JUSTIFICATION FOR AN EXCEPTION TO FAIR OPPORTUNITY

1. <u>Contracting Activity</u>: Department of Veterans Affairs (VA) Office of Acquisition Operations Technology Acquisition Center 23 Christopher Way Eatontown, NJ 07724

2. <u>Description of Action</u>: The proposed action is for a firm-fixed-price (FFP) delivery order to be issued under the National Aeronautics and Space Administration (NASA) Solutions for Enterprise-Wide Procurements (SEWP) V Government-Wide Acquisition Contract (GWAC) for InterSystems Cache and InterSystems HealthShare software and Software Updates and Technical Assurance (SUTA).

3. Description of the Supplies or Services: VA requires access to brand name Intersystems Cache and Intersystems HealthShare software products as well as the associated SUTA for these products. Specifically, the required products are InterSystems Cache' Software and SUTA (ISC-L-C16-010), InterSystems HealthShare Health Connect Software and SUTA (ISC-L-H16-028), InterSystems HealthShare Health Information Exchange Software and SUTA (ISC-L-H16-022), InterSystems HealthShare Health Insight Software and SUTA (ISC-L-H16-030), InterSystems HealthShare Patient Index Software and SUTA (ISC-L-H16-024), InterSystems HealthShare Personal Community Software and SUTA (ISC-L-H16-026) and InterSystems HealthShare Referral Manager Software and SUTA (ISC-L-H16-032). These requirements maintain the current infrastructure supporting VA's current Electronic Health Record (EHR) database as the VA transitions to a new EHR. The additional HealthShare software functionality is required, as discussed below, to permit the routing and transfer of patient data to VA's EHR systems, allow for data exchanges supporting third party Community Care initiatives and to meet the Government and private sector interoperability needs.

VA's EHR resides in a database operating system and application platform called InterSystems Cache. Every EHR of every Veteran serviced by VA resides on this platform. It is, therefore, deemed a mission-critical platform. The application which operates on this platform is the Veterans Information System and Technology Architecture (VistA). VistA, itself, includes over 184 mission-specific applications. The requirements above support maintenance of the current infrastructure of the VistA platform as well as VA's EHR Database. The Intersystems Cache brand name software provides the database platform for storing, securing and retrieving Veteran patient data within this platform. Additionally, VA has committed to and is implementing, numerous and continuous updates to this platform supporting numerous initiatives including, but not limited to, VistA Evolution, VistA Read Only (VRO) and Community Care. In order for VA to update these platforms, the database software must be able to work with VistA Data both, natively and Application Structure and Integration Support; operate on Health Interoperability Buses (ESB - Enterprise Service Bus) and facilitate Health Information Exchange operations with outside health providers and other health record products. The required InterSystems HealthShare products will support current and future VistA Architecture and Platform Development initiatives (VistA Evolution); specifically allowing for the seamless transfer of Veteran patient data to community care providers outside

the VA healthcare network. Finally, VA is in the process of transitioning to a new EHR. The Intersystems HealthShare products will enable the routing and transfer of patient data to a new EHR as well as community care providers.

Additionally, VA requires SUTA on all the software which includes upgrades and updates to the InterSystems products as well as dedicated 24 hours per day, 7 days per week support. The period of performance for this proposed contract action will consist of a one 6-month base period with nine, 6-month option periods. VA anticipates utilizing the current InterSystems infrastructure for a minimum of five years which supports the proposed periods of performance. The total estimated price of the proposed action inclusive of all options is.

4. <u>Statutory Authority</u>: The statutory authority permitting an exception to fair opportunity is Section 41 U.S.C. 4106(c)(2) as implemented by the Federal Acquisition Regulation (FAR) Subpart 16.505(b)(2)(i)(B), entitled "Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized."

5. <u>Rationale Supporting Use of Authority Cited Above</u>: Based on extensive market research, as described in paragraph 8 of this document, it was determined that limited competition is viable among resellers for the aforementioned brand name InterSystems Cache and HealthShare software products and associated maintenance support.

VistA is an enterprise-wide information system built around an EHR, which has been used throughout VA for over three decades and was developed using the Massachusetts General Hospital Utility Multi-Programming System (MUMPS) programming language. VistA consists of nearly 184 integrated software modules for clinical care, financial and other business functions, and infrastructure. As the largest integrated health care system in the United States, VA provides care at over 1,233 health care facilities of varying complexity, conducting nearly 100 million patient encounters to more than 8.9 million Veterans per year supported by over 340,000 employees that includes 25,000 physicians and 93,600 nurses throughout the continental U.S., Alaska, and Hawaii on a single electronic healthcare information network.

No other brand name product can meet VA's interoperability and compatibility requirements. Specifically, the VistA platform only utilizes the InterSystems Cache databases to store and access critical information. The InterSystems Cache databases work with the 184 VistA client applications that comprise VistA, of which 76 are EHR applications. These are only coded to work with InterSystems Cache. Some of these applications include FileMan, TaskMan, Patient Care Encounter, VistAWeb, Prosthetics, Computerized Patient Record System (CPRS) applications, various mental health applications, laboratory applications, and various pharmacy applications. If any other brand name software was utilized, a complete code re-write would have to occur on all 184 applications. This would require a minimum of 8 to 10 years to accomplish and result in duplicated costs of \$362-400 million. This estimate is based on previous efforts

to code these applications utilizing hundreds of full time developers for decades. Given that VistA was created by hundreds of developers over a number of decades, at least a decade of similar effort by individuals with equivalent skills would be required.

Furthermore, these applications work in tandem with Intersystems software to store and archive data. If another brand name software was used, there is a high risk of data corruption. Specifically, transferring the data while re-coding the applications to another brand name software will risk the integrity of the data. When code is transposed from one language to another, judgments and compromises are made as one language never has the exact approach to resolve a problem as another. Given that the InterSystems Cache coding language is completely different from any other, the risk of data corruption would be amplified. A line-for-line translation of the code could not be achieved. Thus, every VistA application would need to be re-written from scratch. Additionally, from the data storage perspective, the internal data structures of a Cache database are entirely different than that of any other product. Virtually every other product used to store data utilizes a "relational" schema. That is, it's comprised of tables of records. Cache' data is constructed to be available via any approach, and not just the records and relational approach. A specific data point is stored and referenced as its own entity (key/value). Further, this data is broken down into blocks that are internally referenced via a data-chaining algorithm. This means the data would need to be translated, interpolated, and transposed in ways it was never designed or architected, thereby; introducing corruption and the possibility of incurring data loss should another brand name product be used. As the majority of this data is Veteran patient data, the loss of data would directly impact Veteran care by failing to provide clinicians with critical care data to make proper treatment decisions. A clinician could prescribe a drug to which a patient is allergic if the data point that indicated the patient wasn't allergic to that drug. Corruption of the data could bring even further lifethreatening scenarios to the patient. By way of example, misdiagnosis and mistreatment of Veterans department wide could result in the event one patient's diagnosis is ascribed to another patient, or the health history of two patients are merged. The corruption of data could endanger the health of the Veterans and could lead to possible deaths of Veteran patients.

In addition, no other brand name software can meet all of VA's functional requirements. Specifically, only the InterSystems software can provide the canonical information model library function, Cache to Sequence Query Language projection functions, business rule implementation, Enterprise Service Bus ability, support Fast Healthcare Interoperability Resources (FHIR), Integrated Health Enterprise (IHE), other health exchange standards, structured and unstructured data standards such as JavaScript Object Notation, Representational State Transfer and Extensible Mark-up Language, Free-Text Analysis and structuring. Additionally, only the InterSystems software operates on multiple platforms that exist within VA, such as Virtual Memory System (VMS), Linux and Windows, with the data and code as it exists today without the introduction of risk to the patient for interpolation, transposition, and translation. Specifically, while a product may have the capability to perform a few of these functions, they cannot do so with VistA data residing in Cache. No other product can natively read and interoperate with VA's existing InterSystems Cache .dat files without conversion, translation, or transposition. More specifically, no other product can read the Cache .dat file, offer key-value, multidimensional schema-less database structures, and operate on multiple platforms, such as Virtual Memory System, Linux, and Windows.

InterSystems Healthshare is the only software extraction tool that can meet all of VA's functional requirements. Specifically, no other brand name software is interoperable and compatible with the existing InterSystems Cache software due to the proprietary format of the infrastructure. The InterSystems Cache databases work with the 184 VistA client applications that comprise VistA, of which 76 are EHR applications. These are only coded to work with InterSystems Cache; therefore, only InterSystems software can extract the data from these applications due to these proprietary constraints.

Specifically, VA runs all VistA systems on the InterSystems Cache version of MUMPS programming language. Use of any other brand name product or service would result in various interoperability and compatibility issues with the current VistA infrastructure. VistA is comprised of multitudes of client applications that support clinicians, including CPRS, mental health applications, laboratory applications, and pharmacy applications that constantly communicate with the database servers. These servers communicate over a high-efficiency proprietary protocol called Enterprise Cache protocol, a product of InterSystems Cache. Substituting another product would prevent the applications from communicating with the database rendering each non-operational. MUMPS code is a mix of database access and code execution functionality and any perturbation to this system with incompatible protocols will cause the application programs to fail.

If another product was introduced, data backup would be adversely affected because systems engineers use Cache backup software. There are thousands of backup tapes and other media in VA's possession that would be rendered incompatible with old tapes or other storage formats; thereby rendering backup data unusable. In the event of a data loss scenario (disaster, corruption, etc.), restoration of the lost data would be almost impossible because the data would be based on different and incompatible systems.

Further, only InterSystems products can provide for the creation of object-oriented solutions; provide a text analysis tool to convert unstructured text to structured data; are fully compliant with the all information security standards; and has multi-platform capabilities. The Cache database is the only one which offers key-value, multidimensional schema-less database structures, while operating on multiple platforms such as VMS, Linux, and Windows. All of these functions are critical to successful operation of the current VistA system.

InterSystems HealthShare provides added functionality that the VA requires. While this upgrade provides a multitude of new features, the critical ones are the Enterprise Service Bus functionality, provision of text analysis tools for unstructured text conversion, inter-EHR translation of medical data without requiring translation, transposition, or conversion of VA data in its native format. Only InterSystems

HealthShare products and services can meet VA's needs and ensure complete interoperability, compatibility, and continuity of operations. Use of any other brand name product or service would result in various interoperability and compatibility issues with the current infrastructure which comprises VistA. HealthShare code is a mix of database accesses and code execution and any perturbation to this system with incompatible protocols will cause the application programs to fail.

As stated, VA's foundational application for delivery healthcare to Veterans is VistA, and VistA is programmed and stores data within Cache. VA is evolving VistA through its VistA Evolution initiative and will require the HealthShare functionality for Cache. This effort begins with its core applications, primarily Fileman. Fileman provides the means by which all interaction with patient data is made by other VistA applications. It is here, via the VistA Data Access Architecture VistA Evolution Project that VA data will be reached for all external consumption. Further, FileMan also provides access not only to patient data contained within VistA data sources, but also other data, such as VistA benefits, VistA administrative, VistA finance and VistA logistics data stored within VistA data sources. Combined, these activities will allow VistA to meet both Affordable HealthCare Act requirements for EHRs, as well Meaningful Use requirements set forth in the Health Information Technology for Economic and Clinical Health Act.

Finally, only InterSystems and its authorized resellers can meet VA's needs for updates and services and ensure complete interoperability, compatibility, and continuity of operations. InterSystems owns the proprietary source code and is the only source able to facilitate all InterSystems license and service requirements. InterSystems has proprietary rights to the software code for the InterSystems software associated with this acquisition requirement and, as such, is the only known vendor, along with its authorized resellers, that can provide this software and required SUTA updates and services. Without the aforementioned proprietary source code, no sources can ensure the services provided are properly configured to meet VA's needs. InterSystems was contacted in August of 2017 to ascertain if its proprietary technical data was for sale and advised VA it was not for sale.

Based on the above information, the Government's technical experts determined that only InterSystems brand name products and services can meet all of VA's needs.

6. <u>Efforts to Obtain Competition</u>: Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Government's requirements. It was determined however that limited competition is viable among authorized resellers for this brand name item. In accordance with FAR 5.301 and 16.505(b)(2)(ii)(D), the award notice for this action will be synopsized on the Federal Business Opportunities Page (FBO) and this justification will be made publicly available within 14 days of award.

7. <u>Actions to Increase Competition</u>: VA development teams will continue to conduct market research to identify other platforms that run on or are compatible and interoperable with VistA. Should such products become available; VA will review and

consider these products for future requirements. Furthermore, the Government's technical experts will conduct market research prior to exercising each option period under this proposed action to ascertain if any other brand name products or services are available to enable competition. If such products or services become available prior to the commencement of the option period(s), and it is determined that such products are more advantageous to the Government, VA will not exercise the option period(s). Additionally, this action itself will produce tertiary competition realized in a new set of opportunities in VistA tools and application development. A significant goal of the VistA Evolution initiative is to open VistA data structures to standardized interfaces that will allow for private sector interests to develop tools and products for the VistA platform.

8. Market Research: The Governments technical experts considered other similar commercial products as well as competitor companies to InterSystems through the months of June, July, and August of 2017. Five database system products and providers were identified as market competitors including Greystone Technology M (GT.M), Oracle, International Business Machines Database 2, Microsoft Structured Query Language (SQL) Server, Teradata, and MySQL. Their product documentation was reviewed as well as their support databases when available. Web-based database capability summary tools were also employed. In spite of these efforts, no other database product or provider was found that meets all of the VA's requirements as described in section 5 of this justification. None of these met the requirements of providing a database that can natively read and interoperate with, without conversion, translation, or transposition), VA's existing InterSystems Cache .dat files. More specifically, no other product can read the Cache .dat file, offer key-value, multidimensional schema-less database structures, and operate on multiple platforms such as VMS, Linux, and Windows. While GT.M runs the MUMPS language which is like Cache, it does not operate on multiple platforms and does not provide any of the ESB and other modernization capabilities this action requires such as free-text field data analysis.

Furthermore, VA analyzed the open source format of Node.js as an alternative to the Intersystem HealthShare software and it was determined that it could not provide the functionality of the Intersystem software nor meet the functionality that is required by the VA. Node is alone cannot provide a canonical information model library, which is a foundational requirement for Vista Data Access Architecture as well as libraries that support health information exchange standards including FHIR, IHE profiles, C-CDA/CDA/CCD, CEN/ISO 13606, eHealth Exchange, Direct (SMTP/XDM/XDR), HL7v2.x, HL7v3, DICOM, X12, ITK, NEHTA, and DMP. VistA Evolution will use the canonical information model library and Health Exchange Standards to map and exchange EHR and other healthcare data throughout VA as well as external medical industry providers. Data to and from the existing, established VistA data structures via a common mapping and exchange capability will then be fully interoperable with other industry-established EHR ESB connectors. No other existing product other that HealthShare does this with VistA data as it exists without conversion or extrapolation, leaving it fully intact and therefore, fully accurate without corruption or risk of loss. No other EHR or current database system has this capability.

Additional market research was conducted by posting a Request for Information (RFI) on July 31, 2017 on the FBO page. The RFI sought alternative technologies based on listed basic technical functions VA required. The purpose of the RFI was to ascertain the ability of any other brand name items and services capability to meet VA's needs. Responses were received from four providers. All but one response responded with InterSystems products. The one that did not respond with InterSystems products stated it could not meet the primary requirements but would like to work with VA on the services efforts on the contract. Based on this market research, the Government's technical experts confirmed and concluded that only InterSystems brand name products and services can meet all of VA's needs.

Finally, market research was conducted in August 2017 by the Contract Specialist by utilizing the NASA SEWP V GWAC Provider Lookup tool that identified two prospective Service-Disabled Veteran-Owned Small Business GWAC holders, one in Group B(2) and the other in Group D that are resellers of Intersystem products that meet the requirements of this acquisition.

Based on the aforementioned market research, the brand name InterSystems Cache' and InterSystems HealthShare software products is required for this action. Even through the market research reveals that there two SDVOSB NASA SEWP GWAC holders that are authorized resellers of the brand name InterSystems software products, there is no non-manufacturer rule waiver in place and both SDVOSBs are not able to meet the limitations in subcontracting requirements in accordance with Code of Federal Regulations 125.6, and therefore, the action cannot be set-aside to SDVOSBs. Therefore, to maximize competition the requirement will be solicited on NASA SEWP to all contract holders in Groups B(1), B(2), C and D under the Value Added Reseller North American Industry Classification System code 541519. In addition, the VIP database (www.vetbiz.gov) was utilized to identify prospective SDVOSB and Veteran owned small business (VOSB) sources using the key words search "InterSystems" and the NAICS code 541519. The VIP search returned zero matches.

9. Other Facts: None.