MEMORANDUM

Agenda Item No. 8(E)(1)

TO:

Honorable Chairwoman Audrey M. Edmonson

and Members, Board of County Commissioners

DATE:

April 7, 2020

FROM:

Abigail Price-Williams

County Attorney

SUBJECT:

Resolution approving terms of an agreement between Miami-Dade County, by and through the Miami-Dade Fire Rescue Department and the Centers for Medicare & Medicaid Services to participate in the Emergency Triage, Treat and Transport Pilot Program; authorizing the County Mayor to execute the pilot program participation agreement; and authorizing the County Mayor to execute all other agreements or documents

necessary to participate in the pilot program subject to Board

ratification

The accompanying resolution was prepared by the Fire Rescue Department and placed on the agenda at the request of Prime Sponsor Commissioner Joe A. Martinez.

APW/lmp

County Attorney

Memorandum MIA



Date:

April 7, 2020

To:

Honorable Chairwoman Audrey M. Edmonson

and Members, Board of County Commissioners

From:

Carlos A. Gimenez

Mayor

Subject:

Resolution Approving the Agreement between Miami-Dade County and the

Center for Medicare and Medicaid Services to Participate in the Emergency

Triage, Treat and Transport Program

Recommendation

It is recommended that the Board of County Commissioners (Board) approve the attached resolution approving the Agreement (Attachment A) between Miami-Dade County (the County), by and through Miami-Dade Fire Rescue (MDFR) to participate in the Emergency Triage, Treat and Transport (ET3) pilot program created by Centers for Medicare and Medicaid Services (CMS). CMS is the agency within the US Department of Health and Human Services that is charged with administering the Medicare and Medicaid programs. In October 2019, MDFR submitted an application to CMS for approval to participate in the pilot program and was recently informed by CMS that the department was selected. The resolution also authorizes the Mayor or Mayor's designee to execute all required documents or agreements, including an agreement with CMS to participate in the program.

Scone

This item impacts the Miami-Dade Fire Rescue (MDFR) District.

Delegation of Authority

The Mayor or Mayor's designee will be authorized to execute all required documents or agreements, including the attached agreement with CMS.

Fiscal Impact

The fiscal impact of this item is unknown. This is a five-year pilot program and may impact Emergency Medical Services Basic Life Support (BLS) transport revenue. In FY 2019 MDFR transported 18,793 BLS patients and total BLS transport revenue was \$3,456,533. Of those patients, 5,919 were covered by Medicare and \$1,759,874 was collected. This program will allow MDFR to charge for Medicare patients transported to alternative destinations and for telemedicine. MDFR will closely monitor the effect on EMS charges and revenues to document any impact this program may have, and report back any negative financial outcomes.

Track Record Monitor

This program will be implemented and monitored by Rowan Taylor, Miami-Dade Fire Rescue Emergency Medical Services Division Chief.

Honorable Chairwoman Audrey M. Edmonson and Members, Board of County Commissioners Page 2

Background

MDFR transports approximately 75,000 patients annually to local hospital emergency rooms. This CMS initiative will waive the requirement of 42 C.F.R. § 410.40 (F) (1) to transport all patients, whether advanced life support (ALS) or BLS, to either standalone emergency rooms or hospitals, urgent care centers are not an option. This waiver will allow payment to be made to the Participant (MDFR) for the transport of an ET3 Model Beneficiary to the nearest appropriate Alternative Destination Partner that has the real-time capacity to furnish the required level and type of care for the ET3 Model Beneficiary's illness or injury. This five-year pilot program will allow MDFR to transport BLS patients to alternative destinations such as urgent care centers. Additional CMS waivers will allow MDFR to offer telemedicine to patients through Baptist Health and MD Now on county computers carried by MDFR paramedics.

The attached participation agreement with CMS has a five-year performance period, which commences with the first one-year performance period (May 1, 2020 through April 30, 2021) and concludes after the end of the fifth performance period (April 30, 2025). The participation agreement must be returned to CMS by April 24, 2020.

CMS has authorized MDFR to bill Medicare for transportation to pre-approved urgent care centers and will also reimburse MDFR for telemedicine services and treat-in-place options. MDFR proposes to maintain the same fee for transportation to alternative destinations as the current fee for a hospital destination.

CMS also requires MDFR to provide copies of agreements with ET3 partners such as telemedicine providers and alternate destination facilities. Attached (Attachment B) is the proposed agreement with Baptist Health as the only Alternative Destination Partner currently approved by CMS. MDFR also anticipates agreements with Jackson Health System and MD NOW if approved by CMS in the future. Those agreements, in substantially the form attached thereto, will also be executed by the Mayor or the Mayor's designee upon Board approval of this resolution.

MDFR has established an ET3 Committee to oversee implementation of the program. The MDFR Protocol Advisory Committee has developed guidelines for Alternative Destination Intervention and Telehealth Treatment in Place Interventions. These guidelines were approved by CMS when submitted as part of the ET3 application.

Maurice L. Kemp Deputy Mayor



MEMORANDUM

(Revised)

FROM: Apiga	Table Chairwoman Audrey M. Edmonson Members, Board of County Commissioners and Price-Williams ty Attorney	SUBJECT: Agenda Item No. 8(E)(1
Please no	ote any items checked.	
	"3-Day Rule" for committees applicable if ra	ised
	6 weeks required between first reading and p	oublic hearing
	4 weeks notification to municipal officials rechearing	quired prior to public
	Decreases revenues or increases expenditure	s without balancing budget
	Budget required	
	Statement of fiscal impact required	
	Statement of social equity required	
	Ordinance creating a new board requires de report for public hearing	tailed County Mayor's
	No committee review	
	Applicable legislation requires more than a represent, 2/3 membership, 3/5's 7 vote requirement per 2-116.1(3)(h) or (4)(c) requirement per 2-116.1(3)(h) or (4)(c), requirement per 2-116.1(4)(c)(2)) to applicable depth and a requirement per 2-116.1(4)(c)(2))	, unanimous, CDMP), CDMP 2/3 vote or CDMP 9 vote
	Current information regarding funding sour balance, and available capacity (if debt is co	

Approved	Mayor	Agenda Item No. 8(E)(1)
Veto		4-7-20
Override	=	
	RESOLUTION NO.	

RESOLUTION APPROVING TERMS OF AN AGREEMENT BETWEEN MIAMI-DADE COUNTY, BY AND THROUGH THE MIAMI-DADE FIRE RESCUE DEPARTMENT AND THE CENTERS FOR MEDICARE & MEDICAID SERVICES TO PARTICIPATE IN THE EMERGENCY TRIAGE, TREAT AND TRANSPORT PILOT PROGRAM; AUTHORIZING THE COUNTY MAYOR OR COUNTY MAYOR'S DESIGNEE TO EXECUTE THE PILOT PROGRAM **PARTICIPATION** AGREEMENT; AND AUTHORIZING THE COUNTY MAYOR OR COUNTY MAYOR'S DESIGNEE TO EXECUTE ALL OTHER AGREEMENTS OR DOCUMENTS NECESSARY TO PARTICIPATE IN THE PILOT PROGRAM SUBJECT TO **BOARD RATIFICATION**

WHEREAS, as set forth in the attached memorandum, the Centers for Medicare and Medicaid Services (CMS) created a pilot program called Emergency Triage, Treat and Transport (the "ET3 Program"); and

WHEREAS, Miami-Dade Fire Rescue (MDFR) applied to CMS to participate in the ET3

Program and was recently informed that it was selected to participate; and

WHEREAS, participation in the ET3 Program will allow MDFR to provide alternative methods to triage, treat and transport patients who require medical services; and

WHEREAS, MDFR's participation in the ET3 Program requires approval by the Board of County Commissioners of the ET3 Program Participation Agreement with CMS attached hereto as Attachment A; and

WHEREAS, MDFR's participation in the ET3 Program will also require MDFR to enter into agreements with ET3 Program partners, such as health care and telemedicine providers and alternate destination facilities, attached hereto as Attachment B,

NOW, THEREFORE, BE IT RESOLVED BY THE BOARD OF COUNTY COMMISSIONERS OF MIAMI-DADE COUNTY, FLORIDA, that:

Section 1. This Board hereby authorizes MDFR to participate in the ET3 Program and

approves the terms of the ET3 Program Participation Agreement between Miami-Dade County,

by and through the Miami-Dade Fire Rescue Department, and CMS.

Section 2. This Board hereby authorizes the County Mayor or Mayor's designee to

execute the ET3 Program Participation Agreement with CMS in substantially the form of

Attachment A hereto.

Section 3. This Board hereby authorizes the County Mayor or Mayor's designee to

execute any and all other agreements or documents necessary for MDFR to participate in the ET3

Program, including without limitation agreements with ET3 partners, such as health care and

telemedicine providers or alternative destination facilities, in substantially the form of Attachment

B hereto, subject to ratification by this Board.

The foregoing resolution was offered by Commissioner

who moved its adoption. The motion was seconded by Commissioner

and upon being put to a vote, the vote was as follows:

Audrey M. Edmonson, Chairwoman

Rebeca Sosa, Vice Chairwoman

Esteban L. Bovo, Jr.

Jose "Pepe" Diaz Eileen Higgins

Joe A. Martinez

Dennis C. Moss

Xavier L. Suarez

Daniella Levine Cava

Sally A. Heyman

Barbara J. Jordan

Jean Monestime

Sen. Javier D. Souto

Agenda Item No. 8(E)(1) Page No. 3

The Chairperson thereupon declared this resolution duly passed and adopted this 7th day of April, 2020. This resolution shall become effective upon the earlier of (1) 10 days after the date of its adoption unless vetoed by the County Mayor, and if vetoed, shall become effective only upon an override by this Board, or (2) approval by the County Mayor of this resolution and the filing of this approval with the Clerk of the Board.

MIAMI-DADE COUNTY, FLORIDA BY ITS BOARD OF COUNTY COMMISSIONERS

HARVEY RUVIN, CLERK

By:____

Deputy Clerk

Approved by County Attorney as to form and legal sufficiency.

8

Chris C. Kokoruda

Agreement





Centers for Medicare & Medicaid Services

Center for Medicare & Medicaid Innovation

Prevention and Population Health Group

7500 Security Blvd.

Mail Stop WB-06-05

Baltimore, MD 21244

Emergency Triage, Treat, and Transport Model

Participation Agreement

Last Updated: February 28, 2020

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PARTICIPATION AGREEMENT

This Participation Agreement (" Agreement ") is betw	reen 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 Partner 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:

I. Agreement Term; Model Performance Period; Performance Years

A. 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).

B. 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 Section XVIII, in which case the Agreement shall expire either on the effective date of termination or, if the Agreement is terminated by CMS pursuant to Section XVIII.C.1, on the effective date of the new agreement described in Section XVIII.C.1.

C. Model Performance Period

The performance period for this Agreement ("Model Performance Period") begins on May 1, 2020 ("Start Date") and ends on April 30, 2025, unless the Agreement is sooner

terminated by either Party in accordance with Section XVIII, 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: May 1, 2020 through April 30, 2021 Performance Year 2: May 1, 2021 through April 30, 2022 Performance Year 3: May 1, 2022 through April 30, 2023 Performance Year 4: May 1, 2023 through April 30, 2024 Performance Year 5: May 1, 2024 through April 30, 2025

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 is not a Medicare-covered destination as identified in 42 C.F.R. § 410.40(f)(1) and that (1) is a Medicare-Enrolled provider or supplier that furnishes Covered Services to an ET3 Model Beneficiary following Transport to an Alternative Destination Partner, or (2) is an individual or entity that is not Medicare-Enrolled and arranges for Covered Services to be furnished by a Downstream Practitioner to an ET3 Model Beneficiary following Transport to an Alternative Destination Partner.

"Available Interventions" means (1) ET3 Model Interventions; and (2) Medicare-Covered Ground Ambulance Transport.

"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 Section V.C.

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

- The District of Columbia.
- b. Parishes in Louisiana.
- c. Boroughs, city and boroughs, 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.

"Data-Sharing Partners" means relevant stakeholders that may use Patient health information in clinical decision-making or care management such as Alternative Destination Partners; Qualified Health Care Partners; Downstream Practitioners; a health care provider (e.g., primary care physician) identified by a Patient as the Patient's routine source of care; other payers, including Medicaid payers; and, any other entities, systems, or individuals that the Participant believes will have access to data related to an ET3 Model Intervention, including, but not limited to, beneficiary-identifiable data.

"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) has a written arrangement with an ET3 Partner that meets all applicable requirements of Section IV.B, under which the Downstream Practitioner agrees to participate in the Model and comply with all applicable terms and conditions under this Agreement; and (2) is a Medicare-Enrolled Physician or Non-Physician Practitioner who furnishes Covered Services to ET3 Model Beneficiaries following Transport to an Alternative Destination Partner or as part of a Treatment in Place intervention.

"Encounter" means an encounter with an ET3 Model Beneficiary 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 ET3 Model Beneficiary 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 Partner; 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 Section IV.B; and (3) is identified as an ET3 Partner on the ET3 Partner List.

"ET3 Partner List" means the list of the Participant's ET3 Partners, and any Downstream Practitioners that furnish and bill Medicare for Covered Services as part of a Treatment in Place intervention, as established and updated in accordance with Section IV.E.

"Implementation Plan" means a complete description of Participant's plan to implement the ET3 Model Intervention(s) in the Model Region established pursuant to Section V.A.

"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, as well as Covered Services furnished by the Participant to initiate or facilitate the In-Person Treatment in Place Intervention.

"Learning System" means a structured approach to sharing, integrating, and actively applying quality improvement concepts, tactics, and lessons learned, all aimed at improving 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 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 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. The term Medicare FFS does not include Medicare Part C (Medicare Advantage) or Medicare Part D (Prescription Drug Benefit).

"Model Participant" means an entity other than the Participant 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 and ET3 Model Interventions to ET3 Model Beneficiaries during the Model Performance Period.

"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 Record 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.

"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 or at an Alternative Destination Partner after Transport to an Alternative Destination Partner.

"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 (1) is a Medicare-Enrolled Provider or Supplier that furnishes a Treatment in Place intervention, or (2) is an individual or entity that is not Medicare-Enrolled and that arranges for a Treatment in Place intervention to be furnished by a Downstream Practitioner 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 telehealth services as described in 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

Covered Services furnished by Participant to initiate and facilitate the such Telehealth Treatment in Place Intervention.

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

"Transport to an Alternative Destination Partner" means medically necessary (as described in 42 C.F.R. § 410.40(e)(1)) unscheduled emergency ground ambulance transport of an ET3 Model Beneficiary by the Participant from the scene of a 9-1-1 emergency response to an Alternative Destination Partner 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 use of Clinical Protocols to: (1) assess a Patient's condition after arriving on the scene of a 9-1-1 emergency response, and (2) if the Patient is identified as an ET3 Model Beneficiary, determine which Available Intervention (if any) is most clinically appropriate.

III. Participant Requirements

A. General Requirements

- 1. 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.
- 2. 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.
- 3. 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.
- 4. The Participant must ensure compliance with the applicable terms and conditions of this Agreement by all ET3 Partners, Downstream Practitioners, and other entities and individuals performing functions or services related to the ET3 Model Interventions, 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, 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.

B. Participant Changes

1. 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.

2. 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 Section XX.G.

3. 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.

C. State and Local Requirements for Ambulance Services

- 1. 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 emergency medical services protocols, agency license, medical director license, personnel certifications, and vehicle licenses and requirements.
- 2. 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 emergency medical services protocols, business license, or other local authorizations and licenses.

D. <u>Non-Duplication of Participation</u>

- 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.
- 2. The Participant must give written notice to CMS if the Participant is selected to participate in any CMS initiative after the Effective Date. Such notice must be given within 30 Days of receiving notification that the Participant has been selected to participate in the initiative.
- 3. 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.

IV. ET3 Partners

A. General Requirements

- 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 Section VI.D.2.
- 2. 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 ensure that each ET3 Partner provides such documents to each potential Downstream Practitioner.
- 3. If the requirements of Sections IV.A.1 and IV.A.2 are not satisfied prior to the Participant's execution of an arrangement with an ET3 Partner pursuant to Section IV.B, the requirements of this Section IV.A are not satisfied.

B. <u>ET3 Partner Arrangement</u>

- 1. 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 with an ET3 Partner that is an Alternative Destination Partner:
 - a. 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 Partner:
- b. The arrangement requires the Alternative Destination Partner to ensure it has the capacity to meet the needs of ET3 Model Beneficiaries who are transported to the Alternative Destination Partner by the Participant including, but not limited to, the capacity to bill Medicare or to ensure that Medicare is billed for Covered Services furnished to ET3 Model Beneficiaries at the Alternative Destination Partner;
- c. 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 capacity to furnish and bill Medicare for Covered Services described in Section XIV.B; and
- d. If the Alternative Destination Site responds to a request made by the Participant pursuant to Section V.E.2.iv.a.4 by confirming that it has the real-time capacity to serve an ET3 Model Beneficiary, the arrangement requires the Alternative Destination Partner to ensure it has the capacity to furnish the required level and type of care for the ET3 Model Beneficiary's illness or injury.
- iii. Arrangements with Qualified Health Care Partners. If the Participant has elected to offer the Treatment in Place intervention, for an arrangement with an ET3 Partner who is a Qualified Health Care Partner:
 - a. 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;
 - b. 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 and bill Medicare for Covered Services
 that satisfy the requirements of Section XIV.A;
 - c. 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 Participant makes data submissions to CMS in accordance with Section XI and requires the Qualified Health Care Partner to impose this requirement on its Downstream Practitioners; and

- d. 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 Section XIV and, if applicable, also requires the Qualified Health Care Partner to ensure that its Downstream Practitioners provide written confirmation of the Downstream Practitioners' consent to bill and receive payment for such Covered Services.
- 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 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 Section IX.B.2, and also requires the ET3 Partner to ensure that its Downstream Practitioners 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 Downstream Practitioners upon request by the Participant. Such list must include each Downstream Practitioner's legal name, correspondence address, NPI, Medicare Provider Identification Number (if issued), CMS Certification Number (if applicable), and an indication of whether the Downstream Practitioner will bill Medicare for Covered Services they furnish as part of an ET3 Intervention.
- vii. If the ET3 Partner is Medicare-Enrolled, the arrangement requires the ET3
 Partner to update its Medicare enrollment information on a timely basis in
 accordance with Medicare program requirements, and also requires the ET3
 Partner to ensure that its Downstream Practitioners are obligated to do the
 same.
- viii. 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 Downstream Practitioners are obligated to do the same if they are on the ET3 Partner 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.
- ix. The arrangement requires the ET3 Partner to notify the Participant within 7
 Days of becoming aware that it or any of its Downstream Practitioners 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 provide such notice to the ET3 Partner if the

 Downstream Practitioner is the subject of such investigations or sanctions.
- x. 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 permit the ET3 Partner to take such actions against a Downstream Practitioner to address noncompliance with the applicable terms of this Model as set forth in this Agreement or program integrity issues identified by CMS.
- xi. The arrangement permits early termination if CMS removes the ET3 Partner from the ET3 Partner 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 Downstream Practitioners who are removed from the ET3 Partner List by CMS.
- 2. CMS provides no opinion on the legality of any contractual or other arrangement that the Participant, ET3 Partner, a Downstream Practitioner, 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.

C. Notification of Termination and Other Changes

- 1. 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 Section IV.B.

- 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 Partner List.
- iii. The Participant must provide written notice to CMS within 30 Days after becoming aware of any Change of Control of any individual or entity listed on the ET3 Partner 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 Partner 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 Partner 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.
- 2. After review of a notice described under Section IV.C.1, CMS may conduct a Program Integrity Screening with respect to such individual or entity listed on the ET3 Partner List, terminate such individual or entity on the ET3 Partner List, or take any of the actions set forth in Section XVIII.

D. <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.

E. <u>ET3 Partner List</u>

1. General

- i. The Participant must ensure that all proposed ET3 Partners and all proposed Downstream Practitioners who 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 Partner List pursuant to this Section IV.E prior to furnishing a Covered Services as part of an ET3 Model Intervention under the terms of this Agreement.
- ii. An individual or entity will be included on the ET3 Partner List only upon written approval of CMS.

- iii. CMS will maintain the ET3 Partner List in a manner that permits the Participant to review the list. The Participant must periodically review its ET3 Partner List to ensure that the list is true, accurate, and complete, and must make any updates to the ET3 Partner List in accordance with Section IV.E.3.
- iv. The Participant must maintain documentation of all ET3 Partner Lists, both current and historical, in accordance with Section XVII.C.
- v. CMS may periodically conduct a Program Integrity Screening of each individual and entity listed on the ET3 Partner List. The presence of an individual or entity on the ET3 Partner 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 Partner List.

2. Initial ET3 Partner List

- i. The Parties acknowledge that, if applicable, the Participant submitted to CMS a list of proposed ET3 Partners. Medicare-Enrolled ET3 Partners were identified by legal 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). ET3 Partners who are not Medicare-Enrolled were identified by legal 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.
- ii. CMS states that it has reviewed the list of proposed ET3 Partners and conducted a Program Integrity Screening of the proposed ET3 Partners for which it received all information necessary to conduct a Program Integrity Screening.
- iii. CMS states that it has submitted to the Participant a list of individuals and entities that it approved to be ET3 Partners. The Participant states that it has reviewed this list and made any necessary corrections to it, including the removal of any individuals or entities that have not agreed to participate in the Model as of the Effective Date of this Agreement pursuant to a written arrangement meeting the requirements of Section IV.B.
- iv. The Participant states that it has submitted to CMS an initial ET3 Partner List that the Participant has certified is a true, accurate, and complete list of all of

the Participant's ET3 Partners. No additional ET3 Partners may be added to the ET3 Partner List at this time.

v. After the Start Date, the Participant must update the ET3 Partner List in accordance with Section IV.E.3.

3. Updates to ET3 Partner List

- i. Removals from the ET3 Partner List
 - a. 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 Partner List has ceased to be an ET3 Partner or Downstream Practitioner 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 or Downstream Practitioner. The removal of the individual or entity from the ET3 Partner List will be effective on the date the individual or entity ceased to be an ET3 Partner or Downstream Practitioner.
 - b. CMS may terminate an individual or entity and update the ET3 Partner List to reflect this termination or subject the Participant to additional monitoring pursuant to Section IX.B.6.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 Partner List. Such notice will specify the termination date.

ii. Additions to the ET3 Partner List

- a. If, after the Start Date, the Participant wishes to add an individual or entity to the ET3 Partner List as an ET3 Partner or a Downstream Practitioner who will furnish and bill Medicare for Covered Services furnished as part of a Treatment in Place intervention, it must submit a request to CMS, in a form and manner and by a deadline specified by CMS, that meets the following requirements:
 - 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 Partner List, including without limitation the information specified in Section IV.E.2.i for ET3 Partners and, for each Downstream Practitioner who will furnish and bill Medicare for Covered Services furnished as part of a Treatment in Place intervention, the Participant must include legal name, correspondence address, NPI, Medicare Provider

- Identification Number (if issued), and CMS Certification Number (if applicable).
- 2. For each individual or entity proposed for inclusion on the ET3
 Partner List, the Participant must indicate whether the individual
 or entity is proposed as an ET3 Partner or as a Downstream
 Practitioner who will furnish and bill Medicare for Covered
 Services furnished as part of a Treatment in Place intervention.
- 3. The Participant must ensure that it has a written arrangement that meets the requirements of Section IV.B with any proposed ET3 Partner.
- b. For each Downstream Practitioner proposed for inclusion on the ET3 Partner List, the Participant must identify the approved or proposed Qualified Health Care Partner with which the Downstream Practitioner has a fully executed written arrangement meeting the requirements of Section IV.B. CMS will conduct a Program Integrity Screening of each individual or entity proposed for inclusion on the ET3 Partner List by the Participant.
- c. CMS will notify the Participant regarding whether the proposed individual or entity has been approved or rejected as an ET3 Partner or Downstream Practitioner on the basis that the individual or entity fails to satisfy the definition of an "ET3 Partner" or is not a Downstream Practitioner who will furnish and bill Medicare for Covered Services as part of a Treatment in Place intervention as applicable, or on the basis of a Program Integrity Screening. If CMS approves the request, the individual or entity will be added to the ET3 Partner List, effective on the date the addition is approved by CMS.

V. Implementation of Available Interventions

A. Implementation Plan

- 1. The Participant shall submit to CMS, by a deadline and in a form and manner specified by CMS, an Implementation Plan, subject to CMS's review and acceptance.
- 2. The Implementation Plan is a complete description of the Participant's plan to implement ET3 Model interventions, and must include, at a minimum, the following information:
 - Model Region (see Section V.B);
 - ii. ET3 Model Interventions (See Section V.E.2, and if applicable, Section V.E.3);
 - iii. Payer Strategy (see Section V.F.);
 - iv. Access Plan (see Section V.G);

- v. Patient Data Sharing Plan (see Section VI.E.2); and
- vi. Compliance Plan (see Section IX.A).
- 3. CMS will review the Participant's Implementation Plan 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 the period of review of the Implementation Plan, within 30 Days of CMS's receipt thereof.
- 4. 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 Section XVIII.
- 5. The Participant shall update its Implementation Plan on an annual basis by a date specified by CMS, and additionally as specified in this Agreement. All updates to the Implementation Plan will be reviewed by CMS in accordance with the processes described in Sections V.A.3 and V.A.4.
- 6. The Participant shall ensure adherence to the applicable requirements of the Implementation Plan by the Participant, ET3 Partners, and Downstream Practitioners. If the Participant is unable to substantially implement its Implementation Plan during the Model Performance Period, CMS reserves the right to take remedial action under Section XVIII.
- 7. 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, or other individuals or entities included in the Implementation Plan, such as payers included in the Participant's Multi-Payer Strategy described in Section V.F (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.

B. Model Region

- 1. The Participant must establish a Model Region in which it will operationalize its Implementation Plan.
- 2. The Parties acknowledge that the Participant identified a proposed Model Region in its Application.
- 3. In compliance with Section V.A, the Participant must include in its Implementation Plan a description of its Model Region, including a description of any changes to the Model Regional since the submission of the Participant's Application.

4. Pursuant to Section V.A.5, the Participant must update its Implementation Plan annually to reflect any material changes to its Model Region. Such material changes include, but are not limited to, adding or removing a County or Equivalent Entity, or a state from the Model Region.

C. Clinical Protocols

- 1. 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 per the requirements of Section IX.A.3.iv.
- 2. 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 to the ET3 Model Beneficiary.

D. 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.

E. <u>ET3 Model Interventions</u>

1. General

- i. No earlier than the Start Date, and no later than November 1, 2020, the Participant must begin to offer Transport to an Alternative Destination Partner to ET3 Model Beneficiaries in accordance with a CMS accepted Implementation Plan and the Participant's Clinical Protocols, and must thereafter continue to offer Transport to an Alternative Destination Partner to ET3 Model Beneficiaries for the remaining duration of the Model Performance Period.
- ii. The Participant may elect to offer the optional Treatment in Place intervention to ET3 Model Beneficiaries during the Model Performance Period in accordance with Section V.E.3.
- iii. The Participant must ensure that Covered Services furnished to an ET3 Model Beneficiary following Transport to an Alternative Destination Partner or as part of a Treatment in Place intervention are furnished by a Medicare-Enrolled ET3 Partner or a Downstream Practitioner.
- iv. The Participant may furnish an ET3 Model Intervention to a Patient only after the Participant has:

- a. identified the Patient as an ET3 Model Beneficiary in accordance with the Eligibility Plan developed pursuant to Section V.F.1.ii;
- identified an ET3 Model Intervention by a Triage Decision made pursuant to the Participant's Clinical Protocols as described in Section V.C.2;
- c. offered the ET3 Model Intervention to the ET3 Model Beneficiary in accordance with Section VI.A.; and
- d. obtained the ET3 Model Beneficiary's consent to receive the ET3 Model Intervention in accordance with Section VI.A.
- 2. Transport to an Alternative Destination Partner Intervention
 - The Parties acknowledge that the Participant has included in its Application a plan for implementing the Transport to an Alternative Destination Partner intervention.
 - ii. Pursuant to Section V.A, the Participant must include in its Implementation
 Plan information related to the Transport to an Alternative Destination Partner
 intervention, including the following information:
 - a. A description of any Alternative Destination Partners approved by CMS for inclusion on the ET3 Partner List in accordance with Section IV.E and any individual or entities the Participant intends to add to the ET3 Partner List as an Alternative Destination Partner, subject to CMS review and approval, including the Alternative Destination Partner's capacity to serve Medicare beneficiaries;
 - b. A proposed date by which the Participant will begin offering Transport to an Alternative Destination Partner to ET3 Model Beneficiaries;
 - c. A description of how the Participant will implement the Transport to an Alternative Destination Partner intervention during the Model Performance Period in accordance with the requirements of this Agreement, including how the Participant will meet each of the requirements of Section V.E.2.iv.a; and
 - d. Any relevant changes or updates to the plan provided in the Participant's Application regarding its proposed implementation of the Transport to an Alternative Destination Partner intervention.
 - iii. Pursuant to Section V.A.5, the Participant must update its Implementation Plan annually to reflect changes to the Transport to an Alternative Destination Partner intervention and also must promptly update its Implementation Plan to include material changes to the Implementation Plan related to the Participant's implementation of the Transport to an Alternative Destination Partner intervention. Such material changes include, but are not limited to, changes to the Participant's proposed implementation date for the Transport

to an Alternative Destination Partner intervention and interruptions in the Participant's ability to offer Transport to an Alternative Destination Partner to ET3 Model Beneficiaries, such as gaps or anticipated gaps in the Participant's ability to offer the Transport to an Alternative Destination Partner intervention.

- iv. Implementation of the Transport to an Alternative Destination Partner Intervention
 - a. The Participant must, prior to offering the Transport to an Alternative

 Destination Partner intervention to ET3 Model Beneficiaries and no later
 than November 1, 2020 or such later date as may be specified by CMS:
 - 1. Update its ET3 Partner List in accordance with Section IV.E.3.ii to include:
 - at least one Medicare-Enrolled Alternative Destination
 Partner that has agreed to furnish Covered Services to ET3
 Model Beneficiaries following Transport to an Alternative
 Destination Partner and has the capacity to furnish and bill
 Medicare for Covered Services described in Section XIV.B,
 or
 - ii. at least one Alternative Destination 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 a Downstream Practitioner who has the capacity to furnish and bill Medicare for Covered Services described in Section XIV.B, as well as such Downstream Practitioner;
 - 2. Be capable of identifying ET3 Model Beneficiaries in accordance with the Eligibility Plan developed pursuant to Section V.F.1.ii;
 - Be capable of implementing Clinical Protocols and making a Triage Decision for any Patient identified as an ET3 Model Beneficiary in accordance with Section V.C; and
 - 4. Be capable of implementing a method to determine an Alternative Destination Partner's real-time capacity to furnish the required level and type of care for the ET3 Model Beneficiary's illness or injury prior to transporting an ET3 Model Beneficiary to the Alternative Destination Partner.
 - b. After the Participant begins offering Transport to an Alternative

 Destination Partner, the Participant must ensure that it continues to comply with the requirements of Section V.E.1.iv.a.

- c. The Participant must ensure that each Transport to an Alternative Destination Partner furnished to an ET3 Model Beneficiary:
 - 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, and
 - is made to the nearest appropriate Alternative Destination
 Partner that has the real-time capacity to furnish the required level and type of care for the ET3 Model Beneficiary's illness or injury.

3. Optional Treatment in Place Intervention

- i. The Parties acknowledge that the Participant has indicated in its Application whether it intends to implement the optional Treatment in Place intervention and, if the Participant has chosen to implement the optional Treatment in Place intervention, a plan for implementing the Treatment in Place intervention.
- ii. In compliance with Section V.A, the Participant must include in its Implementation Plan information related to the optional Treatment in Place intervention, including a statement indicating whether the Participant has elected to implement the Treatment in Place intervention. If the Participant has elected to implement the Treatment in Place invention, the Implementation Plan must also contain the following information:
 - a. The Participant's proposed date of implementation of the Treatment in Place intervention;
 - b. 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 statement indicating whether the Participant will offer the In-Person Treatment in Place Intervention, the Telehealth Treatment in Place Intervention, or both, and including how the Participant will meet each of the requirements of Section V.E.3.v below; and
 - Any relevant changes or updates to the information provided in the Participant's Application regarding its plan for implementing the Treatment in Place intervention.
- iii. If the Participant elects not to provide the Treatment in Place intervention at the time the Implementation Plan is submitted, the Participant may elect to provide the optional Treatment in Place intervention at a later time during the Model Performance Period by updating its Implementation Plan in accordance

- with Section V.A.5. Such update must include the information described in Sections V.E.2.i.a-b. The updated Implementation Plan must be submitted no later than 45 Days prior to the Participant's proposed implementation date of the Treatment in Place intervention.
- iv. Pursuant to Section V.A.5, the Participant must update its Implementation Plan annually to reflect any changes to the Participant's implementation of the Treatment in Place intervention and also must promptly update its Implementation Plan to reflect any material changes to the Implementation Plan related to the Participant's implementation of the Treatment in Place intervention. Such material changes include, but are not limited to, the Participant's decision to no longer offer the optional Treatment in Place intervention, changes to the Participant's proposed implementation date for 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) offered by the Participant.
- v. Implementation of the Optional Treatment in Place Intervention
 - a. If the Participant has elected to offer the optional Treatment in Place intervention, the Participant must implement the Treatment in Place intervention in accordance with a CMS accepted Implementation Plan and the Participant's Clinical Protocols and the Participant must, prior to offering a Treatment in Place intervention to ET3 Model Beneficiaries:
 - 1. update its ET3 Partner List in accordance with Section IV.E.3.ii to include:
 - at least one 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 has the capacity to furnish and bill
 Medicare for Covered Services described in Section XIV.A,
 or
 - ii. at least one 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 a Downstream Practitioner who has the capacity to furnish and bill Medicare for Covered Services described in Section XIV.A, as well as such Downstream Practitioner,
 - 2. obtain written consent in accordance with Section V.E.3.vi and Section V.E.3.vii,

- 3. ensure that each Qualified Health Care Partner listed on the ET3
 Partner List in accordance with Section IV.E has the capacity to
 meet the needs of ET3 Model Beneficiaries, including the capacity
 to furnish and bill Medicare for Covered Services described in
 Section XIV.A or to ensure that such Covered Services are
 furnished by a Downstream Practitioner who has the capacity to
 furnish and bill Medicare for such Covered Services,
- 4. be capable of identifying ET3 Model Beneficiaries in accordance with the Eligibility Plan developed pursuant to Section V.F.1.ii, and
- 5. be capable of implementing Clinical Protocols and making a Triage Decision for any Patient identified as an ET3 Model Beneficiary in accordance with Section V.C.
- b. Once the Participant begins offering the optional Treatment in Place intervention, the Participant must ensure that it continues to comply with the requirements of Section V.E.3.v.a.
- c. 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.
- vi. Consent to Payment Terms for Services Furnished as part of a Treatment in Place intervention
 - The Participant shall obtain written confirmation of consent to receive payment for Covered Services furnished as part of a Treatment in Place intervention under the terms specified in Section XIV, 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. 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 or Downstream Practitioner bills Medicare.

- b. As part of the written confirmation of consent described in Section V.E.3.vi, the individual legally authorized to act for the individual or entity through whose TIN the Medicare-Enrolled Qualified Health Care Partner or Downstream Practitioner bills Medicare must verify the accuracy of the list of Medicare-Enrolled Qualified Health Care Partners or Downstream Practitioners billing under that TIN that have affirmatively consented to receive payment for Covered Services under the terms specified in Section XIV and Appendices B and C of this Agreement.
- c. The written confirmation of consent described in Section V.E.3.vi.a must be renewed annually in advance of the subsequent Performance Year in order for those Qualified Health Care Partners and Downstream Practitioners to continue to participate in the ET3 Model as a Qualified Health Care Partner or Downstream Practitioner for that Performance Year.

vii. Consent to After Hours Upward Payment Adjustment

- a. The Participant shall obtain written confirmation of consent to receive 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. 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 or Downstream Practitioner bills Medicare.
- b. 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 or Downstream Practitioners billing under that TIN that have affirmatively consented to receive the After Hours Upward Payment Adjustment.
- c. Consent to receive the After Hours Upward Payment Adjustment provided by a Medicare-Enrolled Qualified Health Care Partner or Downstream Practitioner must be renewed annually in order for those Qualified Health Care Partners or Downstream Practitioners to continue

to participate in the ET3 Model as a Qualified Health Care Partner or Downstream Practitioner for that Performance Year.

F. Payer Strategy

- 1. Multi-Payer Strategy or Medicare FFS Strategy
 - i. The Participant must elect to implement 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 rendered inperson or through telecommunications technology at the scene of a 9-1-1 emergency response ("Multi-Payer Strategy").
 - ii. As part of its Medicare FFS Strategy or Multi-Payer Strategy, the Participant must design a plan to identify whether a Patient is an ET3 Model Beneficiary prior to offering an ET3 Model Intervention ("Eligibility Plan").
 - iii. The Parties acknowledge that the Participant has provided in its Application either a Medicare FFS Strategy or a Multi-Payer Strategy (each a "Payer Strategy"), including an Eligibility Plan.
 - iv. Pursuant to Section V.A, the Participant must include in its Implementation Plan a Payer Strategy and must identify any changes made to the Payer Strategy between the date the Participant submitted the Application and the date the Participant submits the Implementation Plan.
 - v. Pursuant to Section V.A.5, the Participant must update its Implementation Plan annually to reflect any changes to its Payer Strategy and also must promptly update its Implementation Plan to reflect any material changes to the Implementation Plan related to the Payer Strategy. Such material changes include, but are not limited to, 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 changes to the proposed timeline or partnerships associated with the Payer Strategy.
- 2. 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 Section VI.D.2.

G. Access Plan

- 1. 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.
- 2. The Parties acknowledge that the Participant has identified in its Application a proposed plan to ensure ET3 Model Beneficiary access to at least one ET3 Model Intervention 24 hours per Day, 7 Days per week for the Model Performance Period ("Access Plan").
- 3. Pursuant to Section V.A, the Participant must include in its Implementation Plan an Access Plan, which must include any material changes or updates to the Access Plan provided as part of the Participant's Application between the date the Participant submitted the Application and the date the Participant submits the Implementation Plan.
- 4. Pursuant to Section V.A.5, the Participant must update its Implementation Plan annually to reflect any changes to the Participant's Access Plan and also must promptly update its Implementation Plan to reflect any material changes to the Implementation Plan related to the Access Plan. Such material changes include, but are not limited to, changes to the timeline to achieve 24/7 access, or any changes that limit the Participant's ability to achieve 24/7 access.

VI. Beneficiary Protections

A. <u>Beneficiary Notifications</u>

- 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 Section XV.C.
- Information and education provided to beneficiaries for purposes of obtaining their consent or refusal for Covered Services in compliance with this Section VI.A is not considered promotion, marketing, or advertising for the purposes of Section VI.D.2.
- 3. 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 applicable policies on Emergencies or Urgent Situations / Ambulance Transport.
- 4. The Participant must ensure that any notice furnished to an ET3 Model Beneficiary for purposes of complying with this Section VI.A 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.

B. Availability of Services

The Participant must not restrict, and must ensure that ET3 Partners and Downstream Practitioners do not 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.

C. Beneficiary Freedom of Choice

- 1. 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, to decline such transport, or to decline an ET3 Model Intervention offered to the beneficiary, including transport to a specific Alternative Destination Partner, subject to state and local EMS protocols, Medicare program requirements, and any applicable licensing guidelines or rules.
- 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.
- 3. Subject to Medicare program requirements, the Participant must furnish Medicare-Covered Ground Ambulance 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.

D. Prohibition of Promotion and Inducements

- 1. The Participant is prohibited, and shall prohibit its ET3 Partners and Downstream Practitioners, 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.
- 2. The Participant shall not, and shall ensure that its ET3 Partners and Downstream Practitioners 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.

E. Beneficiary Privacy and Patient Data Sharing

- 1. 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.

2. Patient Data Sharing Plan

- i. The Parties acknowledge that the Participant has identified in its Application an interoperability plan describing the Participant's ability to share Patient data, including PHI if applicable, among Data-Sharing Partners and a plan to identify when and how Patient consent and authorization will be obtained in compliance with state and federal privacy laws, including HIPAA privacy regulations and 42 C.F.R. Part 2 ("Patient Data Sharing Plan").
- ii. Pursuant to Section V.A, the Participant must include in its Implementation Plan a Patient Data Sharing Plan, and must describe any material changes or updates to the Patient Data Sharing Plan between the date the Participant submitted the Application and the date the Participant submits the Implementation Plan. The Patient Data Sharing Plan must include:
 - a. A plan to identify when and how Patient consent and authorization will be obtained, including written Patient consent where required, in compliance with state and federal privacy laws, including HIPAA privacy regulations and 42 C.F.R. Part 2; and
 - b. The Participant's ability to share Patient data, including PHI if applicable, among Data-Sharing Partners in compliance with state and federal privacy laws.
- iii. After submission of the Implementation Plan, the Participant must update CMS of any material changes to the Patient Data Sharing Plan annually in compliance with Section V.A.5.

VII. Participation in Evaluation, Shared Learning Activities, and Site Visits

A. <u>Evaluation Requirements</u>

1. 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 Section VII.A.1.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:
 - a. Supplying data to measure quality of care;
 - b. Participating in surveys, interviews, and site visits; and
 - c. 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 carry out the evaluation activities described in Section VII.A.1.iii.

2. 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, and/or their staff,
- vi. focus groups with the Participant, its ET3 Partners and Downstream Practitioners, 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.

3. Secondary Data

In its evaluation activities, CMS or its designee(s) may use data or information submitted 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.

B. Shared Learning Activities

- 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 the period after the Effective Date but prior to the Start Date. One of these Learning System activities includes development of a visual display of what drives toward the achievement of a project aim ("Driver Diagram"). During the Participant's first year of participation in the Model, the Participant shall develop and submit to CMS, in a form and manner specified by CMS, an individualized the Participant Driver Diagram. This Driver Diagram will serve as a framework to guide and align intervention design and implementation activities. After the Participant submits its Driver Diagram to CMS, the Participant shall update the Driver Diagram and submit such updated Driver Diagram to CMS at least once per Performance Year;
 - Respond to surveys, interviews, or other assessment mechanisms from CMS or its designees, in order to assist CMS in identifying the Participant learning needs;
 - Participate in the identification and dissemination of promising practices which may involve sharing lessons learned with Model Participants (e.g., presenting on webinars);
 - 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 Section XVII;

- 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 in another location. These events will focus on Model Participant learning, collaboration, dissemination of ET3 Model promising practices, and other Model Participant needs.
- The Participant shall ensure ET3 Partners, Downstream Practitioners, and any non-Medicare payers with which the Participant has partnered as part of the Participant's Payer Strategy described in Section V.F 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.

C. Site Visits

- The Participant shall cooperate in periodic site visits by CMS and/or its designees in order to facilitate evaluation, shared learning activities, monitoring, or the fulfilment of the terms of this Agreement, and shall require ET3 Partners and Downstream Practitioners to participate and cooperate in the same. Site visits are expected to involve in-person 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, or Downstream Practitioner.
- 2. 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.
- 3. Notwithstanding the foregoing, and to the extent feasible, CMS may perform unannounced site visits at the office of any Model Participant, ET3 Partner, or Downstream Practitioner at any time to investigate concerns about the health or safety of beneficiaries or other program integrity issues.
- 4. 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.
- 5. Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

D. Rights in Data and Intellectual Property

- 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 multipayer participation, to Model Participants and the public. Data to be disseminated may include measures based upon claims, medical records, and other data sources.
- 2. The Participant may be permitted to comment on evaluation reports for factual accuracy but may not edit conclusions or control the dissemination of reports.
- 3. Notwithstanding any other provision in this Agreement, all proprietary trade secret information and technology of the Participant, an ET3 Partner, or a Downstream Practitioner is and shall remain the sole property of the Participant, ET3 Partner, or Downstream Practitioner, 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, or Downstream Practitioners.
- 4. 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.

VIII. Participant Release of Information

A. <u>CMS Prior Approval</u>

The Participant shall, and shall require its ET3 Partners and Downstream Practitioners 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, or a Downstream Practitioner 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.

B. Required Disclaimer

All external reports and statistical/analytical material that are subject to the requirements of Section VIII.A 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."

IX. Compliance and Oversight

A. Participant Compliance Plan

- 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 hereto and any changes in
 applicable laws and regulations.
- 2. The Parties acknowledge that the Participant has identified in its Application a proposed Compliance Plan.
- 3. Pursuant to Section V.A, the Participant must include in its Implementation Plan a Compliance Plan, including a description of any material changes to the Compliance Plan made after the Participant submitted the Application. The Compliance Plan must include:
 - The basic elements of a compliance program for ambulance suppliers identified in the HHS Office of Inspector General's Compliance Program Guidance for Ambulance Suppliers¹, 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;
 - 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;
 - Regular compliance training and education for the Participant, including Model-related compliance training and education for ET3 Partners,
 Downstream Practitioners, and other individuals or entities performing functions or services related to ET3 Model Interventions;
 - d. Mechanisms for identifying and appropriately addressing compliance problems related to the Participant's operations and performance,

¹ 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).

- including activities related to the Model that are performed by ET3 Partners, and Downstream Practitioners, and other individuals or entities performing functions or services related to ET3 Model Interventions;
- e. A method for employees or contractors of the Participant, ET3 Partners, Downstream Practitioners, 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, 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
- f. 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 Alternative Destination Partners and, if applicable, receive a Treatment in Place intervention. This includes ensuring that any Transport to an Alternative Destination Partner does not duplicate Medicare-Covered Ground Ambulance 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.
- 4. Pursuant to Section V.A.5, the Participant must update its Implementation Plan annually to reflect any material changes to its Compliance Plan. Such material changes include, but are 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 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.

B. Compliance with Monitoring and Oversight Activities

1. 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:
 - a. Providing data related to the Participant, ET3 Partners, Downstream Practitioners, and Patients in accordance with applicable law;
 - Promptly submitting a list of all the Downstream Practitioners of one or more of the Participant's ET3 Partners to CMS and its designees, upon request;
 - c. Being available for site visits by CMS staff and its designees at their respective facilities in accordance with the terms of the Agreement;
 - d. Providing all information and documentation related to desk audits as required and requested by CMS staff and its designees;
 - e. Participating in surveys and interviews as requested by CMS staff and its designees; and
 - f. 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.

2. Agreement to Comply

- i. The Participant shall comply with, and shall require all ET3 Partners and Downstream Practitioners 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, or Downstream Practitioners to comply with the terms of any other CMS contract, agreement, Model, or demonstration.
- 3. 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, or Downstream Practitioners.

4. 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.

5. 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, or Downstream Practitioners.

6. Monitoring for Participant Compliance

 CMS shall screen and continuously monitor the Participant, ET3 Partners, and Downstream Practitioners 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, and

- Downstream Practitioners 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:
 - a. collection and analysis of the Participant's data submitted pursuant to this Agreement, including data submitted as required under Section XI,
 - interviews with any individual or entity involved in ET3 Model
 Interventions such as members of the Participant, an ET3 Partner, or a
 Downstream Practitioner's leadership and management,
 - c. monitoring for inappropriate provision of care, including, but not limited to, unsafe Patient care practices and overutilization of services associated with the Model,
 - d. obtaining information regarding any financial arrangements between the Participant and its ET3 Partners and Downstream Practitioners,
 - e. audits of charts, medical records, and other data from the Participant, ET3 Partners, and Downstream Practitioners,
 - f. site visits (including on-site visits and desk audits) to the Participant, ET3
 Partners, and Downstream Practitioners,
 - g. requests sent to the Participant, ET3 Partners, and Downstream Practitioners, including surveys and questionnaires, and
 - h. 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, and Downstream Practitioners, 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 Section XI, 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.

7. 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 events 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 Destination Partners.

X. Data Sharing and Reports

A. General

- 1. CMS may elect to provide, and Participant retains the right to request, aggregate data from CMS regarding its progress in the Model, which may be used to facilitate the Participant's learning, and certain other data as described in Section X.B and X.C 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.
- 2. Data provided to the Participant will be aggregate data that have been fully deidentified in accordance with the HIPAA Privacy Rule, 45 C.F.R. § 164.514(b)(2).

B. Provision of Certain De-identified Data for Quality Improvement and Safety

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 Section V.C.1, which

- requires the Participant to continuously implement and track quality improvement and safety practices.
- 2. 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.
- 3. The Participant represents and warrants that the use of data provided by CMS under this Section X.B will be used solely to develop and implement improvements in the quality and efficacy of care provided through 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.

C. <u>Provision of De-Identified Dashboard and Summary Information</u>

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):

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

XI. Submission of Required Data Elements

A. General

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

B. <u>Submission Timing and Contents</u>

- 1. Initial Data Submission
 - i. No later than 60 Days prior to the date of the initial submission of Required Data Elements 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 July 1, 2020.
 - ii. By the deadline for the Initial Data Submission, the Participant must submit:
 - a. all Required Data Elements 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

 Required Data Elements for dates of service for a period of time specified by CMS, which will be up to one calendar year prior to the Start Date.

2. 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 Elements for Patients no less frequently than once per calendar month. The Participant may submit Required Data Elements more frequently than once per month.
- ii. The final data submission will include all dates of service up to the last day of the Model Performance Period and will occur no later than 90 days after the end of the Model Performance Period.

C. Required Data Elements

- 1. The Required Data Elements for Performance Year 1 include those PCR Data elements specified by CMS no later than 60 Days prior to the Initial Submission Date.
- 2. On an annual basis, CMS may provide an updated list of Required Data Elements that the Participant must submit to CMS.
- 3. If CMS updates the Required Data Elements List in accordance with Section XI.C.2 to include additional PCR Data elements, the Participant may be required to submit those new PCR Data elements for dates of service up to one calendar year prior to the Start Date.
- 4. Failure to submit all Required Data Elements in the form and manner and timeline specified by CMS may result in CMS taking remedial action under Section XVIII.

D. CMS Quality Reporting Initiatives

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

XII. Certification of Data and Information

- A. With respect to data and information that are generated or submitted by the Participant, ET3 Partners, or Downstream Practitioners 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 his or her knowledge and belief.
 - 1. 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:
 - that Participant, ET3 Partners, Downstream Practitioners, and other individuals and entities performing functions or services related to ET3 Model Interventions are in compliance with the applicable Model requirements, and

ii. the accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the Participant, ET3 Partners, and, if applicable, Downstream Practitioners related to ET3 Model Interventions.

XIII. Payment to Participant

A. General

- 1. The Participant may receive payment for Transport to an Alternative Destination Partner furnished to an ET3 Model Beneficiary as set forth in this Section XIII and Appendix D of this Agreement. If the Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to offer the In-Person Treatment in Place Intervention to ET3 Model Beneficiaries, 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 Section XIII and Appendix B of this Agreement. If the Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to offer the Telehealth Treatment in Place Intervention to ET3 Model Beneficiaries, 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 Section XIII and Appendix C of this Agreement.
- 2. 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.
- 3. 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.
- 4. 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.
- 5. CMS will pay the Participant for Medicare-Covered Ground Ambulance Transport services furnished to an ET3 Model Beneficiary as usual under Medicare FFS, pursuant to Medicare FFS rules and billing guidelines, including rules regarding debt collection.

B. Payment for Transport to an Alternative Destination Partner

1. Eligibility

- i. The Participant may receive payment for Transport to an Alternative Destination Partner only if:
 - a. The transport is furnished in accordance with a CMS-accepted Implementation Plan and Section V.E.2.iv;
 - The transport is an unscheduled ground ambulance transport of an ET3
 Model Beneficiary by the Participant from the scene of a 9-1-1
 emergency response to an Alternative Destination Partner during an Encounter;
 - c. The Alternative Destination Partner is listed on the ET3 Partner List in accordance with Section IV.E and complies with the applicable terms and conditions of the Model as set forth in this Agreement;
 - d. The transport is medically necessary as described in 42 C.F.R. § 410.40(e)(1); and
 - e. The Participant submits the claim for payment to CMS and such claim includes the modifiers and HCPCS codes specified by CMS.

2. Payment Rate

- i. If the requirements of Section XIII.B.1.i are met, CMS will pay the Participant for Transport to an Alternative Destination Partner at a rate equivalent to:
 - a. 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
 - b. 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.

C. Payment for Initiation and Facilitation of Treatment in Place

1. In-Person Treatment in Place Intervention

i. Eligibility

The Participant may receive payment for Covered Services furnished as part of an In-Person Treatment in Place Intervention only if:

- a. The Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to offer the In-Person Treatment in Place Intervention to ET3 Model Beneficiaries;
- b. The In-Person Treatment in Place Intervention is furnished in accordance with Section V.E.3.v;
- The In-Person Treatment in Place Intervention is furnished to an ET3
 Model Beneficiary in person at the scene of a 9-1-1 emergency response
 by a Qualified Health Care Partner or Downstream Practitioner;
- d. The Qualified Health Care Partner or a Downstream Practitioner that furnished the Covered Services as part of the In Person Treatment in Place Intervention is Medicare-Enrolled, listed on the ET3 Partner List in accordance with Section IV.E, and complies with the applicable terms and conditions of the Model as set forth in this Agreement;
- e. The Covered Services furnished by the Participant as part of initiating and facilitating the In-Person Treatment in Place Intervention are Medically Necessary; and
- f. The Participant submits the claim for payment to CMS and such claim includes the modifiers and HCPCS-codes specified by CMS.

ii. Payment Rate

a. If the requirements of Section XIII.C.1.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.

- b. 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.
- c. 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.

2. Telehealth Treatment in Place Intervention

i. Eligibility

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

- a. The Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to offer the Telehealth Treatment in Place Intervention to ET3 Model Beneficiaries;
- b. The Telehealth Treatment in Place Intervention is furnished in accordance with Section V.E.3.v;
- The Telehealth Treatment in Place Intervention is furnished by a
 Qualified Health Care Partner or a Downstream Practitioner to an ET3

 Model Beneficiary located at the scene of a 9-1-1 emergency response;
- d. The Qualified Health Care Partner or a Downstream Practitioner that furnished the Covered Services as part of the Telehealth Treatment in Place Intervention is Medicare-Enrolled, listed on the ET3 Partner List in accordance with Section IV.E, and complies with the applicable terms and conditions of the Model as set forth in this Agreement; and
- e. The Covered Services furnished by the Participant as part of initiating and facilitating the Telehealth Treatment in Place Intervention are Medically Necessary.

ii. Payment Rate

- a. If the requirements of Sections XIII.C.2.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.
- 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.
- c. 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.

D. Performance-Based Payment Adjustment

- CMS will, in its sole and absolute 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.
- 2. 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.

XIV. Payment to ET3 Partners and Downstream Practitioners

A. Payment to Qualified Health Care Partners and their Downstream Practitioners for Covered Services Furnished as part of a Treatment in Place Intervention

1. General

- i. If the Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to offer the In-Person Treatment in Place intervention to ET3 Model Beneficiaries, CMS shall pay Qualified Health Care Partners and Downstream Practitioners for Covered Services furnished as part an In-Person Treatment in Place Intervention as set forth in this Section XIV and Appendix B of this Agreement. If the Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to offer the Telehealth Treatment in Place Intervention to ET3 Model Beneficiaries, CMS shall pay Qualified Health Care Partners and Downstream Practitioners for Covered Services furnished as part of a Telehealth Treatment in Place Intervention as set forth in this Section XIV and Appendix C of this Agreement.
- ii. CMS shall pay a Qualified Health Care Partner or Downstream Practitioner for Covered Services furnished to an ET3 Model Beneficiary as part of a Treatment in Place intervention only if the claim for such services includes the modifiers and codes specified by CMS and the requirements of this Section XIV.A are met.

iii. 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 Downstream Practitioners to receive payment for a Treatment in Place intervention.

2. Eligibility

CMS shall pay a Qualified Health Care Partner or a Downstream Practitioner for Covered Services furnished as part of a Treatment in Place intervention only if:

- The Participant has a CMS-accepted Implementation Plan that indicates that the Participant has elected to offer the Treatment in Place intervention in a manner that includes the type of Covered Services furnished by the Qualified Health Care Partner or Downstream Practitioner;
- ii. The Covered Service is furnished to an ET3 Model Beneficiary as part of a Treatment in Place intervention initiated and facilitated by the Participant;
- iii. In the event that the Covered Service furnished is part of an In-Person Treatment in Place Intervention, it is furnished at the scene of the 9-1-1 emergency response to the ET3 Model Beneficiary;
- iv. In the event that the Covered Service furnished is part of a Telehealth Treatment in Place Intervention, it is furnished to an ET3 Model Beneficiary located at the scene of the 9-1-1 emergency response;
- v. The Qualified Health Care Partner or Downstream Practitioner is Medicare-Enrolled, is listed on the ET3 Partner List in accordance with Section IV.E, and complies with the applicable terms and conditions of the Model as set forth in this Agreement; and
- vi. The Covered Service is Medically Necessary.

3. Payment Rate

Except as specified in Section XIV.A.4, CMS shall pay a Medicare-Enrolled Qualified Health Care Partner or Downstream Practitioner 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 rules regarding debt collection.

4. After Hours Upward Payment Adjustment

If the requirements of Section XIV.A.2 and Section V.E.3.vii are met, CMS shall pay a Qualified Health Care Partner or Downstream Practitioner the After Hours Payment for After Hours Services.

- 5. Loss of Telehealth Technology Connection during a Telehealth Treatment in Place Intervention
 - i. If a Covered 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 Covered Service cannot be completed using an interactive telecommunications system as defined at 42 CFR §410.78(a)(3), a Medicare-enrolled Qualified Health Care Partner or Downstream Practitioner may bill and receive payment for the Telehealth Treatment in Place Intervention, only if the Covered Service is substantially completed when the disruption occurs and the requirements of Section XIV.A.2 are met.
 - ii. If the Participant, Qualified Health Care Partner, or a Downstream Practitioner offers an ET3 Model Beneficiary an Available Intervention during an Encounter in which a Telehealth Treatment in Place Intervention was previously offered but could not be completed due to an interruption in connectivity, the service is not substantially completed.
- B. <u>Payment to Alternative Destination Partners or their Downstream Practitioners for Covered</u>
 <u>Services furnished after Transport to an Alternative Destination Partner</u>

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

XV. Payment to CMS

- A. If CMS determines that a payment made by CMS pursuant to Section XIII and/or Section XIV was made in error, CMS shall send the Participant and/or Qualified Health Care Partner or Downstream Practitioner a demand letter for the amount of such payment, and may take a remedial action as described in Section XVIII. The Participant and/or Qualified Health Care Partner or Downstream Practitioner 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 and/or Qualified Health Care Partner or Downstream Practitioner 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. 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).

XVI. Medicare Payment Waivers

A. <u>General</u>

In accordance with Section 1115A(d)(1) of the Act, 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. 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.

B. Transport to Alternative Destination Partner Waiver

Appendix D specifies the waivers necessary solely for purposes of testing the Transport to an Alternative Destination Partner 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.

C. In-Person Treatment in Place Intervention Waiver

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 offers the In-Person Treatment in Place Intervention to ET3 Model Beneficiaries in accordance with a CMS-accepted Implementation Plan.

D. <u>Telehealth Treatment in Place Intervention Waiver</u>

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 elects to offer the Telehealth Treatment in Place Intervention to ET3 Model Beneficiaries in accordance with a CMS-accepted Implementation Plan.

XVII. Audits and Record Retention

A. Right to Audit and Correction

The Participant agrees, and must require all ET3 Partners, Downstream Practitioners, 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, and other individuals and entities performing functions or services related to ET3 Model Interventions that pertain to the following:

- The Participant's compliance with this Agreement, including provisions that require the Participant to impose duties or requirements on ET3 Partners and Downstream Practitioners;
- ii. Whether ET3 Partners and Downstream Practitioners 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.

B. <u>Maintenance of Records</u>

- 1. The Participant agrees, and must require all ET3 Partners and Downstream Practitioners 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 and Downstream Practitioners; whether ET3 Partners or Downstream Practitioners 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:
 - a. 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
 - b. There has been a termination, dispute, or allegation of fraud or similar fault against the Participant, ET3 Partners, or Downstream Practitioners 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.

XVIII. Remedial Action and Termination

A. Remedial Action

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

- 1. Notify the Participant and, if appropriate, ET3 Partner and/or Downstream Practitioner of the violation by warning letter, email, or otherwise;
- 2. Require the Participant to provide additional information to CMS or its designees;
- 3. Conduct on-site visits, interview Patients after receipt of an ET3 Model Intervention, or take other actions to gather information;
- 4. Place the Participant on a monitoring and/or auditing plan developed by CMS;
- 5. Require the Participant to cease transportation of ET3 Model Beneficiaries to an Alternative Destination Partner and/or to terminate the Participant's arrangement, immediately or within a timeframe specified by CMS, with such Alternative Destination Partner with respect to this Model;
- 6. 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;
- 7. Require the Participant to terminate its relationship with any other individual or entity performing functions or services related to the ET3 Model;
- 8. Terminate the ability of the Participant, Qualified Health Care Partner, or Downstream Practitioners 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;
- 9. 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, 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.

B. <u>Termination of the Agreement by the Participant</u>

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.

C. Termination by CMS

CMS may immediately or with advance notice terminate this Agreement for the reasons stated below, including, but not limited to:

- 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;
- 2. 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;
- 3. CMS modifies or terminates the Model pursuant to Section 1115A(b)(3)(B) of the Act; or
- 4. CMS determines that the Participant, an ET3 Partner, or a Downstream Practitioner:
 - 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 comply with any Medicare, Medicaid, or CHIP programs' laws, regulations, or rules, including the Participant's failure to maintain its Medicare-Enrolled as required under this Agreement;
 - iii. Has failed to comply with a monitoring and/or auditing plan required under the terms of this Agreement;
 - iv. Has failed to meet one or more reporting requirements specified in this
 Agreement, including failure to report data necessary for purposes of model monitoring or evaluation and quality measures;
 - v. Has failed to submit, obtain approval for, implement, or fully comply with the terms of a CAP;
 - vi. Has failed to demonstrate improved performance following any remedial action;
 - vii. Has taken any action that threatens the health or safety of an ET3 Model Beneficiary or other Patient;

- viii. 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;
- ix. Is subject to sanctions or other actions of an accrediting organization or a federal, state or local government agency;
- x. 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;
- xi. Assigns or purports to assign any of the rights or obligations under this Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS;
- xii. Consistently fails to participate in required ET3 Model Learning System activities;
- xiii. 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;
- xiv. Fails to execute arrangements with sufficient Alternative Destination Partners or Qualified Health Care Partners to implement the Model as described in the Participant's Implementation Plan, established in accordance with Section V.A;
- xv. Does not make at least one ET3 Model Intervention available to ET3 Model Beneficiaries 24 hours a Day, 7 Days a week pursuant to the Participant's Access plan developed in accordance with Section V.G;
- xvi. Has failed to repay money owed to the Medicare program as specified in this Agreement;
- xvii. Has interfered with or impeded CMS' and/or its designees' monitoring and evaluation activities;
- xviii. Is unable to implement the Model due to state or local laws or scope of practice barriers;

- xix. Is not in compliance with any of the requirements for participation as a Medicare provider or supplier, including the Conditions of Participation, Conditions for Coverage, or Requirements of Participation; or
- xx. Has failed to implement or adhere to the Implementation Plan, established in accordance with Section V.A.
- 5. In the event of any such termination, CMS will promptly notify the Participant, in writing, of the reasons and the effective date thereof.

D. Notifications to ET3 Partners

If this Agreement is terminated under Section XVIII.B or XVIII.C, the Participant shall provide written notice of the termination to all ET3 Partners and Downstream Practitioners. The Participant shall deliver such written 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.

XIX. Limitations on Review and Dispute Resolution

A. Limitations on Review

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

- 1. The Section of models for testing or expansion under Section 1115A of the Act;
- 2. 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, or Downstream Practitioner;
- 3. The elements, parameters, scope, and duration of such Models for testing or dissemination;
- 4. Determinations regarding budget neutrality under Section 1115A(b)(3) of the Act;
- 5. The termination or modification of the design and implementation of a model under Section 1115A(b)(3)(B) of the Act; and
- 6. 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.

B. <u>Dispute Resolution</u>

- 1. 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 Section XIX.A.
- 2. 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

- act giving rise to the dispute. This written notification must provide a detailed explanation of the basis for the dispute and supporting documentation.
- 3. 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.
- 4. 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.
- 5. 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.
- 6. CMS's determination under Section XIX.B.5 shall be final and binding.
- 7. The Parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.

XX. Miscellaneous

A. 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:

B. 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.

C. Severability

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.

D. 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.

E. 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:

- 1. Section VII.A [Evaluation Requirements];
- 2. Section IX [Compliance and Oversight];
- 3. Section X [Data Sharing and Reports];
- 4. Section XVII [Audits and Record Retention]; and
- 5. Section XX.B [Notice of Bankruptcy].

F. 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.

G. 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 reconciliation 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.

H. 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.

1. Certification

The individual signing this Agreement on behalf of the Participant certifies to the best of his or her 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.

J. 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.

K. 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 e-mail 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.

[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:	<u>.</u>
Ву:	_
Name of authorized signatory	Printer Control
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 Section VII.D 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 offer the In-Person Treatment in Place Intervention during the Model Performance Period it must submit an Implementation Plan in accordance with Section V.E.3 of the Agreement for CMS review and acceptance, which states the Participant's intention to offer the In-Person Treatment in Place Intervention to ET3 Model Beneficiaries. 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 Section V.E.3, Section XIII, and Section XIV 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.

A. 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.

B. 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

Practitioners and Downstream Practitioners 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:
 - 1. 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;
 - the Participant shall not charge the beneficiary for the expenses incurred by such services and shall ensure that its Qualified Health Care Partners and Downstream Practitioners do not charge the beneficiary for the expenses incurred by such services; and
 - 3. 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 Downstream Practitioners 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:
 - 1. CMS shall not make payment to the Participant, Qualified Health Care Partner, and/or Downstream Practitioner for such services;
 - the Participant shall not charge the beneficiary for the expenses incurred by such services and shall ensure that its Qualified Health Care Partners and Downstream Practitioners do not charge the beneficiary for the expenses incurred for such services; and
 - 3. 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 Downstream Practitioners 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:

- CMS shall recoup any payment made to the Participant for such services in accordance with Section XIII of this Agreement, or from the Qualified Health Care Partner, and/or Downstream Practitioner for such services in accordance with applicable Medicare debt collection requirements;
- the Participant shall not charge the beneficiary for the expenses incurred for such services and shall ensure that its Qualified Health Care Partners and Downstream Practitioners do not charge the beneficiary for the expenses incurred for such services; and
- 3. 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 Downstream Practitioners 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 Downstream Practitioners 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 In-Person Treatment in Place Intervention Waiver
- B. In accordance with Section XVIII of the Agreement, CMS may suspend or terminate the Participant, Qualified Health Care Partner, or Downstream Practitioner'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 offer the Telehealth Treatment in Place Intervention during the Model Performance Period, it must submit an Implementation Plan in accordance with Section V.E.3 for CMS review and approval which states the Participant's intention to offer 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 Section V.E.3, Section XIII, and Section XIV 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. <u>Waiver of Originating Site Facility Fee Requirement:</u>

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. <u>Waiver of Originating Site Location Requirement:</u>

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 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 to allow payment to Qualified Health Care Partners and Downstream Practitioners who furnish services from the Distant Site for 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 Downstream Practitioners 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 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:
 - 1. 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,
 - the Participant shall not charge the beneficiary for the expenses incurred by such services and shall ensure that its Qualified Health Care Partners and Downstream Practitioners do not charge the beneficiary for the expenses incurred by such services, and
 - 3. 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 Downstream Practitioner 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 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:
 - 1. CMS shall not make payment to the Participant, Qualified Health Care Partner, and/or Downstream Practitioner for such services,
 - the Participant shall not charge the beneficiary for the expenses incurred by such services and shall ensure that its Qualified Health Care Partners and Downstream Practitioners do not charge the beneficiary for the expenses incurred for such services, and
 - 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 Downstream Practitioners 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:
 - CMS shall recoup any payment made to the Participant for such services in accordance with Section XV of this Agreement, or from the Qualified Health Care Partner, and/or Downstream Practitioner for such services in accordance with applicable Medicare debt collection requirements,
 - the Participant shall not charge the beneficiary for the expenses incurred for such services and shall ensure that its Qualified Health Care Partners and Downstream Practitioners do not charge the beneficiary for the expenses incurred for such services, and
 - 3. 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 Downstream Practitioners 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 Downstream Practitioners 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 Section XVIII of the Agreement, CMS may suspend or terminate the Participant, Qualified Health Care Partner, or Downstream Practitioner's ability 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 Partner, as specified in the Participant's CMS-accepted Implementation Plan, provided that such services are furnished in accordance with Section V.E.2, Section XIII, and Section XIV of 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 Partner 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 Partner, and CMS later determines that such services were furnished in accordance with the terms of this Agreement:
 - 1. 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,
 - the Participant shall not charge the beneficiary for the expenses incurred by such services, and
 - 3. 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 Partner, and CMS later determines that such services were not furnished in accordance with the terms of this Agreement:
 - 1. CMS shall not make payment to the Participant for such services.
 - 2. the Participant shall not charge the beneficiary for the expenses incurred by such services, and
 - 3. 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 Partner furnished to a beneficiary, and CMS later determines that such services were not furnished in accordance with the terms of this Agreement:
 - CMS shall recoup any payment for such services made to the Participant in accordance with Section XIII of this Agreement, and

- 2. the Participant shall not charge the beneficiary for the expenses incurred by such services, and
- 3. 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 Section XVIII.C 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 including, but not limited to, Section V.E.2.iv; Section VI.A; and Section V.F.1.iii.

Letter of Intent

This Letter of Intent ("LOI") is made and entered into on the day of	, 2020, by
and between ("Provider"), whose address is	, and Miami-Dade
County on behalf of its Miami-Dade County Fire Rescue Department ("MDF	R"). Miami-Dade
County and Provider may be collectively referred to as the "Parties."	

WHEREAS, Miami-Dade County Fire Rescue Department as part of the Emergency Triage, Treat, and Transport, or "ET3," Initiative has been awarded a contract by the Centers for Medicare and Medicare ("CMS") FFS Services, which includes Miami-Dade County where Provider is located; and

WHEREAS, from time to time, Provider provides care to covered individuals via an ET3-type model featuring alternate destination or treatment in place in Miami-Dade County on a patient by patient contract basis, when the care and treatment is appropriate; and

WHEREAS, the Centers for Medicare and Medicare FFS Services ("CMS") approved payments based on the Provider's Medicare Physician Fee Schedule (PFS) for the care and treatment provided at _____ (collectively, the "Alternate Destination Site(s)") to eligible persons,

NOW THEREFORE, in consideration of the mutual covenants herein, the Parties hereby mutually agree as follows:

- 1. Provider agrees to make available medically necessary treatment, procedures and services to ET3 patients on a patient-by-patient basis as appropriate and reasonable.
- 2. The term of this LOI shall commence January 1, 2020, and shall terminate December 31, 2024, unless terminated sooner by the replacement of the LOI with a network agreement or the termination of payments.
- 3. This LOI may be terminated without cause by Provider or Miami-Dade County with thirty (30) days prior written notification to the other party via certified mail.
- 4. Any notices required or permitted under this LOI shall be served by certified mail return receipt requested at the address set forth below:

To Miami-Dade County or MDFR:

Rowan Taylor, EMS Division Chief Miami-Dade Fire Rescue Department 9300 N.W. 41 Street Doral, Florida 33178

~	-		•
Tο	Pro	VIC	ler:

Provider's	Medicare Prov	vider lo	dentii	ication	Number(s) is/are:	aı	na	
Provider's	National Prov	ider Id	entifi	er (NPI) Number	is/are:			
_		• •	•		C .1	1 1,	. •		

- 5. Provides a description of the proposed alternative destination site's capacity to treat Medicare FFS beneficiaries who are transported to the alternative destination site through the ET3 model.
- 6. The Parties understand that this LOI is subject at all times to state, local and federal laws, and the rules, regulations and policies of all state, local and federal public health and safety agencies. The Parties intend to comply with all applicable federal, State of Florida and local laws, rules and regulations, including, without limitation, the federal Physician Self-Referral Law (Social Security Act 1877; 42 U.S.C. 1395nn) and the regulations promulgated thereunder (collectively, the "Stark Law"), as well as any similar State and/or local statutes or regulations prohibiting certain financial relationships among health care providers; the federal Anti-Kickback Statute (42 U.S.C. 1320a-7, 1320a-7a, 1320a-7b) and the regulations promulgated thereunder (collectively, the "Anti-Kickback Statute"); the Health Insurance Portability and Accountability Act (HIPAA); the Health Information Technology for Economic and Clinical Health (HITECH) Act; as well as similar State or local statutes and regulations. The Parties further agree to restructure or amend this LOI, if necessary, to facilitate such compliance.
- 7. The Parties agree that this LOI sets forth the entire agreement and understanding of the Parties and supersedes all prior and contemporaneous agreements, arrangements, or understandings relating to the subject matter hereof. There are no conditions or limitations to this undertaking except those stated herein. No modification of this LOI shall be binding upon the Parties unless in writing and duly executed by Provider and Miami-Dade County.
- 8. This LOI shall be construed according to the law of the State of Florida applicable to contracts made and fully performed therein, without giving effect to its laws or rules relating to conflict of laws. Venue for any litigation between the Parties regarding this LOI shall lie exclusively in state or federal court located in Miami-Dade County, Florida.
- 9. This LOI may be executed in several counterparts, each of which shall be deemed an original and all such counterparts together shall constitute but one and the same instrument.
- 10. This LOI shall not be construed against the party preparing it but shall be construed as if all parties hereto jointly prepared this LOI.
- 11. Independent Private Inspector General Review. Pursuant to the Code of Miami-Dade County, Section 2-1076, and Miami-Dade County Administrative Order 3-20, and in connection with this LOI, Miami-Dade County has the right to retain the services of an Independent Private Sector Inspector General ("IPSIG") whenever Miami-Dade County deems it

appropriate to do so. Upon written notice from t Miami-Dade County, the Provider shall make available, to the IPSIG retained by Miami-Dade County, all requested records and documentation pertaining to this LOI, for inspection and copying. Miami-Dade County will be responsible for the payment of these IPSIG services, and under no circumstance shall the Provider's fees for its performance under this LOI be inclusive of any charges relating to these IPSIG services. The terms of this provision herein shall, apply to the Provider, and its officers, agents, employees and assignees. Nothing contained in this provision shall impair any independent right of Miami-Dade County to conduct, audit, or investigate the operations, activities and performance of the Provider in connection with this LOI.

- 12. Miami-Dade County Inspector General Review. According to Section 2-1076 of the Code of Miami-Dade County, Miami-Dade County has established the Office of the Inspector General (IG) that may, on a random basis, perform audits, inspections, and reviews of all County contracts. This random audit is separate and distinct from any other audit by the County. To pay for the functions of the Office of the Inspector General, any and all payments to be made to the Provider under this LOI will be assessed one quarter (1/4) of one (1) percent of the total amount of the payment, to be deducted from each progress payment as the same becomes due unless, as stated in the Special Conditions, this LOI is federally or state funded where federal or state law or regulations preclude such a charge.
 - 1. The Miami-Dade Office of Inspector General is authorized to investigate Miami-Dade County affairs and empowered to review past, present and proposed Miami-Dade County programs, accounts, records, contracts and transactions. In addition, the Inspector General has the power to subpoena witnesses, administer oaths, require the production of witnesses and monitor existing projects and programs. Monitoring of an existing project or program may include a report concerning whether the project is on time, within budget and in conformance with plans, specifications and applicable law. The Inspector General shall have the power to audit, investigate, monitor, oversee, inspect and review operations, activities, performance and procurement process including but not limited to project design, proposal specifications, proposal submittals, activities of the Provider, its officers, agents and employees, lobbyists, Miami-Dade County staff and elected officials to ensure compliance with contract specifications and to detect fraud and corruption.
 - 2. Upon ten (10) days written notice to the Provider, the Provider shall make all requested records and documents available to the Inspector General for inspection and copying. The Inspector General shall have the right to inspect and copy all documents and records in the Provider's possession, custody or control, which in the Inspector General's sole judgment, pertain to performance of the LOI, including, but not limited to original estimate files, proposals and agreements from and with successful subcontractors and suppliers, all project-related correspondence, memoranda, instructions, financial documents, proposal and contract documents, all documents and records that involve cash, trade or volume discounts, insurance proceeds, rebates, or dividends received, payroll and personnel records and supporting documentation for the aforementioned documents and records. The Provider shall make available at its office at all reasonable times the records.

materials, and other evidence regarding the acquisition (proposal preparation) and performance of this LOI, for examination, audit, or reproduction, until three (3) years after final payment under this LOI or for any longer period required by statute or by other clauses of this LOI.

3. In addition:

- a. If this LOI is completely or partially terminated, the Provider shall make available records relating to the work terminated until three (3) years after any resulting final termination settlement; and
- b. The Provider and Miami-Dade County shall make available records relating to appeals or to litigation or the settlement of claims arising under or relating to this LOI until such appeals, litigation, or claims are finally resolved.
- c. The provisions in this section shall apply to the Provider, its officers, agents, employees, subcontractors and suppliers. The Provider shall incorporate the provisions in this section in all subcontracts and all other agreements executed by the Provider in connection with the performance of this LOI.
- d. Nothing in this section shall impair any independent right of Miami-Dade County to conduct audits or investigative activities nor shall any audit rights provided elsewhere in this LOI limit the audit rights set forth in this section. The provisions of this section are neither intended nor shall they be construed to impose any liability on Miami-Dade County by the Provider or third parties.
- e. To the extent required by law but no less than four (4) years after expiration of this LOI, the Provider shall make available for inspection this LOI and all other books, documents and records that support the nature and extent of costs incurred by Miami-Dade County to the following: United States Department of Health and Human Services, the United States Comptroller General and their representatives; any other federal, state or local agency with regulatory authority over Miami-Dade County.

ATTACHMENT B

IN WITNESS WHEREOF, the Parties have duly executed this LOI on the day and year above first written.

MIAMI-DADE COUNTY, FLORIDA	[insert Provider name]
By:	By:
Print name:	Print name:
Print title:	Print title: