SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSIONS

Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers

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 Patient Protection and Affordable Care Act, Public Law 111-148, (the Affordable Care Act) was enacted by President Obama on March 23, 2010. As part of the Act, Congress added PHS Act section 2719, which provides rules relating to internal claims and appeals and external review processes. These interim final regulations set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations. Paragraph (b)(3)(i) requires issuers offering coverage in the individual health insurance market to also comply with the DOL claims procedure regulation as updated by the Secretary of HHS in paragraph (b)(3)(ii) of the interim final regulations for their internal claims processes.

The DOL claims procedure regulation requires plans to provide every claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. In addition, paragraph (b)(3)(ii)(C) of the interim final regulations adds an additional requirement that non-grandfathered ERISA-covered group health plans provide to the claimant, free of charge, any new or additional evidence considered relied upon, or generated by the plan or issuer in connection with the claim.¹ As discussed in more detail in items 12 and 13 below, this requirement increases the administrative burden on plans and issuers to prepare and deliver the additional information to the claimant.

¹ Such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date. Additionally, before the plan or issuer can issue an adverse benefit determination on review based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale. The rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.

Also PHS Act section 2719 and these interim final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. The regulations provide a basis for determining when plans and issuers must comply with an applicable State external review process and when they must comply with the Federal external review process. The hour and cost burden associated with implementing an external review program also is discussed in more detail in items 12 and 13, below.

The claims procedure regulation imposes information collection requirements as part of the reasonable procedures that an employee benefit plan must establish regarding the handling of a benefit claim. These requirements include third-party notice and disclosure requirements that the plan must satisfy by providing information to participants and beneficiaries of the plan.

In addition to these standards, paragraph (b)(3)(i)(H) of the interim final regulations requires health insurance issuers offering individual health insurance coverage to maintain records of all claims and notices associated with their internal claims and appeals processes. The records must be maintained for at least six years, which is the same requirement for group health plans under the ERISA recordkeeping requirements. An issuer must make such records available for examination upon request. Accordingly, a claimant or State or Federal agency official generally would be able to request and receive such documents free of charge.

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.

The information collection requirements included in the claims procedure regulation ensure that participants and beneficiaries (claimants) receive adequate information regarding the plan's claims procedures and the plan's handling of specific benefit claims. Participants and beneficiaries need to understand plan procedures and plan decisions in order to appropriately request benefits and/or appeal benefit denials.

The recordkeeping requirement will allow a participant, beneficiary, or Federal or state official to inspect important information regarding an issuers' internal claims and appeals processes and request and receive documents free of charge.

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 for using information technology to reduce burden.

The claims regulation does not restrict plans' use of electronic technology to process and pay claims, to maintain information as to the basis for claim determination, and to generate correspondence related to claims processing decisions. This burden estimate incorporates the Department's assumptions, described in the response to item 12, below, concerning the rate of use by plans of electronic means of communication.

The Government Paperwork Elimination Act (GPEA) requires agencies to allow customers the option to submit information or transact with the government electronically, when practicable. Where feasible, and subject to resource availability and resolution of legal issues, EBSA has implemented the electronic acceptance of information submitted by customers to the federal government.

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 2 above.

No duplication with other Federal statutes exists. In some circumstances, states may require substantially similar information to be provided to insured persons. However, no duplication occurs because the same information disclosure may be used to satisfy duplicative or overlapping requirements.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

The regulation applies to all employee benefit plans and therefore is likely to affect small entities (small business, small plans) that provide benefits. The Department took into account the potential burden on small entities in structuring the regulation by permitting plan sponsors the maximum possible flexibility in designing their plans, including the possibility of hiring third-party service providers to carry out these administration responsibilities in order to make use of the lowest cost method of compliance available. A large majority of small plans purchase claims administration services from insurers, HMOs, and other service providers, and the Department has taken this fact into account in deriving its burden estimates. These service providers typically develop a single claims processing system to service a large number of customers, including small entities. Thus, the cost of revising and implementing the procedures is spread thinly over a large number of small plans. Moreover, small plans and their respective enrollees benefit equally from the service provider's expertise and ability to provide improved accuracy and timeliness in claims and appeals determinations.

The Departments assume that most of the documents required to be retained to satisfy the recordkeeping requirement already are retained by issuers in the normal course of their business operations.

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.

The information collection requirements arise in connection with the occurrence of individual claims for benefits and consist of third-party notices and disclosures. No information is reported to the Federal government. Every claim event is normally of importance to the specific participant who relies on an employee benefit plan to provide the promised benefit. The information collection provisions of the regulation ensure that sufficient information is provided to: a) participants and beneficiaries so that they may fully exercise their rights under their employee benefit plans, and b) to fiduciaries responsible for operating plans in accordance with their terms.

Without the recordkeeping requirement, it would be more difficult for participants, beneficiaries, or a Federal or state official to inspect and receive critical information regarding a issuer's internal claims and appeals processes.

- 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, grantin-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 a 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 confidentiality to the extent permitted by law.

The DOL claims procedure regulation imposes special timing requirements for the handling of claims under group health plans. Depending on circumstances indicating the urgency of the need for a claims decision, group health plans may be required to notify claimants about health benefit claim determinations in fewer than 30 days.

First, for claims involving "urgent care," the regulation requires, in general, that claimants be notified of health benefit determinations "as soon as possible, but not later than 72 hours after receipt of the claim by the plan. . . ." 29 CFR 2560.503-1(f)(2)(ii).² In cases involving urgent care where the health claim is a request to extend the time period or number of treatments of ongoing medical care, this period is 24 hours. 29 CFR 2560.503-1(f)(2)(ii)(B).

Second, for "pre-service" claims, the regulation requires that claimants be notified of health benefit determinations "within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt of the claim by the plan." 29 CFR 2560.503-1(f)(2)(iii)(A). Pre-service claims involve plan requirements that a claimant obtain approval from the plan prior to receiving health care services or products in order to maintain eligibility for benefits.

Third, for "post-service" health benefit claims, the regulation requires notification of an adverse benefit determination "within a reasonable period of time, but not later than 30 days after receipt of the claim." Even though 30 days is the maximum response time for these claims, a plan must provide a determination sooner if it is reasonable to do so. Disability benefit claims are subject to a similar construct, except that the maximum response time is 45 days.

Appeals of denied claims must be decided within similar, short time limits.

These timing requirements are reasonably related to important policy objectives in an area of important public concern. For example, the shortest time frame for "urgent care" claims applies only under circumstances in which delay could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or where delay would subject the claimant to severe pain. The next shortest time frame applies under circumstances in which medical care, while not urgent, has not been provided to a claimant who needs treatment for a medical problem and where the plan itself requires pre-approval of the medical care before providing coverage. Post-service health claims and disability claims also involve important concerns relating to the sick and disabled, but under these circumstances plans may take at least 30 days to respond if it is reasonably necessary to do so.

Another reason why these time frames are important is that these notices relate to the payment of money by a plan to claimants to whom fiduciary responsibilities are owed. Without enforcement of reasonable deadlines, payors could be given a financial incentive to delay the payments, and this would likely be inconsistent with appropriate fiduciary standards.

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

² For non-grandfather health plans and issuers offering group insurance coverage the interim final regulations shorten the time period from 72 to 24 hours, but no additional hour or cost burden was added to the ICR for this change, because the Department was unable to quantify the impact.

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 interim final regulation provides the public with a 60-day period to submit written comments on the rule and the ICR.

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

Not applicable.

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

This information collection request (ICR) involves disclosures of information by plan administrators to plan participants. Issues of confidentiality between third parties do not fall within the scope of this information collection request.

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.

None.

- 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. Generally, 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 and aggregate the hour burdens in Item 13 of OMB Form 83-I.
- 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.

The Department estimates that this information collection affects 28,000 respondents in its first year. The number of respondents will increase over time as more plans lose grandfathered status and must comply with the regulations. The frequency of response will be on occasion, mirroring the frequency of benefit claims that require responses, totaling about 70 million per year. The hour burden, which will also increase over time as additional plans lose grandfathered status, is estimated to be 566,000 hours the first year.

Under PHS Act section 2719 and the interim final regulations, all sponsors of nongrandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must comply with all requirements of the Department of Labor's DOL claims procedures regulation as well as the new standards that are established by the Secretary of Labor and the Secretary of Health and Human Services in paragraphs (b)(2) and (b)(3) of the interim final regulations. These estimates include only ongoing costs of compliance with the statute and the interim final regulations.

Ongoing burdens are a function of claims volume, as well as the denial and appeal rates of plans.

TABLE. 1Estimated Claims and Appeals in Non-granalathered Coverage (in thousands)								
	201	1	201	2	2013			
	Governmen	Individua	Governmen	Individua	Governmen	Individual		
	t Sector ESI	l Market	t Sector ESI	l Market	t Sector ESI	Market		
Total Enrollees	39,000	15,084	39,000	15,084	39,000	15,084		
Non-Grandfathered	6,898	6,034	12,576	9,654	17,250	11,826		
Enrollees	0,050	0,054	12,570	5,054	17,200	11,020		
Total Claims	70,360	61,543	128,275	98,469	175,947	120,625		
Pre-Service								
Claim Approved	1,794	1,569	3,271	2,511	4,487	3,076		
Claim Denied	317	277	577	443	792	543		
Post-Service								
Claims Approved	55,473.0	45,190.5	101,134.3	72,304.8	138,719.3	88,573.4		
Claim Denied	10,237	8,955	18,664	14,327	25,600	17,551		
Claim Extended	2,539	5,552	4,629	8,883	6,349	10,882		
Total Internal Appeals	24.1	52.8	44.0	84.5	60.4	103.5		
Appeals Upheld	9.7	21.1	17.6	33.8	24.1	41.4		
Appeals Denied	14.5	31.7	26.4	50.7	36.2	62.1		
Medical subtotal	7.0	15.3	12.7	24.4	17.4	29.9		

TABLE. 1--Estimated Claims and Appeals in Non-grandfathered Coverage (in thousands)

Appeals Upheld Appeals Denied Administrative	2.8 4.2	6.1 9.2	5.1 7.6	9.8 14.6	7.0 10.5	12.0 17.9
subtotal Appeals Upheld Appeals Denied	17.2 6.9 10.3	37.5 15.0 22.5	31.3 12.5 18.8	60.1 24.0 36.0	42.9 17.2 25.8	73.6 29.4 44.1
Total New External Appeals	0.6	0.2	1.1	0.3	1.5	0.4

The transaction burden will vary widely with the type and complexity of claim in question, but the mix of claims and associated burdens generally are expected to be similar across plans of the same type. The average time required for the information collection associated with any particular type of health benefit claim transaction will range from one minute for certain routine automatic notices to four and a half hours for certain disclosures on request following adverse claim determinations.

The Department estimates that approximately 93 percent of large group health and all small group health plans administer claims using a third-party provider. Approximately 5 percent of individuals covered by group health insurance as well as all people covered in the individual market insurance claims are administered in-house. In-house administration burdens are accounted for as hours, while purchased services are accounted for as dollar costs. The hourly burden as well as mailing costs for plans processing claims in-house is described below:

	2011		2	2012	2	2013		
	Hour s	Mailing Cost	Hours	Mailing Cost	Hours	Mailing Cost		
Pre-Service								
Claim Approved	27.6	\$160.7	44.4	\$259.0	54.8	\$319.5		
Claim Denied	9.7	\$28.4	15.7	\$45.7	19.3	\$56.4		
Post-Service								
Claim Denied	314.5	\$917.1	506.8	\$1,477.9	625.1	\$1,822.9		
Claim Extended	94.5	\$551.2	151.7	\$884.6	186.3	\$1,086.7		
Denial Appeal								
Total	116.7	\$29.1	264.7	\$46.7	325.2	\$57.4		
Appeal Approved	28.6	\$11.6	60.8	\$18.7	74.7	\$23.0		
Appeal Denied	88.1	\$17.5	203.9	\$28.0	250.5	\$34.4		
Medical	70.1	\$8.4	190.1	\$13.5	233.5	\$16.6		
Claim Approved	28.1	\$3.4	60.0	\$5.4	73.7	\$6.6		
Claim Denied	42.1	\$5.0	130.1	\$8.1	159.8	\$10.0		
Administrative	46.5	\$20.7	74.7	\$33.2	91.7	\$40.8		
Claim Approved	0.5	\$8.3	0.8	\$13.3	1.0	\$16.3		

TABLE 2.--In-House Burden Hours (in
thousands)

Claim Denied Fair and Full Review	46.0 3.1	\$12.4 \$16.1	73.8 5.0	\$19.9 \$25.9	90.7 0.2	\$24.5 \$0.8
Notice of Decision External Review	0.1	0.1	0.1	0.2	0.1	0.2
Total	566.2	\$1,702.9	988.5	\$2,740.0	1,211.1	\$3,343.9

Note: Assumed that 7 percent of large plan process these claims in-house in the Group Market. Large plans account for 67.8 percent of policy-holders and therefore 4.7 percent of claims are processed in-house. Assumed all Individual Market claims are processed in-house.

Total burden hours are estimated at 566,000 hours in 2011, 989,000 hours in 2012 and 1.2 million hours in 2013. Equivalent costs are estimated at \$28.1 million in 2011, \$57.1 million in 2012 and \$70.1 million in 2013.

The Department estimates that the recordkeeping requirements associated with this information collection affects 490 insurance companies each with 15 insurance products or 7,350 respondents each year.

The Department assumes that most of the documents required to be retained in the order course of the insurers' business. Therefore, the Department estimates that the recordkeeping burden imposed by this ICR will require five minutes of a legal professional's time (with a rate of \$119.03/hour) to determine the relevant plan documents that must be retained and ten minutes of clerical staff time (with a labor rate of \$26.14/hour) to organize and file the required documents to ensure that they are accessible to participants, beneficiaries, and Federal and State governmental agency officials.

As shown in table 3 below, overall, the Department estimates that there to be a total hour burden of 1,800 hours with an equivalent cost of \$105,000.

			Labor	Hour	Equivalen		
	Number	Hours	Cost	Burden	t Cost		
	(A)	(B)	(C)	A*B	A*B*C		
Record Keeping							
(attorney):							
individual	7,350	0.08	\$119	613	\$72,906		
Record							
Keeping(clerical)							
: Individual	7,350	0.17	\$26	1,225	\$32,022		
			Total	1,838	\$104,927		

TABLE 3.--Total Hour Burden and Equivalent Cost

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 or 14).

As indicated in question 12, the bulk of Group Market claims will be processed by thirdparty service providers. Total costs is estimated by multiplying the number of responses by the amount of time required to prepare the documents and then multiplying this by the appropriate hourly cost of either clerical workers (\$26.14), doctors (\$154.07) or lawyers (119.03),³ and then adding the cost of copying and mailing responses (0.54 each for those not sent electronically). These costs are described below:

Table 5Out-House Bu		2011			2012			2013		
	Hours Cost	Mailing Cost	Total Costs	Hours Cost	Mailing Cost	Total Costs	Hours Cost	Mailing Cost	Total Costs	
Pre-Service										
Claim Approved	\$744.9	\$166.2	\$911.1	\$1,358.1	\$303.0	\$1,661.1	\$1,862.8	\$415.6	\$2,278.4	
Claim Denied	\$262.9	\$29.3	\$292.2	\$479.3	\$53.5	\$532.8	\$657.5	\$73.3	\$730.8	
Post-Service				1		I	1			
Claim Denied	\$8,500.9	\$948.3	\$9,449.2	\$15,498.3	\$1,728.9	\$17,227.1	\$21,258.0	\$2,371.4	\$23,629.4	
Claim Extended	\$1,054.1	\$235.2	\$1,289.3	\$1,921.8	\$428.8	\$2,350.5	\$2,636.0	\$588.1	\$3,224.1	
Denial Appeal				1		I				
Total	\$6,972.8	\$12.4	\$6,985.2	\$12,712.2	\$22.7	\$12,734.9	\$17,436.6	\$31.1	\$17,467.6	
Appeal			!	1		I	1			
Approved	\$1,870.0	\$5.0	\$1,875.0	\$3,409.3	\$9.1	\$3,418.4	\$4,676.3	\$12.4	\$4,688.7	
Appeal Denied	\$5,102.7	\$7.5	\$5,110.2	\$9,302.9	\$13.6	\$9,316.5	\$12,760.3	\$18.6	\$12,778.9	
Medical	\$4,610.2		\$4,610.2	\$8,404.9		\$8,404.9	\$11,528.4		\$11,528.4	
Claim Approved	\$1,844.1		\$1,844.1	\$3,362.0		\$3,362.0	\$4,611.4		\$4,611.4	
Claim Denied	\$2,766.1		\$2,766.1	\$5,042.9		\$5,042.9	\$6,917.1		\$6,917.1	
Administrative	\$2,362.6		\$2,362.6	\$4,307.3		\$4,307.3	\$5,908.1		\$5,908.1	
Claim Approved	\$26.0		\$26.0	\$47.3		\$47.3	\$64.9		\$64.9	
Claim Denied	\$2,336.7		\$2,336.7	\$4,260.0		\$4,260.0	\$5,843.2		\$5,843.2	
Fair and Full Review	\$36.0	\$6.9	\$42.9	\$65.7	\$12.6	\$78.3	\$318.8	\$60.9	\$379.7	
Notice of Decision				1		I	1			
External Review	\$25.6	\$0.3	\$25.9	\$46.7	\$0.5	\$47.3	\$64.1	\$0.8	\$64.8	
Total Costs	\$17,597.3	\$1,398.6	\$18,995.9	\$32,082.1	\$2,549.9	\$34,632.0	\$44,233.6	\$3,541.2	\$47,774.9	

Table 3.--Out-House Burden Cost (in thousands)

The total estimated cost burden for those plans that use service providers, including the cost of mailing all responses (including mailing costs for those prepared in-house listed in Table 2), is \$20.7 million in 2011, \$37.4 million in 2012, and \$51.1 million in 2013.

³ EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

For the recordkeeping requirements there is no associated annual cost burden to respondents or recordkeepers resulting from the collection of information, because this burden is borne solely by the insurers offering coverage in the individual health insurance market, and these insurers are assumed to process all claims in-house.

14. Provide estimates of 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), 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.

There are no costs to the Federal government associated with this information collection.

15. *Explain the reasons for any program changes or adjustments reporting in Items 13 or 14 of the OMB 83-I.*

This is a new collection of information.

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.

Not applicable.

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.

The collection of information will display a currently valid OMB control number.

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

Not applicable; no exceptions to the certification statement.