Supporting Statement
Paperwork Reduction Act Submission
Department of Veterans Affairs Acquisition Regulation (VAAR)
Gray Market Clauses: 852.212-71 and 852.212-72
2900-XXXX

A. JUSTIFICATION

1. **Explain the circumstances that make the collection of information necessary. Identify legal or administrative requirements that necessitate the collection of information**.

As a result of proposed rule, RIN 2900-AQ41 posted to the Federal Register 86FR64132 on November 17, 2021, VAAR case 2015-V016, this is a request from the Department of Veterans Affairs (VA) for OMB approval of a new Information Collection (IC).

In accordance with Veterans Affairs Acquisition Regulation (VAAR), section 812.301(f), Solicitation provisions and contract clauses for the acquisition of commercial items, VA is proposing to add clauses for insertion in solicitations and contracts for new medical equipment, new medical supplies, new information technology equipment, and maintenance of medical or information technology equipment that includes replacement parts. These clauses will prevent the entrance into the VA supply chain of gray market and counterfeit supplies and parts for such items. The solicitation provisions and contract clauses will also prohibit use of refurbished or remanufactured parts in the maintenance of these items. Two new clauses are proposed: 852.212-71, Gray Market and Counterfeit Items, and 852.212-72, Gray Market and Counterfeit Items—Information Technology Maintenance Allowing Other-than-New Parts.

852.212-71, Gray Market and Counterfeit Items. Clause 852.212-71, Gray Market and Counterfeit Items, is required to be inserted in VA solicitations and contracts to ensure no used, refurbished, or remanufactured supplies or equipment/parts would be offered on VA solicitations or delivered via any awarded contracts to Government facilities which would be entered into VA's critical supply chain and place Veterans and VA information, VA sensitive information and information systems at risk. The clause provides a clear statement and notice that a procurement under a solicitation that may be issued, and which contains this clause, is for new Original Equipment Manufacturer (OEM) items only. To protect VA from offers and delivery of potentially dangerous or fraudulent goods, VA is stating in plain language that no gray market items shall be provided. The clause also would provide a definition of "gray market items" which are OEM goods intentionally or unintentionally sold outside an authorized sales territory or sold by non-authorized dealers in an authorized sales territory.

Further, the clause states in plain language that no counterfeit supplies or equipment/parts shall be provided. The clause also would provide the meaning for "counterfeit items" that includes unlawful or unauthorized reproductions, substitutions, or alterations that have been mismarked, misidentified, or otherwise misrepresented to be an authentic, unmodified item from the original manufacturer, or a source with the express written authority of the original manufacturer or current design activity, including an authorized aftermarket manufacturer. Unlawful or unauthorized substitutions include used items represented as new, or the false identification of grade, serial number, lot number, date code, or performance characteristics.

The clause requires that a vendor shall be an OEM, authorized dealer, authorized distributor or authorized reseller for the proposed equipment/system. The VA requires that this be verified by an authorization letter or other documents from the OEM which is the information collection requirement under this clause.

This information collection requirement is needed to protect the safety and health of the nation's Veterans and to protect the security and integrity of VA information, VA sensitive information, and information systems by prohibiting other than an OEM, authorized dealer, authorized distributor or authorized reseller.

852.212-72, Gray Market and Counterfeit Items—Information Technology Maintenance Allowing Other-than-New Parts. Clause 852.212-72, Gray Market and Counterfeit Items—Information Technology Maintenance Allowing Other-than-New Parts, is required to be inserted in VA solicitations and contracts. This clause would permit used, refurbished, or remanufactured parts to be provided. However, no gray market supplies or equipment shall be provided. To protect VA from offers and delivery of potentially dangerous or fraudulent goods, VA is stating in plain language that no gray market items shall be provided. The clause also would provide a definition of "gray market items" which are OEM goods intentionally or unintentionally sold outside an authorized sales territory or sold by non-authorized dealers in an authorized sales territory.

Further, the clause states in plain language that no counterfeit supplies or equipment/parts shall be provided. The clause also would provide the meaning for "counterfeit items" that includes unlawful or unauthorized reproductions, substitutions, or alterations that have been mismarked, misidentified, or otherwise misrepresented to be an authentic, unmodified item from the original manufacturer, or a source with the express written authority of the original manufacturer or current design activity, including an authorized aftermarket manufacturer. Unlawful or unauthorized substitutions include used items represented as new, or the false identification of grade, serial number, lot number, date code, or performance characteristics.

The clause requires that a vendor shall be an OEM, authorized dealer, authorized distributor or authorized reseller for the proposed equipment/system. The VA requires that this be verified by an authorization letter or other documents from the OEM which is the information collection requirement under this clause.

This information collection requirement is needed to protect the safety and health of the nation's Veterans and to protect the security and integrity of VA information, VA sensitive information, and information systems by prohibiting other than an OEM, authorized dealer, authorized distributor or authorized reseller.

2. Indicate how, by whom, and for what purposes the information is to be used; indicate actual use the agency has made of the information received from current collection.

Clause 852.212-71 Gray Market and Counterfeit Items, is required in solicitations and contracts for new medical supplies, new medical equipment, new information technology equipment, and maintenance of medical or information technology equipment that includes replacement parts if used, refurbished, or remanufactured parts are unacceptable, when the associated solicitation

includes FAR provisions 52.212-1, Instruction to Offerors-Commercial Items, and 52.212-2, Evaluation-Commercial Items.

Clause 852.212-72 Gray Market and Counterfeit Items – Information Technology Maintenance Allowing Other-than-New Parts, is required in solicitations and contracts for the maintenance of information technology equipment that includes replacement parts, if used, refurbished, or remanufactured parts are acceptable, when the associated solicitation includes FAR provisions 52.212-1, Instruction to Offerors-Commercial Items, and 52.212-2, Evaluation-Commercial Items.

Clause 852.212-71 Gray Market and Counterfeit Items, is intended to prevent the inadvertent acquisition of gray market and counterfeit medical equipment and IT equipment and their entrance into VA's critical supply chain which would place Veterans and VA information, VA sensitive information and information systems at risk. While Clause 852.212-72 Gray Market and Counterfeit Items – Information Technology Maintenance Allowing Other-than-New Parts, does permit used, refurbished, or remanufactured parts to be provided when the clause is incorporated, "gray market items" and "counterfeit items" are also prohibited.

Both clauses require that the vendor shall be an OEM, authorized dealer, authorized distributor or authorized reseller and requires the submission of an authorization letter or other documents from the OEM to verify their status. This will help VA protect VA's supply chain and will protect Veterans and the security and integrity of VA information, VA sensitive information and information systems

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The information collections do not involve the use of automation, however, if the VA solicitation so permits submission of the proposal electronically, VA would allow submission of the information collection by electronic means as well.

4. Describe efforts to identity duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The inclusion of one of the two clauses in solicitations, contracts, orders and agreements is determined based on the actual requirements in the statement of work / performance work statement. As a general rule, no more than one of the two clauses would be included in each contract as one permits only new OEM items only, and the other clause permits used, refurbished, or remanufactured parts to be provided when the clause is incorporated. Therefore, there will be no duplication. There is no other information available to the Government that could be modified or used to provide for the type of information collection required by these clauses.

5. If the collection of information impacts small businesses or other small entities,

describe any methods used to minimize burden.

There are no additional means to minimize burden to small businesses and no ability to waive the requirement for small businesses to verify by an authorization letter or other documents from the OEM that they are an authorized vendor, i.e., an OEM, authorized dealer, authorized distributor or authorized reseller for the proposed equipment/system. Small businesses will be affected in the same way as large businesses in order to prevent the inadvertent acquisition and entrance into VA's supply chain of gray market and counterfeit medical equipment and IT equipment.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently as well as any technical or legal obstacles to reducing burden.

Failure to collect the information could expose vulnerabilities in VA purchasing counterfeit medical equipment and IT equipment.

7. Explain any special circumstances that would cause an information collection to be conducted more often than quarterly or require respondents to prepare written responses to a collection of information in fewer than 30 days after receipt of it; submit more than an original and two copies of any document; retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years; in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study and require the use of a statistical data classification that has not been reviewed and approved by OMB.

VA does not expect that any contractor/subcontractor (i.e., vendor) would submit a response more often than one per solicitation and/or contract in fewer than 30 days after receipt of it.

8. a. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the sponsor's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the sponsor in responses to these comments. Specifically address comments received on cost and hour burden.

Note: this section will be updated when the proposed rule AQ41 (839) is published in the Federal Register and at the end of public comment period. Address comments received related to this IC, if any.

b. Describe efforts to consult with persons outside the agency to obtain their· views on the availability of data, frequency of collection, clarity of instructions and recordkeeping, disclosure or reporting format, and on the data elements to be recorded, disclosed or reported. Explain any circumstances which preclude consultation every three years with representatives of those from whom information is to be obtained.

There were no efforts to consult with persons outside the agency beyond the publication of this proposed rule in the Federal Register.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts have been provided.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

This information is disclosed only to the extent consistent with prudent business practices and current regulations.

11. Provide additional justification for any questions of a sensitive nature (Information that, with a reasonable degree of medical certainty, is likely to have a serious adverse effect on an individual's mental or physical health if revealed to him or her), such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; include specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

The request for information does not include any questions of a sensitive nature.

12. Estimate of the hour burden of the collection of information:

a. The number of respondents, frequency of responses, annual hour burden, and explanation for each form is reported as follows:

Submitting an authorization letter or other documents from the Original Equipment Manufacturer

Total Burden Hours: 2,170
Average Number of Respondents: 4,342
Average Annual Responses: 13,026

(i) VAAR Clause 852.212-71, Gray Market and Counterfeit Items

No. of respondents	x No. of responses per respondent	x No. of minutes	÷ by 60	Number of Burden Hours
2,171	3	10		1,085

(ii) Clause 852.212-72, Gray Market, and Counterfeit Items—Information Technology Maintenance Allowing Other-than-New Parts

No. of respondents	x No. of responses per respondent	x No. of minutes	÷ by 60	Number of Burden Hours
2,171	3	10		1,085

b. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of

OMB 83-1.

No other form is required by VAAR for use in this collection.

c. Provide estimates of annual cost to respondents for the hour burdens for collections of information. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

Total estimated annual cost to all respondents: $102,902 (2,170 hours at $47.42 per hour). This is based on the Bureau of Labor Statistics May 2020 Occupational Employment and Wages code "13-1020 Buyers and Purchasing Agents" mean hourly wage is $34.80 plus 36.25% fringe benefits per OMB Memo M-08-13 dated March 11, 2008.

VAAR Clause 852.212-71: $51,451 (1,085 hours at $47.42 per hour).
VAAR Clause 852.212-72: $51,451 (1,085 hours at $47.42 per hour).

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

There are no capital or start-up costs associated with the information collection.

14. Provide estimates of annual cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operation expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

VAAR Clause 852.212-71, Gray Market and Counterfeit Items; and VAAR Clause 852.212-72, Gray Market and Counterfeit Items—Information Technology Maintenance Allowing Other-than-New Parts:

Total Estimated Burden Hours to the Government: 2,170.
Total Estimated Cost to the Government: $89,534.

$89,534 (2,170 hours at $41.26, based on 2021 OPM Salary Table, including benefits of 36.25% per OMB Memo m-08-13 dated March 11, 2008, of the average GS 11, Step 5, VA contracting officer).

OPM 2021 Salary Table can be located at Pay & Leave : Salaries & Wages - OPM.gov.

15. Explain the reason for any burden hour changes since the last submission

This is a new information collection.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be

used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

There are no plans to publish any data received from this information collection.

17. If seeking approval to omit the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

VA will display the expiration date for OMB approval of the information collection.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB 83-1.

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods will not be employed.