Supporting Statement – Part A
Medicare Prescription Drug Inflation Rebate Program under
Sections 11101 and 11102 of the Inflation Reduction Act (IRA)
CMS-10930, OMB 0938-1485

Please note that this is a new collection of information request. The collection's 0938-1485 control number was assigned by the Office of Management and Budget (OMB) on August 26, 2025, in association with our CY 2026 Physician Fee Schedule (PFS) proposed rule (CMS-1832-P, RIN 0938-AV50).

The contents of this Supporting Statement and the associated attachments have been reviewed to ensure that they are consistent with the Trump administration's policies, goals, and objectives. This includes compliance with Executive Order 14192, and OMB's SPD 15 standards.

Background

Sections 11101 and 11102 of the IRA of 2022 (P.L. 117-169) authorized the Medicare Part B Drug Inflation Rebate Program under section 1847A(i) of the Social Security Act ("the Act") and the Medicare Part D Drug Inflation Rebate Program under section 1860D-14B of the Act. The statutory provisions are codified under 42 CFR part 427 and part 428, respectively.

Part D Drug Inflation Rebate Program

In accordance with section 1860D-14B of the Act, for each 12-month applicable period, starting with the applicable period beginning October 1, 2022, a manufacturer of a Part D rebatable drug will owe a rebate, to be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund, if the annual manufacturer price exceeds the inflation-adjusted payment amount.

As defined in section 1860D-14B(g)(1) of the Act, a "Part D rebatable drug" means, with respect to an applicable period, a drug or biological described at section 1860D-14B(g)(1)(C)[1] that is a covered Part D drug as defined under section 1860D-2(e) of the Act. A drug approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) is only subject to the Part D inflation rebate if it meets certain sole source criteria described at sections 1860D-14B(g)(1)(C)(ii)(I)–(IV) of the Act. As described in section 1860D-14B(g)(1)(B), the definition of a Part D rebatable drug does not include a drug or biological if, as determined by the Secretary, the "average annual total cost" for such drug or biological under Part D for a year per individual that uses such a drug or biological is less than the applicable threshold.

The total rebate amount is equal to the product of the per unit rebate amount and the total number of units dispensed of such drug under Part D (except in the case of a line extension of a Part D

[1] A drug or biological described in section 1860D-14B(g)(1)(C) is a drug or biological that, as of the first day of the applicable period involved is: (1) a drug approved under a New Drug Application (NDA) under section 505(c) of the FD&C Act; (2) a drug approved under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act that meets certain criteria in section 1860D-14B(g)(1)(C)(ii) of the Act; or (3) a biological licensed under section 351 of the Public Health Service (PHS) Act.

rebatable drug that is an oral solid dosage form, for which the total rebate amount is detailed at § 428.201(a)(1)(ii)).

Section 1860D-14B(b)(3) of the Act specifies that the inflation-adjusted payment amount is equal to the benchmark period manufacturer price increased by the percentage by which the applicable period Consumer Price Index for All Urban Consumers (CPI-U) exceeds the benchmark period CPI-U.

CY 2026 Physician Fee Schedule (PFS) Final Rule

The purpose of this collection of information request is for the Centers for Medicare & Medicaid Services (CMS) to collect information to implement the Medicare Part D Drug Inflation Rebate Program pursuant to the policies adopted in the CY 2026 PFS final rule ("final rule").

Specifically, section 1860D-14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provided a discount under the 340B Program. Because this requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units in Part D will only apply for the last three quarters of this applicable period. That is, CMS will exclude 340B units starting on January 1, 2026.

In the final rule, CMS adopted its proposal to establish a 340B repository to receive voluntary submissions from 340B covered entities (hereinafter "covered entities") of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program in a future applicable period. CMS will allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program beginning in 2026 to begin testing the usability of the 340B repository. OMB's approval of this collection of information request will enable CMS to collect information to implement this voluntary reporting. Additionally, in the final rule, CMS adopted its proposal to utilize the Prescriber-Pharmacy Methodology, with revisions based on commenter feedback, to implement the statutory exclusion at section 1860D-14B(b)(1)(B) of the Act beginning January 1, 2026.

Establishment of a 340B Repository

In the final rule, CMS adopted its proposal to establish a 340B repository and allow covered entities to optionally begin submitting to the 340B repository data elements from all of that covered entity's Part D claims with dates of service during the relevant period which the covered entity determined utilized a drug for which the manufacturer provided a discount under the 340B program for covered Part D drugs billed to Medicare Part D (hereinafter "Part D 340B claims"). CMS will allow covered entities to begin submitting the fields specified by CMS to the 340B repository during the testing period beginning in 2026 for Part D 340B claims with dates of service on or after January 1, 2026. This testing period will provide data for CMS to conduct usability testing for the 340B repository and allow covered entities to develop and test processes for submitting data elements to the 340B repository. CMS will not use the data submitted during

the testing period to remove units from Part D inflation rebate calculations. CMS will not use data submitted to the 340B repository to remove units for the purpose of calculating Part D inflation rebates unless and until a policy to do so is proposed and finalized.

Covered entities may voluntarily submit this data directly to CMS (or a contractor) to be included in the 340B repository. CMS will consider all data elements received by the 340B repository to be associated with Part D 340B claims; that is, CMS (or a contractor) would not further verify that submitted claims are eligible for discounted pricing under the 340B program or that 340B discounts were provided on the units used to fill such claims. Rather, the 340B repository will serve solely to store these data. Under this process, CMS will require a certification from covered entities that choose to submit data to the 340B repository that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B claims for the covered entity at the time of submission for dates of service during the relevant period. If we determine that the data reported to the 340B repository is usable and reliable and, in the future, propose and adopt a policy to use such data to exclude 340B units from Part D inflation rebate calculations, then units associated with prescription drug event (PDE) transactions that match to data elements stored in the 340B repository would be considered those for which the manufacturer provides a discount under the 340B Program. During the testing period, CMS will assess the usability of data submitted to the 340B repository to remove 340B units from the total number of units used to calculate the total Part D inflation rebate amount in a future applicable period.

CMS established in the final rule to require covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 to submit the fields specified by CMS to the 340B repository by a date announced in the future, which would be no sooner than 3 months after the date on which the 340B repository is available to receive submissions from covered entities. CMS established that covered entities that choose to submit data should submit data elements related to all Part D 340B claims with dates of service on or after January 1, 2026. At a point in the future, CMS will provide a deadline that CMS believes will allow sufficient time for covered entities to gather, validate, and submit the specified data to the 340B repository. CMS will provide the submission deadline(s) once the Medicare Prescription Drug Inflation Rebate collection of information request is approved by OMB. During the rest of the testing period, CMS anticipates that covered entities will be expected to report data on a quarterly basis within 3 months of the end of a given calendar quarter. CMS understands that covered entities typically contract with vendors, such as 340B third-party administrators (TPAs), to determine 340B eligibility of claims using data provided by covered entities and their contract pharmacies. CMS will allow covered entities that choose to submit data to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. Covered entities would ultimately be responsible for the accuracy of the data submitted to the 340B repository, even if a covered entity has an arrangement with a vendor to submit on its behalf. The data from these quarterly submissions will be used to assess the usability of such data to remove 340B units from the total number of units used to calculate the total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed at § 428.401(b) and (c), respectively. CMS further established in the final rule that covered entities participating in the 340B repository during the testing period beginning in 2026 must provide information identifying the

covered entity, specifically the covered entity's 340B ID and name as designated in the 340B Office of Pharmacy Affairs Information System (OPAIS), when submitting claim information to the 340B repository. CMS will use the collected identifying information to (1) perform analyses to assess suitability of the data for future use in removing 340B units, and (2) provide a means to follow up with the covered entity on questions related to claims data submission.

Data Elements

In addition to this identifying information, CMS established in the final rule that covered entities participating in the 340B repository during the testing period beginning in 2026 must submit the following data elements from all Part D 340B claims dispensed during the relevant time period: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); (4) Dispensing Pharmacy National Provider Identifier (NPI); and (5) NDC-11. CMS will use these data elements to match claims to PDE transactions and perform further analyses to assess the suitability of the data for future use in removing 340B units from Part D inflation rebate calculations.

- Such data shall be submitted to CMS in a method and format provided by CMS. The attached 340B Repository Data Elements Reporting Example Form provides an example format of the data CMS intends to collect. The example form includes the minimum necessary information in a standardized format to ease reporting burden among all covered entities.

A. Justification

1. Need and Legal Basis

Section 1860D-14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units used to calculate the inflation rebate for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provided a discount under the 340B Program.

Data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable from the data sources specified at section 1860D-14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and CMS does not currently have access to this data through other means. As discussed in the final rule, CMS will establish a 340B repository and allow covered entities to report data from Part D 340B claims for CMS to assess the suitability of the data for future use in removing 340B units in accordance with § 428.203(b)(2), which describes how CMS will exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provides a discount under the 340B Program.

2. Information Users

The information collected by CMS from covered entities would be used by the Medicare Drug Rebate and Negotiations Group within the Center for Medicare to assess the usability of the data to identify the PDE transactions and corresponding units which section 1860D-14B(b)(1)(B) of the Act excludes from the total Part D inflation rebate amount. CMS understands covered entities typically contract with vendors, such as 340B TPAs, to determine 340B eligibility of claims using data submitted by covered entities and their contract pharmacies. CMS will allow covered entities that choose to submit data to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. Covered entities would ultimately be responsible for the accuracy of the submission of data elements to the 340B repository, even if a covered entity has an arrangement with a vendor to submit on its behalf. The data collected from covered entities, or TPAs on their behalf, would then be matched to PDE transactions from the Drug Data Processing System (DDPS) for Part D rebatable drugs dispensed with dates of service during the relevant period to assess the usability of the data to identify PDE transactions and their corresponding units to be removed from the rebate calculation for a Part D rebatable drug as required by section 1860D-14B(b)(1)(B) of the Act. Additional information related to how covered entities should submit data elements to the 340B repository is located in the 340B Repository Data Elements Reporting Instructions.

3. Use of Information Technology

Covered entities that choose to submit data to the 340B repository will submit data elements from Part D 340B claims to the 340B repository on a quarterly basis. Covered entities that choose to submit data to the 340B repository are required to submit data using the CMS-provided format. CMS will receive and intake the claims data elements provided from the covered entities. CMS will match submitted claims data from covered entities to PDE transactions from the DDPS system. During the testing period, CMS will assess the usability of this data to identify units associated with PDE transactions that match to data elements stored in the 340B repository and that would be removed from the total number of units used to calculate the total Part D inflation rebate amount in a future applicable period.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and covered entities do not otherwise exchange information with CMS that identifies Part D 340B claims.

5. Small Businesses

The requirements for covered entities that choose to submit data to the 340B repository during the testing period do not impose any greater burden on small businesses with access to TPAs than on large businesses with access to TPAs because all covered entities regardless of size must be able to verify the status of an eligible 340B transaction to fulfill participation requirements for the 340B Program. Businesses without access to TPAs will need to initially establish processes to produce the ongoing data elements submissions. The collection instrument includes the minimum necessary information to ease reporting burden among all covered entities.

6. Less Frequent Collection

Covered entities that choose to submit data to the 340B repository during the testing period will submit the data fields specified by CMS using the CMS-provided format to the 340B repository on a quarterly basis within 3 months of the end of a given calendar quarter. For example, for claims with dates of service between October 1, 2026, through December 31, 2026, covered entities that choose to submit data elements from Part D 340B claims would submit the data to the 340B repository no later than March 31, 2027. Quarterly submissions are necessary so CMS has more timely information to assess suitability of the data for future use in removing 340B units to develop processes for the 340B repository. In addition, quarterly submissions also minimize the burden on covered entities by reducing the amount of data included in each submission, the amount of quality assurance necessitated, as well as the accuracy and timeliness of submissions as compared to an annual submission.

7. Special Circumstances

See Section 10 below for the confidentiality aspects of the information submitted using the CMS-provided format. Otherwise, this information collection request does not include any special circumstances that would require respondents to:

- Report information to the agency more often than quarterly;
- Require respondents to prepare a written response 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;
- Collect data 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;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include 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
- Submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

Federal Register

Serving as the 60-day notice, the NPRM (CMS-1832-P, OMB 0938-AV50) published in the Federal Register on July 16, 2025 (90 FR 32352).

Comments were received and are responded to within the preamble of the subsequent final rule (CMS-1832-F). We have also attached a summary of the comments that were submitted and our responses that were in relation to this collection of information request.

Please note that we revised the 340B Repository Data Elements Reporting Example Form and the reporting instructions in response to the comments. The revisions (see the attached Crosswalks) are technical changes to the language. We did not make any substantive changes to the instructions or to the requirements. The revisions have no impact on our proposed burden estimates.

The final rule (CMS-1832-F, OMB 0938-AV50) published on November 5, 2025 (90 FR 49266).

Outside Consultation

In the development of the 340B Repository Data Elements Reporting Example Form, CMS sought input from other federal agencies.

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents for completing the information collection. The information submitted by the covered entity will be used to test the 340B repository for use in identifying the appropriate number of 340B units that CMS would exclude from Part D inflation rebate calculations.

10. Confidentiality

CMS will keep confidential, to the extent allowable under law, proprietary information submitted by covered entities via the 340B Repository Data Elements Reporting Example Form using the CMS-provided format. Information provided as part of the 340B repository data elements submission will be protected from disclosure under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3) and (4)).[2] In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. CMS will protect confidential and proprietary information as required by applicable law.

11. Sensitive Questions

There are no sensitive questions associated with this collection. See Section 10 (above) for the confidentiality aspects of the information reported on the 340B Repository Data Elements Reporting Example Form.

12. Collection of Information Requirements and Associated Burden Estimates

[2] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wages Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (consisting of a 100 percent increase) and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
General and Operations Managers	11-1021	64.00	64.00	128.00
Software Quality Assurance Analysts and Testers	15-1253	53.01	53.01	106.02

As noted, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate the total cost for the form is a reasonably accurate estimation method.

Collection of Information Requirements and Associated Burden Estimates

The attached 340B Repository Data Elements Example Form will support CMS' administration of the Medicare Prescription Drug Inflation Rebate Program and allow CMS to collect data elements from 340B Part D claims via the 340B repository. The Part D 340B claim data elements include: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number; (4) Dispensing Pharmacy NPI; and (5) NDC-11. Additional information collected includes the covered entity's 340B ID and name as designated in OPAIS. Covered entities that choose to submit data to the 340B repository would be required to transmit the claim-level data elements and additional identifiers using the CMS-provided format for all 340B Part D claims from the relevant period and certify that all data elements submitted are from verified 340B claims.

Claim-level data elements from all Part D 340B claims with dates of service during the relevant period should be transmitted to the 340B repository on a quarterly basis by covered entities that voluntarily submit 340B data to the 340B repository. For purposes of this burden estimate, CMS assumes covered entities or their TPAs would have a dedicated Quality Assurance Analyst or team of analysts reviewing sample claim-level data elements, administering reporting to furnish the required data elements, and certifying that all data elements submitted are from verified 340B claims. CMS also assumes if a TPA submits claim-level data on behalf of a covered entity, the covered entity would not also submit this data.

For purposes of the burden estimates, CMS estimated the number of covered entities that would respond by providing Part D 340B claims data to the 340B Repository in 2026. We estimated a range of 20 percent to 50 percent of 13,000 (2,600 to 6,500) covered entities would respond to the 340B Repository Data Elements Reporting Example Form in 2026. This range of numbers is representative of the unique 340B ID numbers in the 340B OPAIS database that are active (i.e., not terminated) with at least one (1) contract pharmacy association listed.[3] Based on comments received on the CY 2025 PFS proposed rule from interested parties, including covered entities, requesting and expressing support for the establishment of a 340B repository and historical response rates to voluntary collections, CMS estimates one-fifth to one-half of covered entities would participate in the 340B repository during the testing period beginning in 2026. CMS understands that this is representative of an estimate based on the publicly available information from the 340B OPAIS database and that the number of respondents could be higher or lower than what is outlined here. Potential for underestimates of the number of respondents could include covered entities that do not meet the parameters described above, such as covered entities that have "in-house" pharmacies that are not registered in the 340B OPAIS database as 340B contract pharmacies or 340B-eligible Aids Drug Assistance Programs (ADAPs) that do not appear in the 340B OPAIS database because they collect rebates to receive 340B discounts and therefore do not utilize contract pharmacies registered in the 340B OPAIS database.

CMS anticipates that TPAs would submit claims data to the 340B repository to support their covered entity clients, as is the practice in some state Medicaid 340B clearinghouses today.[4] As a result, CMS expects the number of parties submitting claims data may be less than what is outlined below, which is representative of individual covered entities as potential respondents whereas TPAs may submit claims on behalf of multiple covered entities.

For the purposes of the burden estimates, we estimated a specific number of covered entities, rather than utilizing the range. This is because it is necessary to establish a specific population of covered entities to use to estimate the burden of our policies. We selected the 20 percent participation rate which equates to 2,600 participating covered entities. We expect that each submission will take 6 hours at $106.02/hr for a Software Quality Assurance Analyst and Tester and 2 hours at $128.00/hr for a General and Operations Manager. In aggregate, we estimate an initial year-one burden of 83,200 hours (2,600 covered entities x 8 hr/response x 4 responses/year) at a cost of $9,278,048 (10,400 responses x [(2 hr x $128.00/hr) + (6 hr x $106.02/hr)]).

Total Burden: Year One Testing[5]

Requirement	Occupation Title (Occupation Code)	Respondents	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Voluntary 340B Repository Data Element Reporting	Software Quality Assurance Analyst and	2,600 covered entities	10,400 (2,600 x 4 qtr)	6	62,400	106.02	6,615,648

[3] See: https://340bopais.hrsa.gov/reports.
[4] See: https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20State%20Policy.doc.
[5] For purposes of establishing the population used in our burden estimate, we estimate an absolute number of respondents rather than a range.

	Tester (11-1021)						
	General and Operations Manager (15-1253)	2,600 covered entities	10,400 (2,600 x 4 qtr)	2	20,800	128.00	2,662,400
TOTAL		2,600 covered entities	10,400 (2,600 x 4 qtr)	varies	83,200	varies	9,278,048

Collection of Information Instruments and Instruction/Guidance Documents

340B Repository Data Elements Reporting Example Form (this is a New instrument)

340B Repository Data Elements Reporting Instructions (this is a New instruction)

13. Capital Costs

There are no anticipated capital costs for respondents associated with this information collection.

14. Cost to Federal Government

The federal government estimated labor cost for directing policy and operations of the 340B repository is based on the efforts expended by CMS staff with the following assumptions to establish policy and review data from covered entities and TPAs that submit claim-level data to the 340B repository.

To generate salary estimates, CMS used the 2025 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region.[6] In this regard, the following table presents the FTE equivalent of staff required for the task, the hourly wage (adjusted for the cost of fringe benefits and other indirect costs, calculated at 100 percent of salary), total time, and the total cost of the information collection.

The following estimates in the table below show the total labor cost to the government for operationalizing the 340B repository. This estimate does not include costs for design, development, implementation, or maintenance of the 340B repository or to receive and process data from covered entities and TPAs.

Staffing estimates are based on CMS duties as follows:

- Covered entities and TPAs send submissions formatted in a standardized file template.
- CMS would perform analyses on the submissions of data into the 340B repository, matching covered entities' submissions to PDE transactions, and assess the usability of this data to calculate the appropriate number of 340B units to remove from the Part D inflation rebate calculation.

[6] See: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB_h.pdf.

- Review and analyze the information submitted by covered entities and TPAs and perform follow up outreach for incomplete submissions.

The total labor cost to the federal government for directing policy and operations of the 340B repository in the first year of implementation is estimated at $1,124,418.

Total Labor Cost To Government Over Year One

	FTEs	Time/ FTE	Adjusted Hourly Wage ($/hr)	Total Time (hr)	Total Labor Cost ($)
GS-13 (step 1)	8	1,007.5	115.56	8,060	931,414
GS-14 (step 1)	3	455	136.54	1,365	186,377
GS-15 (step 1)	1	26	160.62	26	4,176
Senior Executive Service	1	13	188.54	13	2,451
TOTAL	13	Varies	varies	9,464	1,124,418

15. Changes to Burden

This is a new information collection request. Therefore, there are no changes to any active requirements and burden estimates. See Section 12 (above) for the new requirements and burden estimates.

16. Publication/Tabulation Dates

The results of this information collection will not be published for statistical use or analysis.

17. Expiration Date

When it becomes available, the expiration date will be displayed within the data collection information technology system (see attached PRA Disclosure Statement).

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

This collection does not employ any statistical methods.