AMENDMENT OF SOLICIT	ATION/MODIE	FICATION OF CONTRACT	1 CONTRACT	ID CODE	PAGE OF PAGE
			J		1 2
AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO		5 PROJECT	NO (Ifapplicable)
00003	26-Oct-2020	SEE SCHEDULE		L	
SSUED BY CODE	W911SR	7 ADMINISTERED BY (If other than item 6)	CO	DE	
JSA CONTRACT NG CMD-APG W911SR EDGEWOOD CONTRACTING DIVISION 456 BRIGADE STREET JUG E4215 WERDEEN PROVING GROUND MD 21010-5401		See Item 6			
NAME AND ADDRESS OF CONTRACTOR	(No Street County	State and Zin Code)	9A. AMENDM	ENT OF SO	LICITATION NO
DUOPROSS MEDITECH CORPORATION	(110., Silee, county,		9B. DATED (S	EE ITEM 11	1)
FARMINGDALE NY 11735-1209		A	X 10A MOD OF W911SR20C0	CONTRAC	T/ORDER NO.
			10B. DATED	(SEE ITEM	13)
DE 8LK11	FACILITY CO		X 03-Aug-2020		
11 The above numbered solicitation is amended as set fo		APPLIES TO AMENDMENTS OF SOLIO	is extended.	is not exter	
Offer must acknowledge receipt of this amendment pr (a) By completing Items 8 and 15, and returning or (c) By separate letter or telegram which includes a RECEIVED AT THE PLACE DESIGNATED FOR T REJECTION OF YOUR OFFER If by virtue of this provided each telegram or letter makes reference to the	copies of the amendme reference to the solicitation THE RECEIPT OF OFFERS amendment you desire to cha	nt; (b) By acknowledging receipt of this amendme and amendment numbers FAILURE OF YOUR A PRIOR TO THE HOUR AND DATE SPECIFIEI ange an offer already submitted, such change may	nt on each copy of the o ACKNOWLEDGMENT D MAY RESULT IN See made by telegram or le	TO BE	
ACCOUNTING AND APPROPRIATION I	DATA (If required)				
		TO MODIFICATIONS OF CONTRACT CT/ORDER NO. AS DESCRIBED IN ITI			
A. THIS CHANGE ORDER IS ISSUED PURS CONTRACT ORDER NO. IN ITEM 10A	UANT TO: (Specify a			MADE IN TI	HE
B. THE ABOVE NUMBERED CONTRACT office, appropriation date, etc.) SET FOR	ORDER IS MODIFIED	TO REFLECT THE ADMINISTRATIONS AND TO THE AUTHORITY OF FA	/E CHANGES (such R 43.103(B).	as changes in	n paying
C. THIS SUPPLEMENTAL AGREEMENT	IS ENTERED INTO P	URSUANT TO AUTHORITY OF:			
D. OTHER (Specify type of modification an	d authority)				
IMPORTANT: Contractor X is not,	is required to sig	gn this document and return	copies to the issuin	g office.	
. DESCRIPTION OF AMENDMENT/MODI where feasible.) Modification Control Number: (b) (6) he purpose of this modification is:	FICATION (Organized	t by UCF section headings, including solic	itation/contract sub	ject matter	
) Add Period of Performance from (b) (4) processing of the invoices per DFAS reque	st.	for CLIN 0014 Change to A	ir Freight T&M, to a	llow for the	
Il other terms and conditions remain the sar	me.				
ept as provided herein, all terms and conditions of the	document referenced in Item	19A or 10A, as heretofore changed, remains uncha	nged and in full force and	d effect	
A. NAME AND TITLE OF SIGNER (Type of	or print)	16A. NAME AND TITLE OF CO	ICER	CER (Type	or print)
B. CONTRACTOR/OFFEROR	15C. DATE SIGNE		EMAL: (b) (6)	160	C. DATE SIGNEI
	-	BY (Signature of Contracting Of		2	6-Oct-2020
(Signature of person authorized to sign)					O OCT LOLO

Prescribed by GSA FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 1449 - CONTINUATION SHEET

DELIVERIES AND PERFORMANCE

The following Delivery Schedule for CLIN 0014 has been added:

DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE
(b) (4)
(b) (4)
(b) (6)
(b) (4)
FOB: Destination

(End of Summary of Changes)

AMENDMENT OF SOLICIT	ATIONMODIE	ICATION OF CONTRACT		1 CONTRACT	D CODE	PAGE OF PAGES
AMENDMENT OF SOLICIT	AHON/MODIF	ICATION OF CONTRACT		J		1 25
AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO			5 PROJECTI	NO (Ifapplicable)
200004	18-Dec-2020	SEE SCHEDULE				
ISSUED BY CODE	W911SR	7 ADMINISTERED BY (Ifother than item 6)		COL	DE	
USA CONTRACT NG CMD-APG W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLOG E4215 ABERDEEN PROVING GROUND MD 21010-5401		See Item 6				
NAME AND ADDRESS OF CONTRACTOR	No. Street County	State and Zip Code)	94	AMENDM	ENT OF SOL	LICITATION NO
DUOPROSS MEDITECH CORPORATION () (6) 27 SARAH DR	(No., Street, County,	state and Zip Code)		B. DATED (SI		
FARMINGDALE NY 11735-1209			X 10	A. MOD. OF 911SR20C00	CONTRAC 45	T/ORDER NO.
			10	B. DATED (SEE ITEM	13)
ODE 8LK11	FACILITY COI	DE	X 03	-Aug-2020		
11	THIS ITEM ONLY A	PPLIES TO AMENDMENTS OF SOLI	CITAT	IONS		
The above numbered solicitation is amended as set for	th in Item 14 The hour and	date specified for receipt of Offer	is e	xtended,	is not exten	ided
Offer must acknowledge receipt of this amendment pr (a) By completing Items 8 and 15, and returning or (c) By separate letter or telegramwhich includes a RECEIVED AT THE PLACE DESIGNATED FOR 7 REJECTION OF YOUR OFFER If by virtue of this provided each telegram or letter makes reference to th	copies of the amendmen reference to the solicitation THE RECEIPT OF OFFERS amendment you desire to cha	nt; (b) By acknowledging receipt of this amendme and amendment numbers FAILURE OF YOUR PRIOR TO THE HOUR AND DATE SPECIFIEI ange an offer already submitted, such change may	ent on eac ACKNOV D MAY F be made b	ch copy of the off WLEDGMENT RESULT IN by telegramor let	IO BE	
2. ACCOUNTING AND APPROPRIATION D	ATA (If required)					
See Schedule						
		TO MODIFICATIONS OF CONTRACT CT/ORDER NO. AS DESCRIBED IN IT		ERS.		
A. THIS CHANGE ORDER IS ISSUED PURS CONTRACT ORDER NO. IN ITEM 10A	UANT TO: (Specify a			EM 14 ARE M	ADE IN TH	Æ
B. THE ABOVE NUMBERED CONTRACT/ office, appropriation date, etc.) SET FOR					as changes in	1 paying
C. THIS SUPPLEMENTAL AGREEMENT D Bilateral IAW FAR 52.212-4(c)	SENTERED INTO PU	JRSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and	d authority)					
IMPORTANT: Contractor is not,	X is required to sig	n this document and return 1	copies	to the issuing	g office.	
4. DESCRIPTION OF AMENDMENT/MODII where feasible.) Modification Control Number:	FICATION (Organized	by UCF section headings, including solid	citation/	contract subj	ect matter	
The purpose of this modification is as follows	S:					
 The Government accepts the proposed co Duopross Meditech. The Government accepts the proposed su 					from	upit
 The Government is adding additional report Remove the duplicate sea freight cost from (b) (4) to ship their product. 	ting requirements lang	uage as part of the consideration by u	pdating		Work.	
Details are outlined on Block 14 Continuation	Page.					
cept as provided herein, all terms and conditions of the	document referenced in Item	9A or 10A, as heretofore changed, remains uncha	nged and	in full force and	effect	
5A. NAME AND TITLE OF SIGNER (Type of	or print)	16A. NAME AND TITLE OF CO	CER		CER (Type o	or print)
5B. CONTRACTOR/OFFEROR	15C. DATE SIGNE	D 16B. UNITED STATES OF AME		MAL (0)(0)		C. DATE SIGNED
(Signature of person authorized to sign)	-	BY (Signature of Contracting Of	ficer)		18	8-Dec-2020
		(againste et contracting of				

Prescribed by GSA FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: P00004

As the result of this Modification the following has been changed:

1- As the result of Government accepting the proposed consideration for the late deliveries the following changes are explained below:

a.	CLIN 0002 Delivery Date for (b) (4) units changes from (b) (4)
b.	CLIN 0003 Delivery Date for (b) (4) units changes from (b) (4)
c.	CLIN 0007 Delivery Date for (b) (4) units changes from (b) (4)
d.	CLIN 0008 Delivery Date for (b) (4) units changes from (b) (4)
e.	CLIN 0009 Delivery Date for (b) (4) units changes from (b) (4)
f.	CLIN 0010 Delivery Date for (b) (4) units changes from (b) (4)
g.	CLIN 0011 Delivery Date for (b) (4) units changes from (b) (4)
h.	CLIN 0012 Delivery Date for (b) (4) units changes from (b) (4)

- 2- As the result of Government accepting the proposed substitute safety needle instead of the safety syringe and needle combo the following changes are explained below:
 - a. Substitute (b) (4) safety syringe needle CLIN 0001 with (b) (4) safety syringe needle CLIN 0004.
 - b. Substitute (b) (4) safety syringe needle CLIN 0002 with (b) (4) safety syringe needle CLIN 0005.
 - c. Substitute (b) (4) safety syringe needle combo CLIN 0007 with ^{(b) (4)} safety syringe needle CLIN 0004.
 - d. Substitute (b) (4) safety syringe needle combo CLIN 0008 with (b) (4) safety syringe needle CLIN 0005.
 - e. Substitute (b) (4) safety syringe needle combo CLIN 0009 with safety syringe needle CLIN 0003.
 - f. Substitute (b) (4) safety syringe needle combo CLIN 0012 with (b) (4) safety syringe needle CLIN 0006.

3- Remove the duplicate sea freight cost from CLIN 0010 in the amount of (b) (4) by reducing the Unit Price from (b) (4). The amount of (b) (4) was calculated by multiplying the estimated sea shipping cost per (b) (4) with the 75,068,000 units that DuoPross Meditech is using (b) (4) flights to ship their product. The (b) (4) was accepted as delta cost between sea freight and air freight in the execution of Modification P00002 adding Time and Materials (T&M) CLIN 0014.

The actual costs of the re-palletization will continue to be invoiced under the T&M CLIN 0014 without the delta cost between sea freight and air freight.

4- The Government is adding additional reporting requirements language as part of the consideration. See updated Statement of Work in red font text.

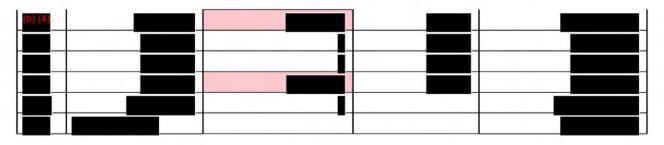
CLIN#	Description	(Quantity	Unit Price	Total Amount
(b) (4)					

Table 1- shows quantities and prices per CLIN prior to Modification.

 Table 2- shows new quantities and prices per CLIN after all Modification changes above.

 New Quantities after Modification Changes accepting consideration

	New Quantities arter Mounication Changes accepting consideration							
CLIN#	New Quantity	Quantity Change	Unit Price	New Total Amount				
(b) (4)								



All other terms and conditions remain the same.

The following have been modified: <u>REVISED STATEMENT OF WORK</u> Changes are shown below in red font text.

REVISED STATEMENT OF WORK PROCUREMENT OF SAFETY NEEDLES AND SYRINGES FOR COVID-19

1.0 <u>SCOPE</u>: The Contractor, as an independent Contractor and not as an agent of the Government, shall furnish the necessary resources as specified in this Statement of Work (SOW), to manufacture and/or supply Safety Needles and Syringes.

2.0 BACKGROUND:

On Friday, March 13, 2020, the President declared a national emergency concerning the novel coronavirus disease (COVID-19) under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act).

The mission of the Division of Strategic National Stockpile (DSNS), of the United States (U.S.) Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), is to ensure the availability and rapid deployment of lifesaving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. When state, local, tribal, and territorial public health and medical systems request federal assistance to support their response efforts, DSNS ensures the right medicines and supplies get to those who need them most during an emergency. When the vaccine becomes available the Government will have an immediate need to begin vaccinating the entire U.S. population. To administer the vaccine the Government will require needles and syringes to be available.

There is an insufficient domestic supply of safety needles and syringes to meet the projected needs to vaccinate the nation's entire population against COVID-19. Should vaccine programs

be accelerated, demand could outpace available devices to administer a vaccine.

3.0 <u>**OBJECTIVE**</u>: The HHS currently has contracts in place with three (3) major manufacturers to provide needles and syringes supplies to support the initial preparedness needs at the onset of a pandemic outbreak. The objective of this acquisition is to supplement the current supply and establish contracts with additional manufacturers and suppliers to provide a quantity of up to 500 million safety needles and syringes supplies.

4.0 **<u>REQUIREMENTS</u>**:

4.1. General:

4.1.1. The Contractor shall "host" a *Kick-Off Meeting* within one (1) calendar day after contract award via <u>teleconference</u>. The Contractor shall provide *Meeting Minutes* containing a detailed overview of the meeting discussions in accordance with (IAW) Contract Data Requirements List (CDRL) A001.

4.1.1.1. The Contractor shall provide a *Certificate of Analysis* with each shipment per the DD Form 1423, Contract Data Requirements List (CDRL) A002, confirming the supplies described below meet the Performance Specifications in paragraph 4.2 below.

4.1.2. The Contractor shall provide copies of *510(k) Approval Letters* for ALL supplies (dispensing syringes or needles) to demonstrate compliance with Section 510(k) of the *Food*, *Drug and Cosmetic Act* as part of their proposal. The Contractor shall provide, if necessary, *510(k) Approval Letters Updates* if any information from the initial 510(k) Approval Letters is changed/needs to be updated.

4.1.2.1.1. The Contractor shall ensure all supplies have a "*Shelf-Life*" with expiration dates of no less than five (5) years from the date of sterilization, <u>and</u> must have at least four (4) years of remaining expiry from the time of shipment.

4.1.2.1.2. The Contractor shall only use *Current Good Manufacturing Practice (cGMP)* processes to manufacture the needles and syringes.

4.1.2.1.3. Period of Performance/Delivery Dates. See the "Delivery Schedule" section of this Contract and "Attachment 2-Shipping Information" for all delivery requirements and shipping locations.

4.2. Technical Requirements:

4.2.1. The Contractor shall provide sterile needle (with Luer hub connection) and syringe (with Luer lock connection) units approved by the Food and Drug Administration (FDA) <u>and</u> comply with *Occupational Safety and Health Administration (OSHA) Needlestick Safety and Prevention Act* requirements as a "*safety-engineered product.*" Safety-engineered supplies include needles preventing sharp injuries by either; being completely enclosed after use by an attached shield, or be fully retracted within the syringe. **The Contractor may provide individual syringes and**

individual needles as long as there is a <u>one-to-one (1:1) ratio</u>. In order to meet the specified quantities upon contract award and comply with the specifications in this SOW, the following may be provided: (1) individually wrapped sterile syringes with individually wrapped sterile needles in a one-to-one (1:1) ratio, (2) sterile needle/syringe combination unit, or (3) a mixture of sterile combination units <u>and</u> individually wrapped sterile syringes with equal number of individually wrapped sterile needles.

4.2.2. The Contractor shall only provide acceptable product sizes as described below:

Individual Syringe:

Syringe	
1mL	
3mL	

Individual Needle:

<u>Needle</u> <u>Gauge</u>	Needle Length
23G	1"
23G	1.5"
25G	1"

Combination Unit:

Syringe	<u>Needle</u> Gauge	<u>Needle</u> Length
lmL	23G	1"
lmL	23G	1.5"
lmL	25G	1"
3mL	23G	1"
3mL	23G	1.5"
3mL	25G	1"

4.2.3. Dispensing Syringe: *Description*: A dispensing syringe allows for the controlled and precise flow of liquid. The dispensing syringe is used to inject medications or other liquids into body tissues. Manual syringes consist of a barrel, stopper, and plunger.

4.2.3.1. The Contractor shall ensure dispensing syringes comply with Title 21 Code of Federal Regulations (CFR) 880.5860 and follow International Standards Organization (ISO) 7886-1:2017 and the following material specifications:

4.2.3.1.1. A device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle;

4.2.3.1.2.	Heavy duty barrel - The barrel has a scale showing the capacity of the syringe.
4.2.3.1.3.	Stopper - The stopper maintains the fluid in the barrel between the syringe nozzle and the plunger;
4.2.3.1.4.	Plunger - The plunger is used to aspirate and inject fluids into and out of the syringe;
4.2.3.1.5.	Disposable;
4.2.3.1.6.	Luer lock to accept luer hub applicator (e.g. needle);
4.2.3.1.7.	Sizes as specified in Section 4.2.2 above; and
4.2.3.1.8.	Sterile individually wrapped packaging.

4.2.4. Hypodermic Needle: *Description*: A Hypodermic needle is a slender, hollow instrument for introducing material into the body parenterally.

4.2.4.1. The Contractor shall ensure hypodermic needles comply with 21 CFR 880.5570, OSHA Needlestick Safety and Prevention Act, and follow International Standards Organization (ISO) 7864, and the following specifications:

4.2.4.1.1. Disposable;

- **4.2.4.1.2. Luer hub** to attach to luer lock syringe;
- **4.2.4.1.3.** See Tables in Sections 4.2.2 above for acceptable needle length and gauges;
- **4.2.4.1.4.** Sterile individually wrapped packaging; and
- 4.2.4.1.5. Safety-engineered.

4.3. Delivery Location and Shipping Requirements: See Attachment 2-"Shipping Information" for all delivery locations and shipping requirements.

4.3.1. The Contractor shall provide *Packing Slips* with <u>all shipments</u> per CDRL A003. The Packing Slips shall include the following: (1) Contract number, (2) Item description, (3) Part number, (4) Lot numbers; and (5) Quantities. The Packing Slips shall include <u>BOTH</u>: (1) a *Packing Slip Paper Copy* with the shipment; and (2) a *Packing Slip Paper Emailed Copy* to the Designated Government Representative.

4.3.2. No Partial Case or Packages quantities will be accepted unless approved by the Contracting Officer prior to shipping.

4.3.3. The Contractor shall **<u>NOT</u>** Mixed Lot #'s per Case or per Packages. The Contractor shall only provide full <u>case</u> quantities <u>only</u>, *unless* approved by the Designated Government Representative in advance via email.

4.3.4. The Contractor shall ensure all pallets have the identical TyHi stack pattern, except for the final pallet; which would be a partial pallet or individual boxes.

4.3.5. All supplies shall be delivered on a standard 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, clear-wrapped is preferred, and secured to the pallet for safe transport.

4.3.6. The Contractor shall contact the Designated Government Representative to schedule delivery appointments. The Government will provide the Designated Government

Representative(s)' information at the Kick-Off Meeting.

4.3.7. Contractor shall contact the Designated Government Representative to schedule delivery appointments.

4.3.8. The Contractor shall ship ALL deliverables via AIR FREIGHT through February 28, 2021, effective immediately. The Contractor shall charge the Delta in costs between Air Freight costs and Sea Freight costs already built into this contract. The Contractor shall NOT submit any costs (e.g. labor, overhead, profit) other than "*other direct costs*" per FAR Clause 52.214-4 Alternative one (1) as those cost are already included in the contract. The Contractor shall only be reimbursed for **actual** *REASONABLE* **costs** and shall provide documented proof (e.g. receipts and paid invoices). The Government's pallet dimension limitations (stated in Section 4.3.5) is how the pallets will be <u>delivered</u>, it does NOT restrict pallet heights or other packing dimensions of HOW the items are to be <u>shipped</u> (either by air or sea). The Contractor shall follow commercial best practices and to maximize/optimize Air Cargo Load, palletization or repalletization (if needed), and drayage. The Government reserves the right to stop this Air Freight requirement prior to February 28, 2021 via email notification from the Contracting Officer due to urgency, followed by a bi-lateral modification. The Government also reserves the right to provide transportation (e.g. planes) or other logistical services (e.g. palletization) and will notify the Contractor via an email from the Contracting Officer.

4.3.9. Based on mutual agreement at the Post-Award Meeting for delivery schedules, the Contractor shall provide an *Initial Updated Syringe-Needle Delivery Schedule*. The template for the Initial Updated Syringe-Needle Delivery Schedule will be provided by the COR. The Initial Updated Delivery Schedule shall be provided to the COR within three (3) business days after the "Sea to Air Freight Modification." Thereafter, the Contractor shall, at a minimum, provide *Weekly Delivery Schedule Updates* to the COR by Tuesday, 1400 Eastern Time.

5.0 Operation Warp Speed (OWS) Contract Language:

5.1. Disclosure of Information:

5.1.1. Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

5.1.2. The Contractor shall comply with all Government requirements for protection of nonpublic information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

5.1.3. No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

5.2. <u>Publications and Publicity</u>:

5.2.1. The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government:

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published;

(b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications;

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided;

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows: "This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

5.3. Confidentiality of Information:

5.3.1. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

5.3.2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will

furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

5.3.3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

5.3.4. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

5.3.5. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

5.3.6. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

5.3.7. All above requirements MUST be passed to all Sub-contractors.

5.4. Organizational Conflicts of Interest:

5.4.1. Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

5.4.2. The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

5.4.3. The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore,

the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

5.4.4. Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

Additional Reporting Requirements.

WAREHOUSED ITEMS - Contract Items stored/staged at interim locations prior to air shipment at contractor warehouses and/or warehouses utilized by contractor subcontractors and/or transportation agents. The contractor is required to provide a daily report not later than 1700 US Eastern Standard Time (EST) including the following information:

Location of Warehouse(s):

Complete physical address of warehouse(s):

Warehouse POC:

Warehouse POC telephone number and email address:

For each warehouse location, detailed descriptions and quantities/count by individual item warehoused and ready for shipment.

ADDITIONAL NOTES:

1. Concurrently, all information required under this contract modification shall be provided by email to the following individuals:

(b) (6)

The following have been deleted: <u>STATEMENT OF WORK</u>

SECTION SF 1449 - CONTINUATION SHEET

SOLICITATION/CONTRACT FORM

The total cost of this contract was decreased by (b) (4)

SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The pricing detail quantity has decreased by (b) (4) The total cost of this line item has decreased by (b)

CLIN 0002

The pricing detail quantity has decreased by (b) (4)	
The total cost of this line item has decreased by (b) (4)	

CLIN 0003

The pricing detail quantity has increased by (b) (4) The total cost of this line item has increased by (b) (4)

CLIN 0004

The pricing detail quantity has increased by (b) (4) The total cost of this line item has increased by (b) (4)

CLIN 0005

The pricing detail quantity has increased by (b) (4) The total cost of this line item has increased by (b) (4)

CLIN 0006

The pricing detail quantity has increased by

o) (4) y(b) (4)

С	LIN 0007 The pricing detail quantit	ty has decreased h	(h) (4)			
	The total cost of this line					
С	LIN 0008					
	The pricing detail quantit The total cost of this line					
C	LIN 0009 The pricing detail quanti	tr has decreased by				
	The total cost of this line					
С	LIN 0010					
	The unit price amount ha The total cost of this line	item has decrease	d by <mark>(b) (4)</mark>			
С	LIN 0012				<u></u>	
	The pricing detail quantit The total cost of this line					
S	UBCLIN 000301 is added as	s follows:				
ITEM NO 000301	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE		AMOUNT
	Funding for additional qua FFP	intity				
	Funding for additional qua PURCHASE REQUEST N		units for CLI	N 0003.		
				NET AMT		(b) (4)
	ACRN AB CIN: (b) (4)				(b) (4)

SUBCLIN 000401 is added as follows:

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ITEM NO 000401	SUPPLIES/SERVICES QUANTITY U	NIT	UNIT PRICE		AMOUNT
000401	Funding for additional quantity				
	FFP Funding for additional quantity of (b) (4) for C	LIN 0004			
	PURCHASE REQUEST NUMBER: (b) (4)	LIN 0004			
			NET AMT		(b) (4)
				10	
	ACRN AB CIN: G(b) (4)			(D)) (4)
S	UBCLIN 000501 is added as follows:				
ITEM NO	SUPPLIES/SERVICES QUANTITY U	NIT	UNIT PRICE		AMOUNT
000501	Funding for additional quantity				(0) (4)
	FFP				
	Funding for additional quantity of (b) (4) for C PURCHASE REQUEST NUMBER: (b) (4)	CLIN 0005			
					151741
			NET AMT		(0)(4)
	ACRN AB			(b)) (4)
	CIN: (b) (4)				
S	UBCLIN 000601 is added as follows:				
ITEM NO	SUPPLIES/SERVICES QUANTITY U	NIT	UNIT PRICE		AMOUNT
000601					(b) (4)
	Funding for additional quantity FFP				
		LIN 0006			
	PURCHASE REQUEST NUMBER: (b) (4)				
			NET AMT		(b) (4)
	ACRN AB			(b) (4)
	CIN: (b) (4)				

ACCOUNTING AND APPROPRIATION

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was decreased by (b) (4) CLIN 0001: SUBCLIN 000301: Funding on SUBCLIN 000301 is initiated as follows: ACRN: AB CIN: (b) (4) SUBCLIN 000401: Funding on SUBCLIN 000401 is initiated as follows: SUBCLIN 000501: Funding on SUBCLIN 000501 is initiated as follows: b) (4)

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(b) (4)			
SUBCLIN 000601: Funding on SUBCLIN 000601 is initiated	as follows:		
	as follows.		
(b) (4)			
			2.20
CLIN 0007:			
(b) (A)	_	_	
(D) (4)			
CLIN 0010:			
	<u></u>		
(b) (4)			
DELIVERIES AND PERFORMANCE			

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE QUANTITY SHIP TO ADDRESS

DODAAC / CAGE

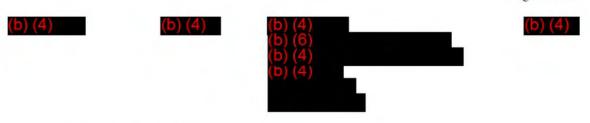
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
			(b) (4)	
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (4) (b) (4)	(b) (4)
The fol	lowing Delivery Schedule it	em for CLIN 0002 h	as been changed from:	
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (6)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
The fol	lowing Delivery Schedule it	em for CLIN 0002 h	as been changed from:	
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC /

DODAAC / CAGE

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				Page 18 of 25
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
The fo	ollowing Delivery Schedule i	tem has been added	to CLIN 0002:	
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
The fo	ollowing Delivery Schedule i	tem for CLIN 0003	has been changed from:	
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

CAGE



The following Delivery Schedule item for CLIN 0003 has been changed from:







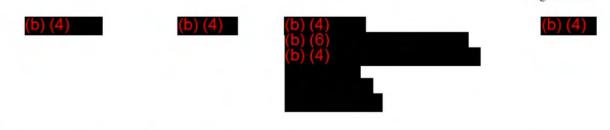
The following Delivery Schedule item for CLIN 0007 has been changed from:

	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
_				
To:	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
The fol	llowing Delivery Schedule i	item for CLIN 0008	has been changed from:	
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE



The following Delivery Schedule item for CLIN 0008 has been changed from:





The following Delivery Schedule item for CLIN 0009 has been changed from:



DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE (b) (4) D) (4) b) (4) To: DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE b) (4) b) (4)

The following Delivery Schedule item for CLIN 0010 has been changed from:

The following Delivery Schedule item for CLIN 0011 has been changed from:



The following Delivery Schedule item for CLIN 0012 has been changed from:

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	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6)	(b) (4)
			(b) (4)	
INSPE	ECTION AND ACCEPTAN	ICE		
	llowing Acceptance/Inspect			
	INSPECT AT	INSPECT E		ACCEPT BY
	N/A	N/A	N/A	N/A
The fo	llowing Acceptance/Inspect	tion Schedule was add	led for SUBCLIN 000401	
	INSPECT AT	INSPECT E		ACCEPT BY
	N/A	N/A	N/A	N/A
Thefe	11	in Cababila mar a d	A for SUDCL DI 000501.	
	ollowing Acceptance/Inspect INSPECT AT	INSPECT E		ACCEPT BY
	N/A	N/A	N/A	N/A
The fo	llowing Acceptance/Inspect	ion Schedule was ad	led for SUBCLIN 000601	
	INSPECT AT	INSPECT E		ACCEPT BY
	N/A	N/A	N/A	N/A

(End of Summary of Changes)

AMENDMENT OF SOLIC	TATIONMODI	FICATION OF CONTRACT		1 CONTRACT	ID CODE	PAGE OF PAGES
AMENDMENT OF SOLIC	TATION/MODI	SICATION OF CONTRACT		S		1 20
AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO			5 PROJECTI	NO (Ifapplicable)
200005	26-Feb-2021	SEE SCHEDULE				
ISSUED BY CODE	W911SR	7 ADMINISTERED BY (Ifother than item 6)		COL	DE	
USA CONTRACT NG CMD-APG W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401		See Item 6				
NAME AND ADDRESS OF CONTRACTO	OR (No Street County	State and Zin Code)	94	AMENDM	ENT OF SOI	LICITATION NO
DUOPROSS MEDITECH CORPORATION	SR (10., Siler, county,	Gate and Zip Code)		B. DATED (S		
FARMINGDALE NY 11735-1209			X 10	A. MOD. OF	CONTRAC	T/ORDER NO.
			10	B. DATED	SEE ITEM	13)
DDE 8LK11	FACILITY COL			3-Aug-2020		
	11. THIS ITEM ONLY A	APPLIES TO AMENDMENTS OF SOLI	CITAT	IONS		
The above numbered solicitation is amended as set	t forth in Item 14 The hour and	date specified for receipt of Offer	ise	extended,	is not exten	ided
(a) By completing Items 8 and 15, and returning or (c) By separate letter or telegramwhich include RECEIVED AT THE PLACE DESIGNATED FO REJECTION OF YOUR OFFER If by virtue of th provided each telegram or letter makes reference to	es a reference to the solicitation PR THE RECEIPT OF OFFERS his amendment you desire to cha	PRIOR TO THE HOUR AND DATE SPECIFIE ange an offer already submitted, such change may	ACKNO D MAY I be made I	WLEDGMENT RESULT IN by telegram or let	TO BE	
2. ACCOUNTING AND APPROPRIATION	NDATA (If required)					
13. THIS	ITEM APPLIES ONLY	TO MODIFICATIONS OF CONTRACT	S/ORDI	ERS		
		CT/ORDER NO. AS DESCRIBED IN IT				
A. THIS CHANGE ORDER IS ISSUED PU CONTRACT ORDER NO. IN ITEM 10		authority) THE CHANGES SET FORTH	IN ITI	EM 14 ARE N	ADE IN TH	Ε
B. THE ABOVE NUMBERED CONTRAC	TORDER IS MODIFIED	TO REFLECT THE ADMINISTRATE SUANT TO THE AUTHORITY OF FA	VE CH	ANGES (such	as changes in	a paying
C. THIS SUPPLEMENTAL AGREEMEN Bilateral IAW FAR 52.212-4(c)			at 15.1	05(2).		
D. OTHER (Specify type of modification	and authority)					
IMPORTANT: Contractor is not,	X is required to sig	gn this document and return 1	copies	s to the issuin	g office.	
4. DESCRIPTION OF AMENDMENT/MOI where feasible.) Modification Control Number: (b) (6 The purpose of this modification is to:	DIFICATION (Organized	by UCF section headings, including solid	citation	/contract subj	ect matter	
 Extend the Air Freight on the Time and I Update Statement of Work to reflect the Update FAR Clause 52.212-4 Alt I. Clarify allow able costs for "re-palletizat 	above changes.	4 from <mark>(b) (4)</mark>				
All other terms and conditions remain the s	same.					
scept as provided herein, all terms and conditions of 5A. NAME AND TITLE OF SIGNER (Typ		19A or 10A, as heretofore changed, remains uncha 16A. NAME AND TITLE OF CO	-			or print)
in the second seco		(b) (6) / CONTRACTING OFF		ci ili o oi ri		Prant)
		TEL:		MAL: (6) (6)		
	15C. DATE SIGNE	D 16B. UNITED STATES OF AME	RICA		160	
5B. CONTRACTOR/OFFEROR		$_{\rm BY}^{\rm (b)}$ (6)				C. DATE SIGNED

FAR (48 CFR) 53.243

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SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: <u>P00005 STATEMENT OF WORK</u> Changes are shown below in red font text.

REVISED STATEMENT OF WORK P00005 PROCUREMENT OF SAFETY NEEDLES AND SYRINGES FOR COVID-19

1.0 <u>SCOPE</u>: The Contractor, as an independent Contractor and not as an agent of the Government, shall furnish the necessary resources as specified in this Statement of Work (SOW), to manufacture and/or supply Safety Needles and Syringes.

2.0 BACKGROUND:

On Friday, March 13, 2020, the President declared a national emergency concerning the novel coronavirus disease (COVID-19) under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act).

The mission of the Division of Strategic National Stockpile (DSNS), of the United States (U.S.) Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), is to ensure the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. When state, local, tribal, and territorial public health and medical systems request federal assistance to support their response efforts, DSNS ensures the right medicines and supplies get to those who need them most during an emergency. When the vaccine becomes available the Government will have an immediate need to begin vaccinating the entire U.S. population. To administer the vaccine the Government will require needles and syringes to be available.

There is an insufficient domestic supply of safety needles and syringes to meet the projected needs to vaccinate the nation's entire population against COVID-19. Should vaccine programs be accelerated, demand could outpace available devices to administer a vaccine.

3.0 <u>**OBJECTIVE**</u>: The HHS currently has contracts in place with three (3) major manufacturers to provide needles and syringes supplies to support the initial preparedness needs at the onset of a pandemic outbreak. The objective of this acquisition is to supplement the current supply and establish contracts with additional manufacturers and suppliers to provide a quantity of up to 500 million safety needles and syringes supplies.

4.0 **<u>REQUIREMENTS</u>**:

4.1. General:

4.1.1. The Contractor shall "host" a *Kick-Off Meeting* within one (1) calendar day after contract award via <u>teleconference</u>. The Contractor shall provide *Meeting Minutes* containing a detailed overview of the meeting discussions in accordance with (IAW) Contract Data Requirements List (CDRL) A001.

4.1.1.1. The Contractor shall provide a *Certificate of Analysis* with each shipment per the DD Form 1423, Contract Data Requirements List (CDRL) A002, confirming the supplies described below meet the Performance Specifications in paragraph 4.2 below.

4.1.2. The Contractor shall provide copies of *510(k) Approval Letters* for ALL supplies (dispensing syringes or needles) to demonstrate compliance with Section 510(k) of the *Food*, *Drug and Cosmetic Act* as part of their proposal. The Contractor shall provide, if necessary, *510(k) Approval Letters Updates* if any information from the initial 510(k) Approval Letters is changed/needs to be updated.

4.1.2.1.1. The Contractor shall ensure all supplies have a "*Shelf-Life*" with expiration dates of no less than five (5) years from the date of sterilization, <u>and</u> must have at least four (4) years of remaining expiry from the time of shipment.

4.1.2.1.2. The Contractor shall only use *Current Good Manufacturing Practice (cGMP)* processes to manufacture the needles and syringes.

4.1.2.1.3. Period of Performance/Delivery Dates. See the "Delivery Schedule" section of this Contract and "Attachment 2-Shipping Information" for all delivery requirements and shipping locations.

4.2. Technical Requirements:

4.2.1. The Contractor shall provide sterile needle (with Luer hub connection) and syringe (with Luer lock connection) units approved by the Food and Drug Administration (FDA) <u>and</u> comply with *Occupational Safety and Health Administration (OSHA) Needlestick Safety and Prevention Act* requirements as a "*safety-engineered product*." Safety-engineered supplies include needles preventing sharp injuries by either; being completely enclosed after use by an attached shield, or be fully retracted within the syringe. The Contractor may provide individual syringes and individual needles as long as there is a <u>one-to-one (1:1) ratio</u>. In order to meet the specified quantities upon contract award and comply with the specifications in this SOW, the following may be provide: (1) individually wrapped sterile syringes with individually wrapped sterile needles in a one-to-one (1:1) ratio, (2) sterile needle/syringe combination unit, or (3) a mixture of sterile combination units <u>and</u> individually wrapped sterile syringes with equal number of individually wrapped sterile needles.

4.2.2. The Contractor shall only provide acceptable product sizes as described below:

Individual Syringe:

Syringe	
lmL	
3mL	1

Individual Needle:

<u>Needle</u> Gauge	<u>Needle</u> Length
23G	1"
23G	1.5"
25G	1"

Combination Unit:

Syringe	<u>Needle</u> Gauge	<u>Needle</u> Length
lmL	23G	1"
lmL	23G	1.5"
lmL	25G	1"
3mL	23G	1"
3mL	23G	1.5"
3mL	25G	1"

4.2.3. Dispensing Syringe: *Description*: A dispensing syringe allows for the controlled and precise flow of liquid. The dispensing syringe is used to inject medications or other liquids into body tissues. Manual syringes consist of a barrel, stopper, and plunger.

4.2.3.1.	The Contractor shall ensure dispensing syringes comply with Title 21 Code of
Federal Regu	lations (CFR) 880.5860 and follow International Standards Organization (ISO)
7886-1:2017	and the following material specifications:

- **4.2.3.1.1.** A device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle;
- **4.2.3.1.2.** Heavy duty barrel The barrel has a scale showing the capacity of the syringe.
- **4.2.3.1.3.** Stopper The stopper maintains the fluid in the barrel between the syringe nozzle and the plunger;
- **4.2.3.1.4.** Plunger The plunger is used to aspirate and inject fluids into and out of the syringe;
- 4.2.3.1.5. Disposable;
- 4.2.3.1.6. <u>Luer lock</u> to accept luer hub applicator (e.g. needle);

4.2.3.1.7.	Sizes as specified in Section 4.2.2 above; and
4.2.3.1.8.	Sterile individually wrapped packaging.

4.2.4. Hypodermic Needle: *Description*: A Hypodermic needle is a slender, hollow instrument for introducing material into the body parenterally.

4.2.4.1. The Contractor shall ensure hypodermic needles comply with 21 CFR 880.5570, OSHA Needlestick Safety and Prevention Act, and follow International Standards Organization (ISO) 7864, and the following specifications:

- 4.2.4.1.1. Disposable;
- 4.2.4.1.2. Luer hub to attach to luer lock syringe;
- 4.2.4.1.3. See Tables in Sections 4.2.2 above for acceptable needle length and gauges;
- 4.2.4.1.4. Sterile individually wrapped packaging; and
- 4.2.4.1.5. Safety-engineered.

4.3. Delivery Location and Shipping Requirements: See Attachment 2-"Shipping Information" for all delivery locations and shipping requirements.

4.3.1. The Contractor shall provide *Packing Slips* with <u>all shipments</u> per CDRL A003. The Packing Slips shall include the following: (1) Contract number, (2) Item description, (3) Part number, (4) Lot numbers; and (5) Quantities. The Packing Slips shall include <u>BOTH</u>: (1) a *Packing Slip Paper Copy* with the shipment; and (2) a *Packing Slip Paper Emailed Copy* to the Designated Government Representative.

4.3.2. No Partial Case or Packages quantities will be accepted unless approved by the Contracting Officer prior to shipping.

4.3.3. The Contractor shall <u>NOT</u> Mixed Lot #'s per Case or per Packages. The Contractor shall only provide full <u>case</u> quantities <u>only</u>, *unless* approved by the Designated Government Representative in advance via email.

4.3.4. The Contractor shall ensure all pallets have the identical TyHi stack pattern, except for the final pallet; which would be a partial pallet or individual boxes.

4.3.5. All supplies shall be delivered on a standard 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, clear-wrapped is preferred, and secured to the pallet for safe transport.

4.3.6. The Contractor shall contact the Designated Government Representative to schedule delivery appointments. The Government will provide the Designated Government Representative(s)' information at the Kick-Off Meeting.

4.3.7. Contractor shall contact the Designated Government Representative to schedule delivery appointments.

4.3.8. The Contractor shall ship ALL deliverables via AIR FREIGHT from (b) (4)

The Contractor shall charge the Delta in costs between Air Freight costs and Sea Freight costs as updated under 'other direct costs' in the FAR Clause 52.212-4 Alt I. The Contractor shall NOT submit any costs (e.g. labor, overhead, profit) other than "other direct costs" per FAR Clause 52.214-4 Alternative one (1) as those cost are already included in the contract. The Contractor shall only be reimbursed for actual REASONABLE costs and shall provide documented proof (e.g. receipts and paid invoices). The Government's pallet dimension limitations (stated in Section 4.3.5) is how the pallets will be delivered, it does NOT restrict pallet heights or other packing dimensions of HOW the items are to be shipped (either by air or sea). The Contractor shall follow commercial best practices and to maximize/optimize Air Cargo Load, palletization or re-palletization (if needed), and drayage. The Government reserves the right to stop this Air Freight requirement prior to (b) (4) via email notification from the Contracting Officer due to urgency, followed by a bi-lateral modification. The Government also reserves the right to provide transportation (e.g. planes) or other logistical services (e.g. palletization) and will notify the Contractor via an email from the Contracting Officer. For purposes of this modification through(b) (4) the Contractor shall continue to use Government-provided-aircraft under b) (4)

to provide the approximate weight allowances and restrictions stated therein through (b) (4) In the event, the Contractor completes/uses all the provided planes under the (b) (4), prior to (b) (4) the Contractor shall notify the Contracting Officer under this award PRIOR to making or incurring any future air freight costs.

4.3.9. Based on mutual agreement at the Post-Award Meeting for delivery schedules, the Contractor shall provide an *Initial Updated Syringe-Needle Delivery Schedule*. The template for the Initial Updated Syringe-Needle Delivery Schedule will be provided by the COR. The Initial Updated Delivery Schedule shall be provided to the COR within three (3) business days after the "Sea to Air Freight Modification." Thereafter, the Contractor shall, at a minimum, provide *Weekly Delivery Schedule Updates* to the COR by Tuesday, 1400 Eastern Time.

5.0 Operation Warp Speed (OWS) Contract Language:

5.1. Disclosure of Information:

5.1.1. Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

5.1.2. The Contractor shall comply with all Government requirements for protection of nonpublic information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

5.1.3. No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

5.2. <u>Publications and Publicity</u>:

5.2.1. The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government:

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published;

(b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications;

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided;

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows: "This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

5.3. Confidentiality of Information:

5.3.1. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

5.3.2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere

in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

5.3.3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

5.3.4. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

5.3.5. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

5.3.6. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

5.3.7. All above requirements MUST be passed to all Sub-contractors.

5.4. Organizational Conflicts of Interest:

5.4.1. Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

5.4.2. The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

5.4.3. The Contractor shall notify the Contracting Officer immediately whenever it becomes

aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

5.4.4. Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

Additional Reporting Requirements.

WAREHOUSED ITEMS - Contract Items stored/staged at interim locations prior to air shipment at contractor warehouses and/or warehouses utilized by contractor subcontractors and/or transportation agents. The contractor is required to provide a daily report not later than 1700 US Eastern Standard Time (EST) including the following information:

Location of Warehouse(s):

Complete physical address of warehouse(s):

Warehouse POC:

Warehouse POC telephone number and email address:

For each warehouse location, detailed descriptions and quantities/count by individual item warehoused and ready for shipment.

ADDITIONAL NOTES:

1. Concurrently, all information required under this contract modification shall be provided by email to the following individuals:

(b) (6)

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SECTION SF 1449 - CONTINUATION SHEET

SUPPLIES OR SERVICES AND PRICES

CLIN 0014

The CLIN extended description has changed from:

This Time and Materials (T&M) CLIN is for the delta costs incurred between the already included Sea Freight (built into the FFP CLINS) and the additional estimated costs for Air Freight on all shipments by (b) (4) The total invoiced amount on this CLIN cannot exceed the total Funding. The Contractor shall contact the Contracting Officer prior to incurring expense against this T&M CLIN if that expense will exceed the Contractor's proposed delta between sea freight and air freight. NOTE: Total invoiced amount against this CLIN cannot exceed the total funded amount/total line item cost.

To:

This Time and Materials (T&M) CLIN 0014 is for the Delta costs incurred between the already included Sea Freight (built into the FFP CLINS) and the additional estimated costs for Air Freight by (b) (4) The Contractor shall contact the Contracting Officer prior to incurring expense against this T&M CLIN 0014 if that expense will exceed the Contractor's proposed delta between sea freight and air freight. Total invoiced amount against this CLIN cannot exceed the total funded amount of Not to Exceed (NTE) amount. NOTE: Other direct costs include only the following: (1) Cost of the mandatory Merchandise Processing Fee (MPF); (2) Costs to pick up supplies from the (b) (4) contractor; (3) The actual re-palletization cost charged from the freight forwarder (b) (4); and (4) Shipping the supplies from (b) (4) to the delivery to (b) (4) sites.

DELIVERIES AND PERFORMANCE

The following Delivery Schedule item for CLIN 0014 has been changed from:

	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (d)	(b) (4) (b) (6) (b) (4)	(b) (4)
To:				
10.	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE







The following have been modified:

This section has been modified. Changes are shown below in red font text.

52.212-4 CONTRACT TERMS AND CONDITIONS -- COMMERCIAL ITEMS (OCT 2018) ALTERNATE I (JAN 2017)

When a time-and-materials or labor-hour contract is contemplated, substitute the following paragraphs (a), (e), (i), (l), and (m) for those in the basic clause.

(a) Inspection/Acceptance.

(1) The Government has the right to inspect and test all materials furnished and services performed under this contract, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the plant or plants of the Contractor or any subcontractor engaged in contract performance. The Government will perform inspections and tests in a manner that will not unduly delay the work.

(2) If the Government performs inspection or tests on the premises of the Contractor or a subcontractor, the Contractor shall furnish and shall require subcontractors to furnish all reasonable facilities and assistance for the safe and convenient performance of these duties.

(3) Unless otherwise specified in the contract, the Government will accept or reject services and materials at the place of delivery as promptly as practicable after delivery, and they will be presumed accepted 60 days after the date of delivery, unless accepted earlier.

(4) At any time during contract performance, but not later than 6 months (or such other time as may be specified in the contract) after acceptance of the services or materials last delivered under this contract, the Government may require the Contractor to replace or correct services or materials that at time of delivery failed to meet contract requirements. Except as otherwise specified in paragraph (a)(6) of this clause, the cost of replacement or correction shall be determined under paragraph (i) of this clause, but the "hourly rate" for labor hours incurred in the replacement or correction shall be reduced to exclude that portion of the rate attributable to profit. Unless otherwise specified below, the portion of the "hourly rate" attributable to profit shall be 10 percent. The Contractor shall not tender for acceptance materials and services required to be replaced or corrected without disclosing the former requirement for replacement or correction, and, when required, shall disclose the corrective action taken. (Insert portion of labor rate attributable to profit.)

(5) If the Contractor fails to proceed with reasonable promptness to perform required replacement or correction, and if the replacement or correction can be performed within the ceiling price (or the ceiling price as increased by the Government), the Government may—

(A) By contract or otherwise, perform the replacement or correction, charge to the Contractor any increased cost, or deduct such increased cost from any amounts paid or due under this contract; or

(B) Terminate this contract for cause.

(ii) Failure to agree to the amount of increased cost to be charged to the Contractor shall be a dispute under the Disputes clause of the contract.

(6) Notwithstanding paragraphs (a)(4) and (5) above, the Government may at any time require the Contractor to remedy by correction or replacement, without cost to the Government, any failure by the Contractor to comply with the requirements of this contract, if the failure is due to—

(i) Fraud, lack of good faith, or willful misconduct on the part of the Contractor's managerial personnel; or

(ii) The conduct of one or more of the Contractor's employees selected or retained by the Contractor after any of the Contractor's managerial personnel has reasonable grounds to believe that the employee is habitually careless or unqualified.

(7) This clause applies in the same manner and to the same extent to corrected or replacement materials or services as to materials and services originally delivered under this contract.

(8) The Contractor has no obligation or liability under this contract to correct or replace materials and services that at time of delivery do not meet contract requirements, except as provided in this clause or as may be otherwise specified in the contract.

(9) Unless otherwise specified in the contract, the Contractor's obligation to correct or replace Governmentfurnished property shall be governed by the clause pertaining to Government property.

(b) Assignment. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (*e.g.*, use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(c) Changes. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(d) Disputes. This contract is subject to 41 U.S.C. chapter 71, Contract Disputes, as amended (41 U.S.C. 601-613). Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) Definitions.

(1) The clause at FAR 52.202-1, Definitions, is incorporated herein by reference. As used in this clause—

(i) Direct materials means those materials that enter directly into the end product, or that are used or consumed directly in connection with the furnishing of the end product or service.

(ii) Hourly rate means the rate(s) prescribed in the contract for payment for labor that meets the labor category qualifications of a labor category specified in the contract that are—

(A) Performed by the contractor;

(B) Performed by the subcontractors; or

(C) Transferred between divisions, subsidiaries, or affiliates of the contractor under a common control.

(iii) Materials means-

(A) Direct materials, including supplies transferred between divisions, subsidiaries, or affiliates of the contractor under a common control;

(B) Subcontracts for supplies and incidental services for which there is not a labor category specified in the contract;

(C) Other direct costs (*e.g.*, incidental services for which there is not a labor category specified in the contract, travel, computer usage charges, etc.);

(D) The following subcontracts for services which are specifically excluded from the hourly rate: **Not Applicable** (Insert any subcontracts for services to be excluded from the hourly rates prescribed in the schedule); and

(E) Indirect costs specifically provided for in this clause.

(iv) Subcontract means any contract, as defined in FAR Subpart 2.1, entered into with a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract including transfers between divisions, subsidiaries, or affiliates of a contractor or subcontractor. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(f) Excusable delays. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(g) Invoice.

(1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include—

(i) Name and address of the Contractor;

(ii) Invoice date and number;

(iii) Contract number, line item number and, if applicable, the order number;

(iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;

(vi) Terms of any discount for prompt payment offered;

(vii) Name and address of official to whom payment is to be sent;

(viii) Name, title, and phone number of person to notify in event of defective invoice; and

(ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.

(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (*e.g.*, 52.232-33, Payment by Electronic Funds Transfer—System for Award Management, or 52.232-34, Payment by Electronic Funds Transfer—Other Than System for Award Management), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR Part 1315.

(h) Patent indemnity. The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) Payments.

(1) Work performed. The Government will pay the Contractor as follows upon the submission of commercial invoices approved by the Contracting Officer:

(i) Hourly rate.

(A) The amounts shall be computed by multiplying the appropriate hourly rates prescribed in the contract by the number of direct labor hours performed. Fractional parts of an hour shall be payable on a prorated basis.

(B) The rates shall be paid for all labor performed on the contract that meets the labor qualifications specified in the contract. Labor hours incurred to perform tasks for which labor qualifications were specified in the contract will not be paid to the extent the work is performed by individuals that do not meet the qualifications specified in the contract, unless specifically authorized by the Contracting Officer.

(C) Invoices may be submitted once each month (or at more frequent intervals, if approved by the Contracting Officer) to the Contracting Officer or the authorized representative.

(D) When requested by the Contracting Officer or the authorized representative, the Contractor shall substantiate invoices (including any subcontractor hours reimbursed at the hourly rate in the schedule) by evidence of actual payment, individual daily job timecards, records that verify the employees meet the qualifications for the labor categories specified in the contract, or other substantiation specified in the contract.

(E) Unless the Schedule prescribes otherwise, the hourly rates in the Schedule shall not be varied by virtue of the Contractor having performed work on an overtime basis.

(1) If no overtime rates are provided in the Schedule and the Contracting Officer approves overtime work in advance, overtime rates shall be negotiated.

(2) Failure to agree upon these overtime rates shall be treated as a dispute under the Disputes clause of this contract.

(3) If the Schedule provides rates for overtime, the premium portion of those rates will be reimbursable only to the extent the overtime is approved by the Contracting Officer.

(ii) Materials.

(A) If the Contractor furnishes materials that meet the definition of a commercial item at 2.101, the price to be paid for such materials shall not exceed the Contractor's established catalog or market price, adjusted to reflect the--

(1) Quantities being acquired; and

(2) Any modifications necessary because of contract requirements.

(B) Except as provided for in paragraph (i)(1)(ii)(A) and (D)(2) of this clause, the Government will reimburse the Contractor the actual cost of materials (less any rebates, refunds, or discounts received by the contractor that are identifiable to the contract) provided the Contractor—

(1) Has made payments for materials in accordance with the terms and conditions of the agreement or invoice; or

(2) Makes these payments within 30 days of the submission of the Contractor's payment request to the Government and such payment is in accordance with the terms and conditions of the agreement or invoice.

(C) To the extent able, the Contractor shall-

(1) Obtain materials at the most advantageous prices available with due regard to securing prompt delivery of satisfactory materials; and

(2) Give credit to the Government for cash and trade discounts, rebates, scrap, commissions, and other amounts that are identifiable to the contract.

(D) Other Costs. Unless listed below, other direct and indirect costs will not be reimbursed.

(1) Other Direct Costs. The Government will reimburse the Contractor on the basis of actual cost for the following, provided such costs comply with the requirements in paragraph (i)(1)(ii)(B) of this clause and Section 4.3.8 of the Revised Statement of Work P00005: Any Delta in cost between the already included Sea Freight and Air Freight for shipments prior to (b) (4) and a quantity of approximately (b) (4) units (1:1 syringe/needle) that are being delivered via air freight by Government provided aircraft under (b) (4) contract award number (b) (4) . The Contractor Other direct costs include only the following: (1) Cost of the mandatory Merchandise Processing Fee (MPF); (2) Costs to pick up supplies from the contractor; (3) The actual re-palletization cost charged from the freight forwarder (b) (4) and (4) Shipping the supplies from (b) (4) to the delivery to (b) (4) sites.

(2) Indirect Costs (Material Handling, Subcontract Administration, etc.. The Government will reimburse the Contractor for indirect costs on a pro-rata basis over the period of contract performance at the following fixed price:

(2) Total cost. It is estimated that the total cost to the Government for the performance of this contract shall not exceed the ceiling price set forth in the Schedule and the Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within such ceiling price. If at any time the Contractor has reason to believe that the hourly rate payments and material costs that will accrue in performing this contract in the next succeeding 30 days, if added to all other payments and costs previously accrued, will exceed 85 percent of the ceiling price in the Schedule, the Contractor shall notify the Contracting Officer giving a revised estimate of the total price to the Government for performing this contract, the Contractor has reason to believe that the total price of this contract will be substantially greater or less than the then stated ceiling price, the Contractor shall so notify the Contracting Officer, giving a revised estimate of the total price for performing reasons and documentation. If at any time season to believe that the work to be required in performing this contract will be substantially greater or less than the total price for performing thas contract, with supporting reasons and documentation. If at any time during performance of the total price for performing this contract, with supporting reasons and documentation. If at any time during performance of the total price for performing this contract, with supporting reasons and documentation. If at any time during performance of this contract, the Government has reason to believe that the work to be required in performing this contract will be substantially greater or less than the stated ceiling price, the Contracting Officer will so advise the Contractor, giving the then revised estimate of the total amount of effort to be required under the contract.

(3) Ceiling price. The Government will not be obligated to pay the Contractor any amount in excess of the ceiling price in the Schedule, and the Contractor shall not be obligated to continue performance if to do so would exceed the ceiling price set forth in the Schedule, unless and until the Contracting Officer notifies the Contractor in writing that the ceiling price has been increased and specifies in the notice a revised ceiling that shall constitute the ceiling price for performance under this contract. When and to the extent that the ceiling price set forth in the Schedule has been increased, any hours expended and material costs incurred by the Contractor in excess of the ceiling price before the increase shall be allowable to the same extent as if the hours expended and material costs had been incurred after the increase in the ceiling price.

(4) Access to records. At any time before final payment under this contract, the Contracting Officer (or authorized representative) will have access to the following (access shall be limited to the listing below unless otherwise agreed to by the Contractor and the Contracting Officer):

(i) Records that verify that the employees whose time has been included in any invoice meet the qualifications for the labor categories specified in the contract;

(ii) For labor hours (including any subcontractor hours reimbursed at the hourly rate in the schedule), when timecards are required as substantiation for payment—

(A) The original timecards (paper-based or electronic);

(B) The Contractor's timekeeping procedures;

(C) Contractor records that show the distribution of labor between jobs or contracts; and

(D) Employees whose time has been included in any invoice for the purpose of verifying that these employees have worked the hours shown on the invoices.

(iii) For material and subcontract costs that are reimbursed on the basis of actual cost-

(A) Any invoices or subcontract agreements substantiating material costs; and

(B) Any documents supporting payment of those invoices.

(5) Overpayments/Underpayments. Each payment previously made shall be subject to reduction to the extent of amounts, on preceding invoices, that are found by the Contracting Officer not to have been properly payable and shall also be subject to reduction for overpayments or to increase for underpayments. The Contractor shall promptly pay any such reduction within 30 days unless the parties agree otherwise. The Government within 30 days will pay any such increases, unless the parties agree otherwise. The Contractor's payment will be made by check. If the Contractor becomes aware of a duplicate invoice payment or that the Government has otherwise overpaid on an invoice payment, the Contractor shall--

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the--

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected line item or subline item, if applicable; and

(D) Contractor point of contact.

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(6)(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury, as provided in 41 U.S.C.

7109, which is applicable to the period in which the amount becomes due, and then at the rate applicable for each six month period as established by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) Final Decisions. The Contracting Officer will issue a final decision as required by 33.211 if--

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt in a timely manner;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see FAR 32.607-2).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on--

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures prescribed in 32.608-2 of the Federal Acquisition Regulation in effect on the date of this contract.

(viii) Upon receipt and approval of the invoice designated by the Contractor as the ``completion invoice" and supporting documentation, and upon compliance by the Contractor with all terms of this contract, any outstanding balances will be paid within 30 days unless the parties agree otherwise. The completion invoice, and supporting documentation, shall be submitted by the Contractor as promptly as practicable following completion of the work under this contract, but in no event later than 1 year (or such longer period as the Contracting Officer may approve in writing) from the date of completion.

(7) Release of claims. The Contractor, and each assignee under an assignment entered into under this contract and in effect at the time of final payment under this contract, shall execute and deliver, at the time of and as a condition

precedent to final payment under this contract, a release discharging the Government, its officers, agents, and employees of and from all liabilities, obligations, and claims arising out of or under this contract, subject only to the following exceptions.

(i) Specified claims in stated amounts, or in estimated amounts if the amounts are not susceptible to exact statement by the Contractor.

(ii) Claims, together with reasonable incidental expenses, based upon the liabilities of the Contractor to third parties arising out of performing this contract, that are not known to the Contractor on the date of the execution of the release, and of which the Contractor gives notice in writing to the Contracting Officer not more than 6 years after the date of the release or the date of any notice to the Contractor that the Government is prepared to make final payment, whichever is earlier.

(iii) Claims for reimbursement of costs (other than expenses of the Contractor by reason of its indemnification of the Government against patent liability), including reasonable incidental expenses, incurred by the Contractor under the terms of this contract relating to patents.

(8) Prompt payment. The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315.

(9) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.

(10) Discount. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date that appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(j) Risk of loss. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) Taxes. The contract price includes all applicable Federal, State, and local taxes and duties.

(1) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid an amount for direct labor hours (as defined in the Schedule of the contract) determined by multiplying the number of direct labor hours expended before the effective date of termination by the hourly rate(s) in the contract, less any hourly rate payments already made to the Contractor plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system that have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred that reasonably could have been avoided.

(m) Termination for cause. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon written request, with adequate assurances of future performance. Subject to the terms of this contract, the Contractor shall be paid an amount computed under paragraph (i) Payments of this clause, but the ``hourly rate" for labor hours expended in

furnishing work not delivered to or accepted by the Government shall be reduced to exclude that portion of the rate attributable to profit. Unless otherwise specified in paragraph (a)(4) of this clause, the portion of the ``hourly rate" attributable to profit shall be 10 percent. In the event of termination for cause, the

Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) Title. Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) Warranty. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(p) Limitation of liability. Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) Other compliances. The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.

(r) Compliance with laws unique to Government contracts. The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 41 U.S.C. 4712 and 10 U.S.C. 2409 relating to

whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. chapter 21 relating to procurement integrity.

(s) Order of precedence. Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

(1) The schedule of supplies/services.

(2) The Assignments, Disputes, Payments, Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause;

(3) The clause at <u>52.212-5</u>.

(4) Addenda to this solicitation or contract, including any license agreements for computer software.

(5) Solicitation provisions if this is a solicitation.

(6) Other paragraphs of this clause.

(7) The Standard Form 1449.

- (8) Other documents, exhibits, and attachments.
- (9) The specification.
- (t) Reserved.
- (u) Unauthorized Obligations.

(1) Except as stated in paragraph (u)(2) of this clause, when any supply or service acquired under this contract is subject to any End User License Agreement (EULA),

Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement is invoked through an ``I agree" click box or other comparable mechanism (e.g., ``click-wrap" or ``browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.

(2) Paragraph (u)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(v) Incorporation by reference. The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICIT.	ATION/MODU	TICATION OF CONTRACT		CT ID CODE	PAGE OF PAGE
AMENDMENT OF SOLICIT.	AHOIMMODI	ication of contract		6	1 11
AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO		5 PROJECT	NO (Ifapplicable)
00006	15-Apr-2021	SEE SCHEDULE			
SSUED BY CODE	W911SR	7 ADMINISTERED BY (If other than item 6)	(ODE	
JSA CONTRACT NG CMD-APG W911SR EDGEWOOD CONTRACTING DIVISION 456 BRIGADE STREET 3LDG E4215 YBERDEEN PROVING GROUND MD 21010-5401		See Item 6			
NAME AND ADDRESS OF CONTRACTOR	(No. Street County	State and Zip Code)	9A. AMEND	MENT OF SO	LICITATION NO
DUOPROSS MEDITECH CORPORATION	(no., orect, county,			(SEE ITEM 1	
FARMINGDALE NY 11735-1209			X 10A MOD W911SR200	OF CONTRAC	T/ORDER NO.
			10B. DATEI	(SEE ITEM	13)
DDE 8LK11	FACILITY CO	DE	X 03-Aug-202	0	
11.	THIS ITEM ONLY A	APPLIES TO AMENDMENTS OF SOLI	CITATIONS		
The above numbered solicitation is amended as set for	h in Item 14 The hour and	date specified for receipt of Offer	is extended,	is not exter	nded
(a) By completing Items 8 and 15, and returning or (c) By separate letter or telegram which includes a r RECEIVED AT THE PLACE DESIGNATED FOR THE REJECTION OF YOUR OFFER If by virtue of this a provided each telegram or letter makes reference to the	eference to the solicitation HE RECEIPT OF OFFERS mendment you desire to cha	PRIOR TO THE HOUR AND DATE SPECIFIEI ange an offer already submitted, such change may	ACKNOWLEDGME D MAY RESULT IN be made by telegram of	NT TO BE	
ACCOUNTING AND APPROPRIATION D	ATA (If required)				
12 10110 101			CORDERC		
		TO MODIFICATIONS OF CONTRACT CT/ORDER NO. AS DESCRIBED IN IT			
A. THIS CHANGE ORDER IS ISSUED PURS CONTRACT ORDER NO. IN ITEM 10A.				E MADE IN T	HE
B. THE ABOVE NUMBERED CONTRACT/ office, appropriation date, etc.) SET FOR				ch as changes i	n paying
C. THIS SUPPLEMENTAL AGREEMENT I: Bilateral IAW FAR 52.212-4(c) D. OTHER (Specify type of modification and		URSUANT TO AUTHORITY OF:			
D. OTTER (specify type of mountaining and	uunoiny)				
IMPORTANT: Contractor is not,	X is required to sig	gn this document and return 1	copies to the issu	ing office.	
DESCRIPTION OF AMENDMENT/MODIF where feasible.) Modification Control Number: (b) (6) he purpose of this modification is to: - Extend the Air Freight on the Time and Mate - The Contractor shall continue to use Gover order number (b) (4) - Update Statement of Work to reflect the ab I other terms and conditions remain the sam	erials (T&M) CLIN 001 rnment-provided-airci ne approximate w eigh ove changes.	4 from <mark>(b) (4)</mark>	number (b) (4)	ubject matter , task (4)	5
cept as provided herein, all terms and conditions of the d A. NAME AND TITLE OF SIGNER (Type or B. CONTRACTOR/OFFEROR		16A. NAME AND TITLE OF CO (b)(6) / CONTRACTING OFF TEL:	NTRACTING OF ICER EMAL: (1)(6)	FICER (Type	or print) C. DATE SIGNE
		(D) (D)			
(Signature of person authorized to sign)	-	(Signature of Contracting Of	ficer)	1	5-Apr-2021

Prescribed by GSA FAR (48 CFR) 53.243

W911SR20C0045 P00006 Page 2 of 11

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 1449 - CONTINUATION SHEET

SUPPLIES OR SERVICES AND PRICES

CLIN 0014

The CLIN extended description has changed from:

This Time and Materials (T&M) CLIN 0014 is for the Delta costs incurred between the already included Sea Freight (built into the FFP CLINS) and the additional estimated costs for Air Freight by (b) (4)

The Contractor shall contact the Contracting Officer prior to incurring expense against this T&M CLIN 0014 if that expense will exceed the Contractor's proposed delta between sea freight and air freight. Total invoiced amount against this CLIN cannot exceed the total funded amount of Not to Exceed (NTE) amount.

NOTE: Other direct costs include only the following: (1) Cost of the mandatory Merchandise Processing Fee (MPF); (2) Costs to pick up supplies from the (b) (4) contractor; (3) The actual re-palletization cost charged from the freight forwarder (b) (4); and (4) Shipping the supplies from (b) (4) to the delivery to (b) (4) sites.

To:

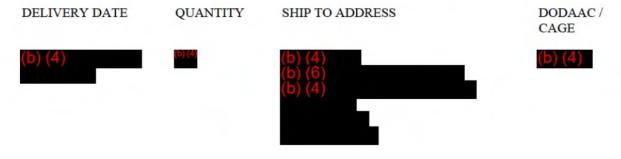
This Time and Materials (T&M) CLIN 0014 is for the Delta costs incurred between the already included Sea Freight (built into the FFP CLINS) and the additional estimated costs for Air Freight by (b) (4)

The Contractor shall contact the Contracting Officer prior to incurring expense against this T&M CLIN 0014 if that expense will exceed the Contractor's proposed delta between sea freight and air freight. Total invoiced amount against this CLIN cannot exceed the total funded amount of Not to Exceed (NTE) amount.

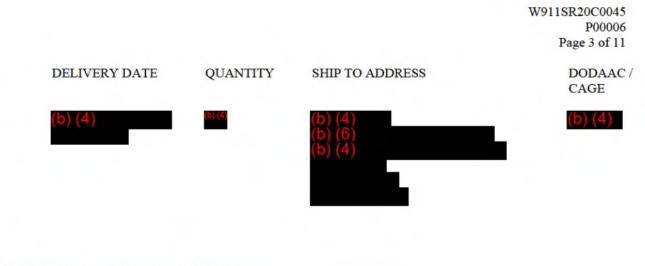
NOTE: Other direct costs include only the following: (1) Cost of the mandatory Merchandise Processing Fee (MPF); (2) Costs to pick up supplies from the (b) (4) contractor; (3) The actual re-palletization cost charged from the freight forwarder (b) (4); and (4) Shipping the supplies from (b) (4) to the delivery to (b) (4) sites.

DELIVERIES AND PERFORMANCE

The following Delivery Schedule item for CLIN 0014 has been changed from:



To:



The following have been added by full text: <u>P00006 STATEMENT OF WORK</u> Changes are shown below in red font text.

REVISED STATEMENT OF WORK P00006 PROCUREMENT OF SAFETY NEEDLES AND SYRINGES FOR COVID-19

1.0 <u>SCOPE</u>: The Contractor, as an independent Contractor and not as an agent of the Government, shall furnish the necessary resources as specified in this Statement of Work (SOW), to manufacture and/or supply Safety Needles and Syringes.

2.0 BACKGROUND:

On Friday, March 13, 2020, the President declared a national emergency concerning the novel coronavirus disease (COVID-19) under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act).

The mission of the Division of Strategic National Stockpile (DSNS), of the United States (U.S.) Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), is to ensure the availability and rapid deployment of lifesaving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. When state, local, tribal, and territorial public health and medical systems request federal assistance to support their response efforts, DSNS ensures the right medicines and supplies get to those who need them most during an emergency. When the vaccine becomes available the Government will have an immediate need to begin vaccinating the entire U.S. population. To administer the vaccine the Government will require needles and syringes to be available.

There is an insufficient domestic supply of safety needles and syringes to meet the projected needs to vaccinate the nation's entire population against COVID-19. Should vaccine programs be accelerated, demand could outpace available devices to administer a vaccine.

3.0 **OBJECTIVE**: The HHS currently has contracts in place with three (3) major

manufacturers to provide needles and syringes supplies to support the initial preparedness needs at the onset of a pandemic outbreak. The objective of this acquisition is to supplement the current supply and establish contracts with additional manufacturers and suppliers to provide a quantity of up to 500 million safety needles and syringes supplies.

4.0 **REQUIREMENTS**:

4.1. General:

4.1.1. The Contractor shall "host" a *Kick-Off Meeting* within one (1) calendar day after contract award via <u>teleconference</u>. The Contractor shall provide *Meeting Minutes* containing a detailed overview of the meeting discussions in accordance with (IAW) Contract Data Requirements List (CDRL) A001.

4.1.1.1. The Contractor shall provide a *Certificate of Analysis* with each shipment per the DD Form 1423, Contract Data Requirements List (CDRL) A002, confirming the supplies described below meet the Performance Specifications in paragraph 4.2 below.

4.1.2. The Contractor shall provide copies of **510(k)** Approval Letters for ALL supplies (dispensing syringes or needles) to demonstrate compliance with Section 510(k) of the Food, Drug and Cosmetic Act as part of their proposal. The Contractor shall provide, if necessary, **510(k)** Approval Letters Updates if any information from the initial 510(k) Approval Letters is changed/needs to be updated.

4.1.2.1.1. The Contractor shall ensure all supplies have a "*Shelf-Life*" with expiration dates of no less than five (5) years from the date of sterilization, <u>and</u> must have at least four (4) years of remaining expiry from the time of shipment.

4.1.2.1.2. The Contractor shall only use *Current Good Manufacturing Practice (cGMP)* processes to manufacture the needles and syringes.

4.1.2.1.3. Period of Performance/Delivery Dates. See the "Delivery Schedule" section of this Contract and "Attachment 2-Shipping Information" for all delivery requirements and shipping locations.

4.2. Technical Requirements:

4.2.1. The Contractor shall provide sterile needle (with Luer hub connection) and syringe (with Luer lock connection) units approved by the Food and Drug Administration (FDA) <u>and</u> comply with *Occupational Safety and Health Administration (OSHA) Needlestick Safety and Prevention Act* requirements as a "*safety-engineered product.*" Safety-engineered supplies include needles preventing sharp injuries by either; being completely enclosed after use by an attached shield, or be fully retracted within the syringe. The Contractor may provide individual syringes and individual needles as long as there is a <u>one-to-one (1:1) ratio</u>. In order to meet the specified quantities upon contract award and comply with the specifications in this SOW, the following may be provide: (1) individually wrapped sterile syringes with individually

wrapped sterile needles in a one-to-one (1:1) ratio, (2) sterile needle/syringe combination unit, or (3) a mixture of sterile combination units <u>and</u> individually wrapped sterile syringes with equal number of individually wrapped sterile needles.

4.2.2. The Contractor shall only provide acceptable product sizes as described below:

Individual Syringe:

Syringe
1mL
3mL

Individual Needle:

<u>Needle</u> Gauge	<u>Needle</u> Length
23G	1"
23G	1.5"
25G	1"

Combination Unit:

Syringe	<u>Needle</u> Gauge	<u>Needle</u> Length
lmL	23G	1"
lmL	23G	1.5"
lmL	25G	1"
3mL	23G	1"
3mL	23G	1.5"
3mL	25G	1"

4.2.3. Dispensing Syringe: *Description*: A dispensing syringe allows for the controlled and precise flow of liquid. The dispensing syringe is used to inject medications or other liquids into body tissues. Manual syringes consist of a barrel, stopper, and plunger.

4.2.3.1. The Contractor shall ensure dispensing syringes comply with Title 21 Code of Federal Regulations (CFR) 880.5860 and follow International Standards Organization (ISO) 7886-1:2017 and the following material specifications:

- **4.2.3.1.1.** A device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle;
- **4.2.3.1.2.** Heavy duty barrel The barrel has a scale showing the capacity of the syringe.
- **4.2.3.1.3.** Stopper The stopper maintains the fluid in the barrel between the syringe nozzle and the plunger;

4.2.3.1.4.	Plunger - The plunger is used to aspirate and inject fluids into and out of the syringe;
4.2.3.1.5.	Disposable;
4.2.3.1.6.	Luer lock to accept luer hub applicator (e.g. needle);
4.2.3.1.7.	Sizes as specified in Section 4.2.2 above; and
4.2.3.1.8.	Sterile individually wrapped packaging.

4.2.4. Hypodermic Needle: *Description*: A Hypodermic needle is a slender, hollow instrument for introducing material into the body parenterally.

4.2.4.1. The Contractor shall ensure hypodermic needles comply with 21 CFR 880.5570, OSHA Needlestick Safety and Prevention Act, and follow International Standards Organization (ISO) 7864, and the following specifications:

- **4.2.4.1.1.** Disposable;
- **4.2.4.1.2. Luer hub** to attach to luer lock syringe;
- **4.2.4.1.3.** See Tables in Sections 4.2.2 above for acceptable needle length and gauges;

4.2.4.1.4. Sterile individually wrapped packaging; and

4.2.4.1.5. Safety-engineered.

4.3. Delivery Location and Shipping Requirements: See Attachment 2-"Shipping Information" for all delivery locations and shipping requirements.

4.3.1. The Contractor shall provide *Packing Slips* with <u>all shipments</u> per CDRL A003. The Packing Slips shall include the following: (1) Contract number, (2) Item description, (3) Part number, (4) Lot numbers; and (5) Quantities. The Packing Slips shall include <u>BOTH</u>: (1) a *Packing Slip Paper Copy* with the shipment; and (2) a *Packing Slip Paper Emailed Copy* to the Designated Government Representative.

4.3.2. No Partial Case or Packages quantities will be accepted unless approved by the Contracting Officer prior to shipping.

4.3.3. The Contractor shall <u>NOT</u> Mixed Lot #'s per Case or per Packages. The Contractor shall only provide full <u>case</u> quantities <u>only</u>, *unless* approved by the Designated Government Representative in advance via email.

4.3.4. The Contractor shall ensure all pallets have the identical TyHi stack pattern, except for the final pallet; which would be a partial pallet or individual boxes.

4.3.5. All supplies shall be delivered on a standard 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, clear-wrapped is preferred, and secured to the pallet for safe transport.

4.3.6. The Contractor shall contact the Designated Government Representative to schedule delivery appointments. The Government will provide the Designated Government Representative(s)' information at the Kick-Off Meeting.

4.3.7. Contractor shall contact the Designated Government Representative to schedule delivery

appointments.

4.3.8. The Contractor shall ship ALL deliverables via AIR FREIGHT from (b) (4)

The Contractor shall charge the Delta in costs between Air Freight costs and Sea Freight costs as updated under 'other direct costs' in the FAR Clause 52.212-4 Alt I. The Contractor shall NOT submit any costs (e.g. labor, overhead, profit) other than "other direct costs" per FAR Clause 52.214-4 Alternative one (1) as those cost are already included in the contract. The Contractor shall only be reimbursed for actual REASONABLE costs and shall provide documented proof (e.g. receipts and paid invoices). The Government's pallet dimension limitations (stated in Section 4.3.5) is how the pallets will be delivered, it does NOT restrict pallet heights or other packing dimensions of HOW the items are to be shipped (either by air or sea). The Contractor shall follow commercial best practices and to maximize/optimize Air Cargo Load, palletization or re-palletization (if needed), and drayage. The Government reserves the right to stop this Air Freight requirement prior to (b) (4) via email notification from the Contracting Officer due to urgency, followed by a bi-lateral modification. The Government also reserves the right to provide transportation (e.g. planes) or other logistical services (e.g. palletization) and will notify the Contractor via an email from the Contracting Officer. For purposes of this modification the Contractor shall continue to use Government-provided-aircraft through (b) (4) under TRANSCOM contract award number (b) (4) , task order number ; to provide the approximate weight allowances and restrictions stated therein (b) through (D) In the event, the Contractor completes/uses all the provided planes under the TRANSCOM's task order, (b) (4) , prior to (b) (4) , the Contractor shall notify the Contracting Officer under this award PRIOR to making or incurring any future air freight costs.

4.3.9. Based on mutual agreement at the Post-Award Meeting for delivery schedules, the Contractor shall provide an *Initial Updated Syringe-Needle Delivery Schedule*. The template for the Initial Updated Syringe-Needle Delivery Schedule will be provided by the COR. The Initial Updated Delivery Schedule shall be provided to the COR within three (3) business days after the "Sea to Air Freight Modification." Thereafter, the Contractor shall, at a minimum, provide *Weekly Delivery Schedule Updates* to the COR by Tuesday, 1400 Eastern Time.

5.0 Operation Warp Speed (OWS) Contract Language:

5.1. Disclosure of Information:

5.1.1. Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

5.1.2. The Contractor shall comply with all Government requirements for protection of nonpublic information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

5.1.3. No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

5.2. <u>Publications and Publicity</u>:

5.2.1. The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government:

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published;

(b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications;

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided;

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows: "This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

5.3. Confidentiality of Information:

5.3.1. Confidential information, as used in this article, means information or data of a personal

nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

5.3.2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

5.3.3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

5.3.4. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

5.3.5. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

5.3.6. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

5.3.7. All above requirements MUST be passed to all Sub-contractors.

5.4. Organizational Conflicts of Interest:

5.4.1. Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

5.4.2. The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive

advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

5.4.3. The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

5.4.4. Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

Additional Reporting Requirements.

WAREHOUSED ITEMS - Contract Items stored/staged at interim locations prior to air shipment at contractor warehouses and/or warehouses utilized by contractor subcontractors and/or transportation agents. The contractor is required to provide a daily report not later than 1700 US Eastern Standard Time (EST) including the following information:

Location of Warehouse(s):

Complete physical address of warehouse(s):

Warehouse POC:

Warehouse POC telephone number and email address:

For each warehouse location, detailed descriptions and quantities/count by individual item warehoused and ready for shipment.

ADDITIONAL NOTES:

1. Concurrently, all information required under this contract modification shall be provided by email to the following individuals:

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(End of Summary of Changes)

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6 ISSUED BY	CODE	W911SR	7 ADMINISTERED BY (If other than item 6)		COL	DE	
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	11	THISITEM ONLY	APPLIES TO AMENDMENTS OF SOLI	CITATIC	NS		
The above numbered solicitation	on is amended as set for	th in Item 14 The hour and	date specified for receipt of Offer	is exte	ended,	is not exter	nded
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See Schedule A. THIS CHANGE ORDEL CONTRACT ORDER N B. THE ABOVE NUMBER office, appropriation dr X C. THIS SUPPLEMENT A Bilateral IAW FAR 52.212 D. OTHER (Specify type of E. IMPORTANT: Contractor 14. DESCRIPTION OF AME where feasible.) Modification Control Nur The purpose of this modific See "Block 14 Continuation Except as provided herein, all terms	13. THIS IT IT MOD RISISSUED PURS NO. IN ITEM 10A. RED CONTRACT/ ate, etc.) SET FOR L AGREEMENT I -4(c) of modification and or is not, NDMENT/MODIF mber: (b) (6) ation is: Page" for details.	EM APPLIES ONLY DIFIES THE CONTRA JUANT TO: (Specify a ORDER IS MODIFIEI TH IN ITEM 14, PUF S ENTERED INTO P d authority) CATION (Organized	CT/ORDER NO. AS DESCRIBED IN IT authority) THE CHANGES SET FORTH O TO REFLECT THE ADMINISTRATI SUANT TO THE AUTHORITY OF FA URSUANT TO AUTHORITY OF: gn this document and return 1 d by UCF section headings, including solic aby UCF section headings, including solic aby UCF section headings, including solic the section headings of the section headings of the section headings of the section heading solic aby UCF section headings, including solic aby UCF section heading solic aby UCF section	EM 14. IN ITEM VE CHAN R 43.103 copies to citation/co citation/co citation/co citation/co citation/co consector citation/co consector citation/co consector citation/co consector citation/co consector citation/co consector citation/co consector citation/co consector citation/co consector citation/co consector citation/co consector citation/co consector citation/co co consector citation/co co consector citation/co co consector citation/co co consector citation/co co co co co co co co co co co co co c	I 14 ARE M GES (such a (B).	effect CER (Type	n paying

Prescribed by GSA					
FAR (48 CFR) 53.2	43				

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

The following items are applicable to this modification:

P00007

As the result of this Modification the following has been changed:

- 1- The Government accepts the proposed substitute of all remaining deliveries from as described below:
 - a) Substitute (b) (4)
 safety needle" of CLIN 0002 with (b) (4)
 " safety needle" of CLIN 0003.
 b) Substitute (b) (4)
 (b) (4)
 (c) Substitute (b) (4)
 (d) of CLIN 0009.
 (e) Substitute (b) (4)
 (f) (4)</
- 2- Remove the duplicate sea freight cost of (b) (4) for the Total Quantity of (b) (4) units that DuoPross Meditech is using (b) (6) flights to ship their product. The amount of (b) (4) was calculated by multiplying the estimated sea shipping cost per (b) (4) flights to ship their product. The price of (b) (4) flights to ship their product. The price of (b) (4) in the new CLIN 0015 is calculated by removing (b) (4) from the total amount of (b) (4) of CLINs (0010, 0011 and 0012) and divided by the total quantity of (b) (4) for all these three CLINs (0010, 0011 and 0012).
- 3- De-obligate the amount of (b) (4) from T&M CLIN 0014 since Duopross will continue to use Government-provided aircraft under (b) (6) Contractor has confirmed that the estimated amount to be invoiced for other direct costs under the T&M CLIN until (b) (4)

All other terms and conditions remain the same.

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SUMMARY OF CHANGES

SECTION SF 1449 - CONTINUATION SHEET

SOLICITATION/CONTRACT FORM

The total cost of this contract was decreased by (b) (4)

SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The pricing detail quantity has decreased by (b) (The total cost of this line item has decreased by (b)

CLIN 0002

The pricing detail quantity has decreased by (b) (4) The total cost of this line item has decreased by (b) (4)

CLIN 0003

The pricing detail quantity has increased by (b) The total cost of this line item has increased (b)

CLIN 0007

The CLIN description has changed from (b) (4) to Removed and added to CLIN 0009. The CLIN extended description has changed from:



To:

This CLIN for (b) (4), is REMOVED and the quantity is added to CLIN 0009 to allow the Government to de-obligate the funds from this CLIN and add additional funding to CLIN 0009.

The pricing detail quantity has decreased by (b) (4)

The total cost of this line item has decreased by (b) (4)

CLIN 0008 The pricing detail quantity has decreased by The total cost of this line item has decreased by **CLIN 0009** The pricing detail quantity has increased by The total cost of this line item has increased by **CLIN 0010** The CLIN description has changed from (0) (4) to Removed and added to CLIN 0015. The CLIN extended description has changed from: To: This CLIN for (b) (4) is REMOVED and the quantity is added to CLIN 0015 to allow the Government to de-obligate the funds from this CLIN and add additional funding to CLIN 0015. The pricing detail quantity has decreased by The total cost of this line item has decreased by **CLIN 0011** to Removed and The CLIN description has changed from added to CLIN 0015. The CLIN extended description has changed from: To: This CLIN for (b) (4) is REMOVED and the quantity is added to CLIN 0015 to allow the Government to de-obligate the funds from this CLIN and add additional funding to CLIN 0015. The pricing detail quantity has decreased by The total cost of this line item has decreased by **CLIN 0012** The CLIN description has changed from (b) (4) to Removed and added to CLIN 0015.

The CLIN extended description has changed from:

(b) (4	()					
To:						
This C to allo	LIN for (b) (4) w the Government to de-ob	ligate the funds fro		OVED and the quantity is nd add additional funding		5
•	The pricing detail quant The total cost of this line					
	LIN 0014 The estimated/max cost The total cost of this line	e item has decrease				
SI ITEM NO	UBCLIN 000302 is added a SUPPLIES/SERVICES	s follows: QUANTITY	UNIT	UNIT PRICE		AMOUNT
000302	Funding for additional qu FFP					(b) (4)
	Funding for additional qu PURCHASE REQUEST		units for CLI	N 0003.		
				NET AMT		(b) (4)
	ACRN AC CIN:(b) (4)				()	o) (4)

SUBCLIN 000901 is added as follows:

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ITEM NO 000901	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000901	Funding for additional qu FFP	antity			
	Funding for additional qua PURCHASE REQUEST	antity of <mark>(b) (4)</mark> NUMBER: (b) (4			
		(**) (*			
				NET AMT	(b) (4)
	ACRN AC CIN: (b) (4)				(b) (4)
С	LIN 0015 is added as follow	vs:			
ITEM NO 0015	SUPPLIES/SERVICES	QUANTITY	UNIT Each	UNIT PRICE	AMOUNT
	(b) (4) FFP	1"			
	(b) (4) FOB: Destination				
	MFR PART NR: (b) (4) VENDOR PART NR: (b)	(4)			
	PURCHASE REQUEST PSC CD: 6515	NUMBER: (b) (4)		
	PSC CD: 6515				
				NET AMT	(b) (4)
	ACRN AC CIN: (b) (4)				(b) (4)
ACCO	UNTING AND APPROPR	IATION			
Summ	ary for the Payment Office				
A	s a result of this modification	n, the total funded	amount for th	is document was decreased	by <mark>(b) (4)</mark>
CLDI	0001.				
CLIN	a) (4)			19	
	5)(4)				
CLIN	0002:				

(b) (4)					
SUBCLIN 000302: Funding on SUBCLIN 00030	2 is initiated as fo	ollows:			
(b) (4)					
CLIN 0007:		_			
(b) (4)					
CLIN 0008:					
(b) (4)					
SUBCLIN 000901: Funding on SUBCLIN 00090	1 is initiated as fo	ollows:			
(b) (4)					
				S ¹ ······	
CLIN 0010:					
(b) (4)					
CLIN 0011:					
(b) (4)					

CLIN 0012:

()	o) (4)			
CLIN	0014:			
(1	o) (4)			
CLIN Fundir	0015: ng on CLIN 0015 is initiated	l as follows:		
0	o) (4)			
DELIV	VERIES AND PERFORMA	NCE		
	llowing Delivery Schedule		has been changed from:	
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)
2				
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4) (b) (4)	(b) (4)

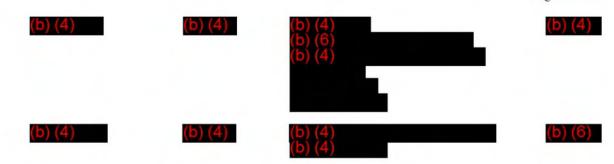
The following Delivery Schedule item for CLIN 0002 has been changed from:





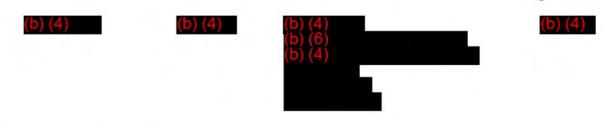
DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE

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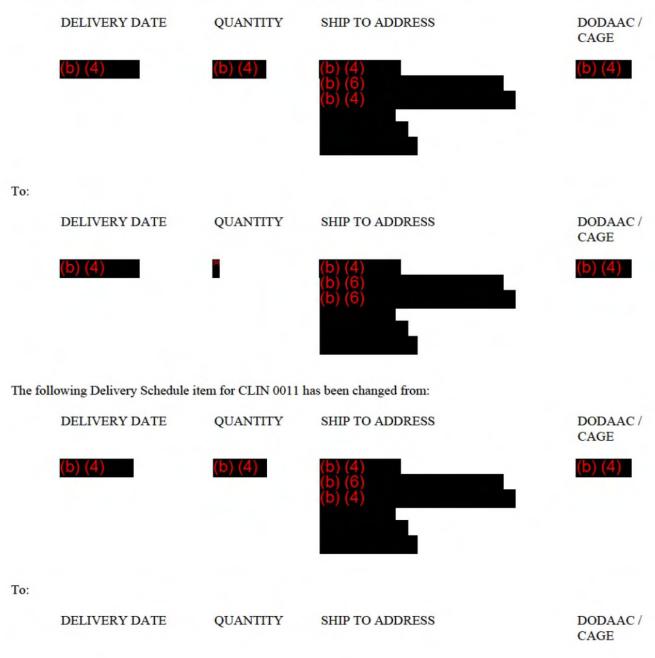


The following Delivery Schedule item for CLIN 0008 has been changed from:

	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE			
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4) (b) (4)	(b) (4)			
To:							
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE			
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)			
The following Delivery Schedule item for CLIN 0009 has been changed from:							
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE			
	(b) (4)	(b) (4)	(b) (4) (b) (6) (b) (4)	(b) (4)			
To:							
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE			

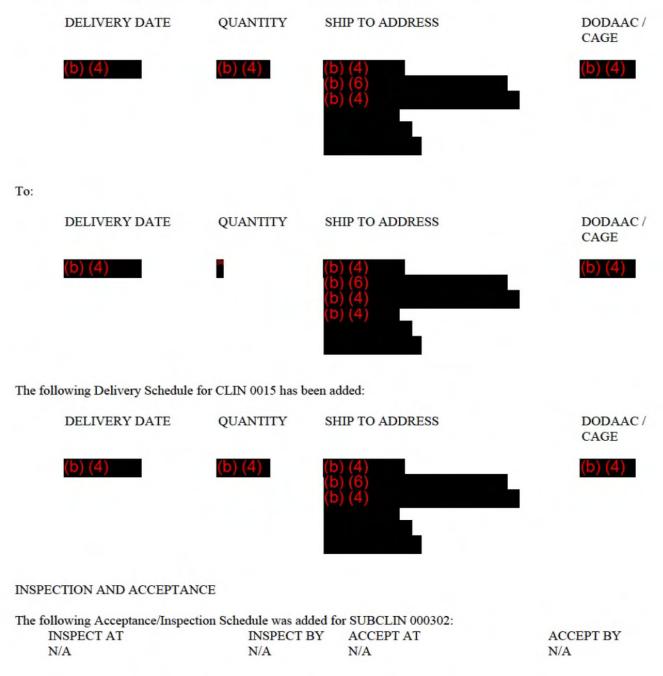


The following Delivery Schedule item for CLIN 0010 has been changed from:





The following Delivery Schedule item for CLIN 0012 has been changed from:



The following Acceptance/Inspection Schedule was added for SUBCLIN 000901:

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INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for CLIN 0015:						
INSPECT AT	INSPECT BY	ACCEPT AT				
Destination	Government	Destination				

ACCEPT BY Government

The following Technical Office was added for CLIN 0015:



(End of Summary of Changes)