A. Background

The Patient Protection and Affordable Care Act (ACA), Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, enacted on March 30, 2010, says a State may elect to expand access to affordable health insurance through the establishment of an Exchange which is designed to facilitate the enrollment of individuals and employees of small businesses into health plans that meet specified requirements. Title I of the Patient Protection and Affordable Care Act (the Affordable Care Act) expands access to health insurance through the establishment of the new American Health Benefit Exchanges (Exchanges). The Exchanges, which will become operational by January 1, 2014, will serve to enhance competition in the health insurance market, and expand access to affordable health insurance for millions of Americans.

The proposed reporting requirements and data collection addresses Federal requirements that States must meet with respect to the establishment and operation of an Exchange, and minimum requirements that health insurance issuers must meet with respect to participation in a State or Federal Exchange.

B. Justification

1. Need and Legal Basis

Section 1311(b) of the Affordable Care Act requires each State to establish an Exchange by January 1, 2014. Section 1311(d) of the Affordable Care Act requires that an Exchange be a governmental agency or nonprofit entity established by a State; make qualified health plans available to eligible individuals and employers; and identifies the minimum functions that an Exchange must perform such as implementing procedures for certification, recertification, and decertification of qualified health plans, providing for the operation of a toll-free telephone hotline, maintaining an internet website containing standardized comparative information on qualified health plans, and establishing and making available by electronic means a calculator to determine the actual cost of coverage after application of any advance premium tax credits and cost-sharing reductions.

Pursuant to section 1311(d)(5), States must ensure that their Exchanges are self-sustaining beginning on January 1, 2015. A State may accomplish this by permitting its Exchange to charge assessments or user fees to participating health insurance issuers, or otherwise generate funding to support Exchange operations.

Under Title VI, section 6005, qualified health plan issuers are directed to provide data on the cost and distribution of prescription drugs covered under the qualified health plan offered by such issuer.

Information Users

The proposed data collection and reporting requirements will assist CMS in assessing the ability of States to operate their own Exchange and creating a seamless and coordinated system of eligibility and enrollment.

3. <u>Use of Information Technology</u>

The proposed collection of information for this rule will be submitted electronically. CMS staff will analyze or review the data in the same manner by which it was submitted and communicate with States and the District of Columbia using e-mail or telephone.

Duplication of Efforts

This information collection does not duplicate any other Federal effort.

Small Businesses

We estimate minimal burden on small business as they are not required to participate in SHOP.

Less Frequent Collection

Due to the required flow of funds for payments for health insurance coverage within the Exchange, it is necessary to collect information as indicated. If frequency is lessened, the result will be late charges to insurers, increase in back payments, and an overall stress on the organizational structure of the Exchanges.

Special Circumstances

In order for the flow of payments to be made in a timely manner (often monthly) for riskreduction programs, it is necessary to collect information such as enrollment data on a monthly basis.

Federal Register/Outside Consultation

The proposed rule published on July 15, 2011 (76 FR 41866). The comments for this proposed rule are due within 60 days of publication. We have consulted with contractors, CMS-9989-P

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academia, States and industry of the feasibility of this information collection. We have based many of the requirements in this information collection from the consultations with outside entities.

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9. <u>Payments/Gifts to Respondents</u>

No payments and/or gifts will be provided to respondents.

10. Confidentiality

To the extent of the law and the U.S. Department of Health and Human Services policies, we will maintain respondent privacy with respect to the information collected.

11. Sensitive Questions

There are no sensitive questions included in this information collection effort.

12. Burden Estimates (Hours & Wages)

For purposes of presenting an estimate of paperwork burden for States, we reflect full participation of all States and the District of Columbia in operating an Exchange which is a requirement for the operation of the reinsurance, risk corridor, and risk adjustment programs. However, we recognize that not all States will elect to operate their own Exchanges, so these estimates should be considered an upper bound of burden estimates. These estimates may be adjusted proportionally in the final rule based upon additional information as States progress in their Exchange development processes.

General Standards Related to the Establishment of an Exchange

As discussed in §155.105, States are required to submit an Exchange plan to HHS. As noted above, we plan to issue a template outlining the required components of the Exchange Plan, subject to the notice and comment process under the Paperwork Reduction Act. We estimate that it will take a State approximately 160 hours (approximately one month) for the time and effort needed to develop the plan and submit to HHS. We estimate minimal burden requirements for developing the Exchange plan as States will be gathering most of the information needed for the CMS-9989-P

plan through the planning grants provided by HHS. States are also required to make the governance principles available to the public. We estimate that it will take States 40 hours for the time and effort to develop these principles and disclose this information to the public. This estimate is similar to estimates provided for reporting requirements for Medicare Part D as described in §423.514.

We estimate that all 50 States and the District of Columbia will establish an Exchange serving the individual market and will be subject to meeting these requirements. Again, this estimate should be considered an upper bound, and we may revise these estimates in the final rule based upon additional information as States progress in their Exchange development processes. We estimate that it will take 200 hours for a State to meet these provisions. The total burden for all States and the District of Columbia is 10,200 hours. For the purposes of this estimate, we assume that meeting these requirements will take a health policy analyst 120 hours (at an average wage rate of \$43 an hour) and a senior manager 80 hours (at \$77 an hour). The wage rate estimates include a 35% fringe benefit estimate for state employees, which is based on the March 2011 Employer Costs for Employee Compensation report by U.S Bureau of Labor Statistics. This fringe benefit estimate will be used throughout this section for all presumed state personnel. The estimated cost burden for each State is \$11,320 with a total estimated burden of \$577,320.

Forms (if necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Exchange Plan	Exchange	51	1	160	8160
Governance Principles	Exchange	51	1	40	2040
Total				200	10,200

Hourly Labor Cost of Reportin g (\$)	Total Burde n Hours	Average Labor Cost per Response	Number of Respondents	Total Labor Costs (All Respondents)
\$42.00	120	\$ E 160 00	51	\$263,160.00
·			51	\$314,160.00
	Labor Cost of Reportin g (\$) \$43.00	Labor Total Cost of Burde Reportin n g (\$) Hours	Labor Cost of Reportin g (\$)Total Burde n HoursAverage Labor Cost per Response\$43.00120\$5,160.00	Labor Cost of Reportin g (\$)Total Burde n HoursAverage Labor Cost per ResponseNumber of Respondents\$43.00120\$5,160.00

Total		\$11,320.0	\$577,320.00
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States must also notify CMS of any changes to its Exchange proposal. We estimate that 5 States submit changes and that it will take each state 12 hours to develop the notification and submit to CMS for a total burden of 60 hours. We presume that it will take a health policy analyst 12 hours (at \$43 an hour) to meet this requirement. The estimated burden cost per State is \$516 for a total cost burden estimate of \$2,580 for five States.

Forms (if necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Changes to Exchange Plan	State	5	1	12	60
Total				12	60

Type of Respondent	Hourly Labor Cost of Reportin g (\$)	Total Burde n Hours	Average Labor Cost per Respons e	Number of Respondents	Total Labor Costs (All Respondents)
Health Policy Analysts	\$43.00	12	\$516.00	5	\$2,580.00
Total			\$516.00		\$2,580.00

General Functions of an Exchange

Exchanges are required to collect and populate the website they develop with information on qualified health plans available, premium and cost-sharing information, benefits and coverage established, metal levels of plans, medical loss ratio information, transparency of coverage, and a provider directory.

The burden estimate related to the website reflects the time and effort needed to collect the information described above and disclose this information on a website; however, we understand

that overall administrative burden and costs will be higher for website development and testing. These costs are reflected in the impact analysis for Exchanges. Assuming that all States and the District of Columbia establish Exchanges, an upper bound estimate, we estimate that it will take 320 hours (approximately 2 months) for each State to meet this requirement for a total estimate of 16,320 hours. We presume that it will take a health policy analyst 40 hours (at \$43 an hour), a financial analyst 90 hours (at \$62 an hour), a senior manager 50 hours (at \$77 an hour), and various network/computer administrators or programmers 140 hours (at \$54 an hour) to meet the reporting requirements for this subpart. We estimate the total cost burden for an Exchange to be \$18,710 for a total estimated burden of \$954,210 for all 50 States and the District of Columbia.

Forms (if necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Website	Exchange	51	1	320	16,320
Total				320	16,320

	Hourly Labor Cost of Reporting	Total Burden	Average Labor Cost per	Number of	Total Labor Costs (All
Type of Respondent	(\$)	Hours	Response	Respondents	Respondents)
Health Policy					
Analysts	\$43.00	80	\$1,720.00	51	\$87,720.00
Financial Analyst	\$62.00	90	\$5,580.00	51	\$284,580.00
Senior Manager	\$77.00	50	\$3,850.00	51	\$196,350.00
Network or Database					
Administrator/					
Computer					
Programmer	\$54.00	140	\$7,560.00	51	\$385,560.00
Total			\$18,710.00		\$954,210.00

Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

Exchanges are required to maintain records of enrollment annually. We estimate that this will take an exchange 52 hours annually to maintain these records. This estimate is similar to

Medicare Part D, where is was estimated that it will take 52 hours on an annual basis for plan sponsors to maintain books, records, and documents on accounting procedures and practices as described in §423.505. Estimates related specifically to the maintenance of records for enrollment were not provided in Medicare Part D.

Exchanges are also required to submit enrollment information to HHS on a monthly basis, and reconcile enrollment information on at least a monthly basis. We estimate that it will take an Exchange 12 hours submit this information and 12 hours to reconcile this information on a monthly basis. Exchanges are also required submit the number of coverage terminations to HHS. We estimated that it will take 12 hours for an Exchange to submit this information. These estimates are similar to estimates provided in Medicare Part D rule for data submission. For example, Medicare Part D estimated that it would take plan sponsors approximately 10 hours annually for plan sponsors to submit data on aggregated negotiated drug pricing from pharmaceutical companies described in §423.104. We provide a slightly higher estimate for the submission of data due to the complexity of the Exchange program.

Exchanges are also required to provide a notice of eligibility to the applicant and a notice of the annual open enrollment period to the applicant. Estimates related to notices in this subpart and throughout the proposed rule for Exchanges take into account the time and effort needed to develop the notice and make it an automated process to be sent out when appropriate. As such, we estimate that it will take approximately 16 hours annually for the time and effort to develop and submit a notice when appropriate. Again, this estimate is slightly higher than the 8 hours estimated for notices discussed in the Medicare Part D rule and reflects the overall complexity of the Exchange program.

States are required to maintain records of termination coverage. Again, we estimate that this will take an exchange 52 hours annually to maintain these records. We estimate that all 50 States and the District of Columbia will establish an Exchange subject to these reporting requirements. This estimate is an upper bound of burden as a result of the reporting requirements in this subpart; we will revise these estimates in the final rule as States progress in their Exchange development. We estimate that it will take 468 hours for an Exchange to meet these reporting requirements for a total of 23,868 hours. We presume that it will take an operations analyst 240 hours (at \$55 an hour), a health policy analyst 128 hours (at \$43 an hour), and a senior manager 100 hours (at \$77 an hour) to meet the reporting requirements for a burden cost estimate of \$26,404 for an Exchange and total estimated burden costs of \$1,346,604 for all 50 States and the District of Columbia.

Forms (if necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Maintenance of records	Exchange	51	1	52	2,652

Forms (if necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Submit enrollment records	Exchange	51	12	12	7,344
Reconcile Files	Exchange	51	12	12	7,344
Notice of eligibility	Exchange	51	1	16	816
Notice of annual open enrollment period	Exchange	51	1	16	816
Submit number of coverage terminations	Exchange	51	1	12	612
Maintenance of records for termination of coverage	Exchange	51	1	52	2652
Total				436	22,236

Type of Respondent	Hourly Labor Cost of Reporting (\$)	Total Burden Hours	Average Labor Cost per Response	Number of Respondent s	Total Labor Costs (All Respondents)
Operations Analyst	\$55.00	224	\$12,320.00	51	\$628,320.00
Health Policy Analyst	\$43.00	119	\$5,117.00	51	\$260,967.00
Senior Manager	\$77.00	93	\$7,161.00	51	\$365,211.00
Total			\$24,598.00		\$1,254,498.00

Exchange Functions: Small Business Health Options Program (SHOP)

The SHOP is required to provide the following notices:

- Notice to employer of reason to doubt information submitted;
- Notice to employer of non-resolution for reason to doubt;
- Notice to individual of inability to substantiate employee status;
- Notice of employer eligibility;
- Notice of employee eligibility;
- Notice of employer withdrawal from SHOP;
- Notification of effective date to employees;
- Notice of employee termination of coverage to employer;
- Notice of annual employer election period; and
- Notice to employee of open enrollment period.

As discussed previously, we estimate that it will take 16 hours annually for a SHOP to provide each notice as described in this subpart. The SHOP is also required to maintain records for SHOP enrollment and reconcile SHOP enrollment files on a monthly basis. Again, we estimate that this will take 52 hours annually for a SHOP to maintain SHOP enrollment records. This estimate is similar to Medicare Part D, where is was estimated that it will take 52 hours on an annual basis for plan sponsors to maintain books, records, and documents on accounting procedures and practices as described in §423.505. Estimates related specifically to the maintenance of records for enrollment were not provided in Medicare Part D. We also estimate that it will take 12 hours for a SHOP to reconcile this information on a monthly basis.

We estimate that that all 50 States and the District of Columbia will establish a SHOP subject to meeting these reporting requirements. This estimate is an upper bound of burden as a result of the reporting requirements in this subpart; we will revise these estimates in the final rule as States progress in their Exchange development. We estimate that it will take each SHOP 356 hours to meet these requirements for a total of 18,156 hours. We presume that it will a health policy analysts 132 hours (at \$43 an hour), a senior manager 80 hours (at \$77 an hour), and an operations analyst 144 hours (at \$55 an hour) to meet these reporting requirements for an estimated cost burden of \$19, 756 for each Exchange. The total estimated cost burden is \$1,007,556 for all 50 States and the District of Columbia.

Forms (if necessary)	Type of Respondent	Number of Respondent s	Number of Responses per Responden t	Average Burden Hours per Response	Total Burden Hours
Notice of reason to doubt	Exchange	51	1	16	816

Forms (if necessary)	Type of Respondent	Number of Respondent s	Number of Responses per Responden t	Average Burden Hours per Response	Total Burden Hours
Notice of non- resolution for reason to doubt	Exchange	51	1	16	816
Notice to individual of inability to substantiate employee status	Exchange	51	1	16	816
Notice of employer eligibility	Exchange	51	1	16	816
Notice of employee eligibility	Exchange	51	1	16	816
Notice of employer withdrawal	Exchange	51	1	16	816
Notification of effective datefor employees	Exchange	51	1	16	816
Maintenance of Records	Exchange	51	1	52	2,652
Reconcile Files	Exchange	51	12	12	7,344
Notice of employee termination of coverage	Exchange	51	1	16	816
Notice of annual employer election period	Exchange	51	1	16	816
Notice to employee of open enrollment period	Exchange	51	1	16	816
Total				356	18,156

Type of Respondent	Hourly Labor Cost of Reporting (\$)	Total Burden Hours	Average Labor Cost per Response	Number of Respondents	Total Labor Costs (All Respondents)
Health Policy Analysts	\$43.00	132	\$5,676.00	51	\$289,476.00
Senior Manager	\$77.00	80	\$6,160.00	51	\$314,160.00
Operations Analyst	\$55.00	144	\$7,920	51	\$403,920.00
Total			\$19,756.00		\$1,007,556.00

Exchange Function: Certification of Qualified Health Plans

As described in §155.1020, §155.1040, and §155.1080, Exchanges are required to collect qualified health plan issuer reports on covered benefits, rates, and cost-sharing requirements. We estimate that it will take 12 hours for an Exchange to collect this information from issuers annually. This estimate is similar to estimates for data collection described in the Medicare Part D rule. Exchanges are also required to collect information on coverage transparency from issuers. Again, we estimate that it will take 12 hours for an Exchange to collect this information. Finally, Exchanges are required to provide a notice of the decertification, if applicable, of a QHP to the QHP issuer, Exchange enrollees, HHS, and the State insurance department. This burden was estimated at 16 hours for an Exchange to provide notice.

We estimate that all 50 States and the District of Columbia will establish an Exchange subject to these reporting requirements. We further estimate that it will take 40 hours for an Exchange to meet the provisions discussed, with a total burden estimate of 2,040 hours for all 50 States and the District of Columbia. We presume that it will take an operations analyst 32 hours (at \$55 an hour) and a senior manager 8 hours (at \$77 an hour) to carry out the requirements in this subpart. HHS estimates that the cost burden for an Exchange to meet the reporting requirements in subpart K to be \$2,376 with a total cost burden estimate of \$121,176 for all 50 States and the District of Columbia.

Forms (if necessary)	Type of Responden t	Number of Respondent s	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Collect reports on	Exchange	51	1	12	612

Forms (if necessary)	Type of Responden t	Number of Respondent s	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
benefit, rate, and cost-sharing			Kespondent	Response	Hours
Collect information on coverage transparency	Exchange	51	1	12	612
Notice of qualified health plan decertification	Exchange	51	1	16	816
Total				40	2,040

	Hourly Labor Cost of Reporting	Total Burde n	Average Labor Cost per	Number of Respondent	Total Labor Costs (All
Type of Respondent	(\$)	Hours	Response	S	Respondents)
Operations Analyst	\$55.00	32	\$1,760.00	51	\$89,760.00
Operations Analyst Senior Manager	\$55.00 \$77.00	32 8	\$1,760.00 \$616.00	51 51	\$89,760.00 \$31,416.00

Qualified Health Plan Minimum Certification Standards

Each qualified health plan issuer is required to report annually to the Exchange information on benefits and rates, justification of rate increases, coverage transparency, and a summary of cost and coverage documents, including notice of coverage of abortion provided by a QHP plan. Issuers are also required to make available enrollee cost sharing information, provide information to applicants and enrollees, provide enrollment packages, collect enrollment information and submit this information to the Exchange, reconcile enrollment files on a monthly basis, and maintain records related to termination of coverage. There are also several notices that issuers must provide to enrollees related to the effective date of coverage, non-renewal of coverage,

termination of coverage, and payment delinquency; and to the Exchange for non-renewal of recertification.

As described in §156.285, for the SHOP program, issuers must provide an enrollment package to SHOP enrollees and a summary of benefits and coverage to employers and employees; reconcile enrollment files for SHOP on a monthly basis; and provide notice to SHOP enrollees of termination of coverage. As discussed previously, estimates related the collection and submission of data; maintenance of records, notices are similar to estimates provided in the Medicare Part D rule.

Qualified health plan issuers must also submit to the Exchange on an annual basis information on drug distribution and costs. We estimate that it will take an issuer 24 hours to submit this data. This estimate is a slight increase from the Medicare Advantage estimate of 15 hours for submitting data for drug claims as described for §423.329 for Medicare Part D and reflects the complexity of reporting this data for the Exchange program.

For the purpose of this estimate and whenever we refer to burden requirements for issuers, we utilize estimates of the number of issuers provided by the Healthcare.gov website as this site provides the best estimate of possible issuers at this time. Based on preliminary findings there are approximately 1827 issuers in the individual and small group markets. While we recognize that not all issuers will offer QHPs, we use the estimate of 1827 issuers as the upper bound of participation and burden.

We estimate that it will take an issuer 588 hours to meet these reporting requirements for a total of burden estimate of 1,074,276 hours for all 1827 issuers. We presume that it will take at least two health policy analysts 80 hours (at an average private industry rate of \$50 an hour), a financial analyst 124 hours (at \$57 an hour), an operations analyst 352 hours (at \$51 an hour), and a senior manager 32 hours (at \$72 an hour) to meet these reporting requirements. These wage estimates include a 30% fringe benefit rate for the private sector as reported by the U.S. Bureau of Labor Statistics in the March 2011 Employer Costs for Employee Compensation report. The estimated burden cost for each issuer is \$31,324. The total estimated burden cost for all issuers is \$57.2 million.

Forms (if necessary)	Type of Respondent	Number of Respondent s	Number of Responses per Responden t	Average Burden Hours per Response	Total Burden Hours
Benefit and rate report	Issuer	1827	1	12	21,924
Rate increase justification	Issuer	1827	1	8	14,616

Forms (if necessary)	Type of Respondent	Number of Respondent s	Number of Responses per Responden t	Average Burden Hours per Response	Total Burden Hours
Coverage transparency report	Issuer	1827	1	12	21,924
Enrollee cost sharing information	Issuer	1827	1	8	14,616
Notice to applicants and enrollees	Issuer	1827	1	16	29,232
Notice of effective date to individuals	Issuer	1827	1	16	29,232
Collect enrollment information	Issuer	1827	1	12	21,924
Submit enrollment information to Exchange	Issuer	1827	1	12	21,924
Provide enrollment information package to enrollee	Issuer	1827	1	12	21,924
Cost and Coverage Document	Issuer	1827	1	12	21,924
Reconcile enrollment files	Issuer	1827	12	144	263,088
Notice of termination of coverage	Issuer	1827	1	16	29,232
Notice of payment	Issuer	1827	1	16	29,232

Forms (if necessary)	Type of Respondent	Number of Respondent s	Number of Responses per Responden t	Average Burden Hours per Response	Total Burden Hours
delinquency					
Maintenance of termination of coverage records	Issuer	1827	1	52	95,004
Provide enrollments package to SHOP enrollee	Issuer	1827	1	12	21,924
Provide summary of benefits and coverage to employers and employees	Issuer	1827	1	12	21,924
Reconcile enrollment files for SHOP	Issuer	1827	12	144	263,088
Notice to SHOP enrollee of termination of coverage	Issuer	1827	1	16	29,232
Notification of QHP issuer non-renewal to Exchange	Issuer	1827	1	16	29,232
Notification of QHP issuer non-renewal to enrollees	Issuer	1827	1	16	29,232
Submit information on drug distribution and costs	Issuer	1827	1	24	43,848
Total				588	1,074,276

Type of Respondent	Hourly Labor Cost of Reportin g (\$)	Total Burde n Hours	Average Labor Cost per Response	Number of Respondents	Total Labor Costs (All Respondents)
Health Policy	3 (1)		•	•	•
Analysts	\$50.00	80	\$4,000.00	1827	\$7,308.000.00
Financial Analyst	\$57.00	124	\$7,068.00	1827	\$12,913,236.00
Operation Analyst	\$51.00	352	\$17,952.00	1827	\$32,798,304.00
Senior Management	\$72.00	32	\$2,304.00	1827	\$4,209,408.00
Total			\$31,324.00		\$57.2 million

Salaries were taken from the Bureau of Labor Statistics (BLS) website (http://www.bls.gov/oco/ooh_index.htm). Fringe Benefit estimates were taken from BLS March 2011 Employer Costs for Employee Compensation report.

13. Capital Costs

There are no additional record keeping/capital costs.

14. Cost to Federal Government

The initial burden to the Federal Government for the establishment of qualified health plans and American Health Benefit Exchanges is \$223,744. The calculations for CCIIO employees' hourly salary was obtained from the OPM website: http://www.opm.gov/oca/10tables/html/dcb h.asp.

Task	Estimated Cost
Certification of Exchanges	
15 GS-13: 15 x \$42.66 x 160 hours	\$102,384.00
Review of State/Exchange data	
15 GS-13: 15 x \$42.66 x 160 hours	\$102,384.00
Managerial Review and Oversight	

2 GS-15: 2 x \$59.30 x 160 hours	\$18,976.00
Total Costs to Government	\$223,744.00

15. Explanation for Program Changes or Adjustments

There are no changes to the burden. This is a new data collection.

16. Publication/Tabulation Dates

TBD.

17. Expiration Date

Not applicable.

18. Certification Statement

There is no exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.