties to submit information to CMS, by a time and in a manner determined by CMS, upon request regarding the Participant, Qualified Health Care Partner, or Downstream Practitioner's use of the Telehealth Treatment in Place Intervention Waiver.
- (b) In accordance with Article 19.1 of the Agreement, CMS may suspend or terminate the ability of the Participant, Qualified Health Care Partner, or the Qualified Health Care Partner's Downstream Practitioner or Billing Party to utilize the In-Person Treatment in Place Waiver, as appropriate, for failure to comply with the terms and conditions of the Agreement or this Appendix C.

#### APPENDIX D: DESTINATION REQUIREMENTS FOR AMBULANCE SERVICES WAIVER

## I. Applicability of Waiver

The waiver specified in Section II of this Appendix D applies as of the start date of the Participant's implementation of the Transport to an Alternative Destination, as specified in the Participant's CMS-accepted Implementation Plan, provided that such services are furnished in accordance with this Agreement.

### II. Waiver and Terms

Waiver of Destination Requirements for Ambulance Services: Under the authority of Section 1115A(d)(1) of the Act, CMS finds it necessary solely for purposes of testing the ET3 Model to waive the requirements of 42 C.F.R. §410.40(f)(1) that limit covered destinations for ambulance services to particular settings and require transports to the nearest covered destination that is capable of furnishing the required level and type of care for the beneficiary's illness or injury, to allow payment to be made to the Participant for the transport of an ET3 Model Beneficiary to the nearest appropriate Alternative Destination that has the real-time capacity to furnish the required level and type of care for the ET3 Model Beneficiary's illness or injury.

## III. Responsibility for Denied Claims

- (a) If CMS denies a claim for Transport to an Alternative Destination, and CMS later determines that such services were furnished in accordance with the terms of this Agreement:
  - (i) CMS shall, notwithstanding such denial, pay for such services under the waiver in Section II of this Appendix D as though the denial had not occurred,
  - (ii) the Participant shall not charge the beneficiary for the expenses incurred by such services, and
  - (iii) the Participant shall return to the beneficiary any monies collected from the beneficiary for such services.
- (b) If CMS denies a claim for Transport to an Alternative Destination, and CMS later determines that such services were not furnished in accordance with the terms of this Agreement:
  - (i) CMS shall not make payment to the Participant for such services,
  - (ii) the Participant shall not charge the beneficiary for the expenses incurred by such services, and
  - (iii) as applicable, the Participant shall return to the beneficiary any monies collected from the beneficiary for such services.
- (c) If CMS pays a claim for Transport to an Alternative Destination furnished to a beneficiary, and CMS later determines that such services were not furnished in accordance with the terms of this Agreement:
  - (i) CMS shall recoup any payment for such services made to the Participant in accordance with Article 9 of this Agreement,

- (ii) the Participant shall not charge the beneficiary for the expenses incurred by such services, and
- (iii) the Participant shall return to the beneficiary any monies collected from the beneficiary by the Participant for such services.

# IV. Compliance and Enforcement

- (a) The Participant shall submit information to CMS, by a time and in a manner determined by CMS, upon request regarding the Participant's use of the Destination Requirements for Ambulance Services Waiver.
- (b) In accordance with Article 19.1 of the Agreement, CMS may suspend or terminate the Participant's ability to utilize the Destination Requirements for Ambulance Services Waiver, as appropriate, if the Participant fails to comply with the terms and conditions of this Agreement or this Appendix D.