

SUPPORTING STATEMENT FOR ELIGIBILITY QUESTIONNAIRE FOR HAVANA ACT PAYMENTS

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Controlled Substances Act (CSA) (21 U.S.C. 801-971) requires all persons that manufacture, distribute, dispense, conduct research with, import, or export any controlled substance to obtain a registration issued by the Attorney General. 21 U.S.C. 822, 823, and 957. Once registered, the person becomes a DEA registrant and has the means to use DEA applications available by way of the DEA Diversion Control Division's website. The Diversion Technology Section strives to keep the Diversion Control Division's applications modern and website up to date, effective and efficient.

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

This proposed survey is needed to help improve the applications created by the Diversion Control Division's for DEA registrants. Registrants would rate the applications based on ease of use and other user experience factors. The survey would also ask registrants to evaluate and rank proposed changes to the applications. Last, DEA registrants would have the opportunity to provide open feedback to the Diversion Control Division.

The proposed survey would also ask questions about the Diversion Control Division's website. They would be able to state how they use the website and then rank the ease, efficiency, speed, and use of the various interactions that they have with the website. This proposed collection would also allow registrants to have the chance to rank the usefulness, effectiveness, and efficiency of the Support Center. Again, registrants would be able to provide additional comments for the website and the support center in two separate open fields.

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 submissions would be 100% electronic. A link to the survey would be distributed to the registrant population.

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

There is no duplication of information requested as a part of this collection. DEA has no other collection that gathers this information from non-registrants.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The DEA expects this collection will not have a significant economic impact on a substantial number of small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

6. Describe the consequence 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.

This will be a one-time survey that will be open for about 10 days.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to 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;**
- **requiring the use of statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentially to the extent permitted by law.**

There are no special circumstances applicable to this information collection.

8. If applicable, provide a copy and identify the date and page number of publication in the *Federal Register* of the agency'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 agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection-of-information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The 60-Day Notice was published in the Federal Register on January 4, 2023 (88 FR 372). The comment period ended on March 3, 2023. No comments were received.

DEA meets regularly with the affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

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

This collection of information does not propose to provide any payment or gift to respondents.

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

Information requested in this collection may be considered confidential business information if marked as such in accordance with 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. The information is protected by DEA through secure

storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, the DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by DEA.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the 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.

This collection of information does not ask any questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. General, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. 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.**

It will be a one-time survey over the course of 10 days given through an electronic link e-mailed to registrants. There are 2,017,980 registrants affected by this information request as of November 11, 2022. The potential number of respondents is estimated to be 1,800,000, since some registrants have the same e-mail address. It is estimated that 6% of potential respondents will respond or 108,000 ($1,800,000 * .06 = 108,000$).

Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate* ¹	Monetized Value of Respondent Time
Survey	108,000	1	108,000	14min	25,200	\$133.56	\$3,365,712
Unduplicated Totals	108,000		108,000		25,200		\$3,365,712

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

- **The cost estimate should be split into two components: (a) a total capital and start up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of service component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample**

¹ Mean hourly wage, 29-1229 Physicians. Bureau of Labor Statistics, Occupational Employment and Wages, May 2021, <https://www.bls.gov/oes/current/oes291229.htm>.
 Mean hourly wage, 29-1171 Nurse Practitioners. Bureau of Labor Statistics, Occupational Employment and Wages, May 2021, <https://www.bls.gov/oes/current/oes291171.htm>.
 Mean hourly wage, 11-1021 General and Operations Managers. Bureau of Labor Statistics, Occupational Employment and Wages, May 2021, <https://www.bls.gov/oes/current/oes111021.htm>.

Physicians are 68.71% of DEA registrants. MLP are 25.97% of DEA registrants. Other registrants are 5.32%. The weighted average mean hourly wage for DEA registrants is then \$94.16 (.6871*\$111.30+.2597*\$56.75+.0532*\$55.41 = \$94.16), where Nurse Practitioners represent MLPs and General and Operations Managers represent Others.

Average benefits for private industry are 29.5% of total compensation. Bureau of Labor Statistics, Employer Costs for Employee Compensation – June 2022 (ECEC), https://www.bls.gov/news.release/archives/ecec_09202022.pdf. The 29.5% of total compensation equates to 41.80% (29.5% / 70.5%) load on wages and salaries. \$94.16 x (1 + 0.4180) = \$133.56.

of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

The estimated annual cost burden is zero. Respondents are not estimated to incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Provide estimates of the annualized cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), 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 into a single table.

Estimated Labor cost to Government:

Labor Category	Number	Hourly Rate ²	Load ³	Hours	Cost
Information Technology Specialist – GS-14/5	1	\$68.55	1.621	30	\$3,333
Technical Clerical - GS 7/5	1	\$27.50	1.621	5	\$ 223
Total					\$3,556

*Figures are rounded.

Estimated Service cost to Government:

Service Contract	Cost	Total duration (weeks)	Remaining (weeks)	Weekly Rate	Cost
Gartner	\$174,885	14	9	\$12,492	\$112,426

² Costs are based on the Office of Personnel Management’s 2022 general schedule locality hourly pay tables for the Washington-Baltimore-Arlington area (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB_h.pdf) for the grade and step listed.

³ Government salary figures include 62.1% (38.3% / 61.7%) load for benefits based on the ECEC data for State and local government. The ECEC data does not include figures for the Federal government.

Total cost to Government:

Cost Category	Cost
Government Labor Cost	\$ 3,556
Government Service Contract	\$112,426
Total	\$115,982

Total costs to Government: \$115,982

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. Explain the reasons for any program changes or adjustments.

This is a new information collection. Therefore, there is no change in burden.

16. For collections of information whose results will be published, outline plans for tabulations, 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.

DEA will not publish the results of the information collected.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

DEA is not seeking approval not to display the expiration date for OMB approval of this information collection.

18. Explain each exception to the certification statement.

DEA is not seeking an exception to the certification statement "Certification for Paperwork Reduction Act Submissions" for this collection of information.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.

This collection does not contain statistical data.