VA262-16-Q-0852

SECTION B – STATEMENT OF WORK (SOW)

1.**Background:**

The VAGLAHS has a requirement for renal therapeutic plasma exchange systems, warmer leg sleeves, and warmer holders.

2.**Supplies/Services:**

The new renal therapeutic plasma exchange systems, warmer leg sleeves, and warmer holders shall be completely new. They shall not be used, refurbished, or in any other form, including substitutions. Contractor shall not add or substitute any component(s) without prior approval from the CO.

Salient characteristics required of item numbers 1–3 in the Price/Cost Schedule of Supplies and Services:

2.1 Therapeutic plasma exchange system:

- **2.1.1** Must deliver multiple modes of therapy without using additional equipment,
- **2.1.2** Must be able to provide therapy options as follows: continuous veno-venous hemodiafiltration (CVVHDF), continuous veno-venous hemodialysis (CVVHD), continuous veno-venous hemofiltration (CVVH), slow continuous ultrafiltration (SCUF), and therapeutic plasma exchange (TPE),
- **2.1.3** Must be designed for those weighing twenty (20) kilograms or more that have acute renal failure and/or fluid overload,
- **2.1.4** Must be capable of providing continuous therapy, and designed for small to large molecular clearance,
- **2.1.5** Must display both prescribed and actual therapy dosage,
- **2.1.6** Must include fluid measurement and removal features,
- **2.1.7** Patient data must be available in real time,
- **2.1.8** System must be capable of storing treatment history,
- **2.1.9** Must deliver slow, continuous 24-hour treatment for fluid removal, acid-base balance, and electrolyte balance,
- **2.1.10** Must be capable of providing information on how much therapy the patient is receiving within an accuracy level of seven (7) milliliters of fluid at any given time,
- **2.1.11** Must monitor accumulated fluid balance/imbalance and adjust accordingly,
- **2.1.12** Must provide automated and integrated anticoagulation options through the 5th fluid pump (pre-blood pump) and syringe pump,

2.1.13 Must not require manual dose programming of ancillary pumps outside the CRRT system,

2.1.14 Must offer both high and low filter sets,

2.1.15 Must not require periodic filter flushings,

2.1.16 Must provide automatic adjustments and visual feedback of the system's condition,

2.1.17 Deareation chamber must automatically remove air during therapy,

2.1.18 Must provide automatic, real-time tracking of all relevant pressures including filter pressure and transmembrane pressure (TMP),

2.1.19 Must self-check at least every two hours,

2.1.20 Must detect system leaks automatically,

2.1.21 Must automatically load and self-prime,

2.1.22 Tubing on hemofilter sets must be preconnected and color coded,

2.1.23 Back-up battery must provide at least ten (10) minutes of uninterrupted therapy delivery upon temporary power disconnect,

2.1.24 Must have on-screen troubleshooting visuals that are accessible both during setup and therapy delivery,

2.1.25 Must not require confirmation that therapy bags are draining equally,

2.1.26 Must allow for real-time automated measuring of fluid loss/gain, and

2.1.27 Warmer leg sleeve and warmer leg holder must be compatible with the therapeutic plasma exchange system.

2.2 Warmer leg sleeves must be designed for use with and compatible with the therapeutic plasma exchange system.

2.3 Warmer holders must be designed for use with and compatible with the therapeutic plasma exchange system.

(End of Section B)