

Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

A. Background

The Medicare program is complex. As a result, every policy decision that is made has a ripple effect across the program. The implications of adding a new benefit have potential long range consequences that are not immediately recognizable. The Medicare Current Beneficiary Survey (MCBS) serves to measure what impact the changes have on the program and its beneficiaries.

The MCBS is a comprehensive data collection effort that fills an information gap in the Centers for Medicare and Medicaid Services (CMS), and is depended on to help manage the program. Being able to examine various characteristics and to chart evolving trends offers policy makers a reliable tool for making informed decisions. The MCBS is used to identify potential new policy direction or modifications to the Medicare program and once those program enhancements are implemented, monitor the impact of those changes.

First fielded in September 1991, the MCBS is an ongoing, multi-purpose survey used by the Centers for Medicare and Medicaid Services (CMS), other operating divisions of the Department of Health and Human Services (such as the Assistant Secretary for Planning and Evaluation, the National Center for Health Statistics, and the Agency for Healthcare Research and Quality), and others concerned with Medicare policy, such as Congressional Budget Office, Congressional Research Service, and the Medicare Payment Advisory Commission. The survey is a nationally-representative stratified random sample of the total Medicare population, whether aged or disabled, living in the community or facility, or served in managed care or fee-for-service.

The central goals of the MCBS are to determine medical care expenditures and sources of payment for all services, including copayments, deductibles, and non-covered services; to ascertain all types of health insurance coverage and relate coverage to actual payments; and to trace processes over time, such as changes in health status, spending down to Medicaid eligibility, and the impacts of program changes. The data are designed to support both cross-sectional and longitudinal analyses.

The core of the MCBS is a series of interviews with a stratified random sample of the Medicare population, including aged and disabled enrollees, residing in the community or in institutions. Questions are asked about enrollees' patterns of health care use, charges, insurance coverage, and payments over time. Respondents are asked about their sources of health care coverage and payment, their demographic characteristics, their health and work history, and their family living circumstances. In addition to collecting information through the core questionnaire, the MCBS collects information on special topics through supplements. For example, questions are asked about enrollees' income and assets, access to health care, health and functional status and satisfaction with care.

The MCBS respondents are interviewed three times per year using four-month recall periods. Round 1 for the survey, which is administered to new survey sample members, collects baseline information for the analysis of access to care and establishes a recall boundary for the next interview (the interview reference period is since the date of the previous interview). Subsequent rounds of the survey collect cost and utilization information (core) and administer selected supplements on income and assets and access to care. Supplemental samples of newly eligible enrollees are added in the fall round each year.

This is a request to modify the existing Medicare Current Beneficiary Survey (MCBS) clearance to return facility data collection back to three rounds per year. This request for modification proposes no changes in the core instrumentation. Clearance for the MCBS (OMB No. 0938-0568) was last granted in October 1990 for the pilot, August 1991 for Round 1, January 1992 for Rounds 2-6, September 1993 for Rounds 7-10, November 1994 for Rounds 10-19, December 1997 for Rounds 20-28, April 2001 for Rounds 29-37, March 2004 for Rounds 38-47, August 2007 Round 49 - 58, and December 12, 2010 for Rounds 59 - 67. The present clearance request is for a non-substantive change to the current clearance. All aspects of the MCBS: the community baseline and core questionnaires, the facility screener, baseline and core questionnaires, and supplementary sections such as the income and assets supplement and the access to care supplement (i.e., usual sources of care, health status and functioning, satisfaction with care and the demographic questions) will remain unchanged. We are requesting a return of data collection in the facility setting back to the original three rounds per year, from two.

B. Justification

1. Need and Legal Basis

The legislative authority for the MCBS is located in Section 723 of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003. The following is an excerpt from Section 723 (Chronically Ill Medicare Beneficiary Research, Data, Demonstration Strategy):

(a) Development of Plan.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall develop a plan to improve quality of care and reduce the cost of care for chronically ill Medicare beneficiaries.

(b) Plan Requirements.—The plan will utilize existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill Medicare beneficiaries. The plan shall—

(1) integrate existing data sets including, the Medicare Current Beneficiary Survey (MCBS), Minimum Data Set (MDS), Outcome and Assessment Information Set (OASIS), data from Quality Improvement Organizations (QIO), and claims data;

The administrative authority for the MCBS is described in the Statement of Organization, Functions, and Delegations of Authority for the Centers for Medicare and Medicaid Services. Part of CMS, the Office of Research, Development, and Information (ORDI) is responsible for the following functions, identified in the Federal Register (Thursday, December 29, 2005, pages 77161 and 77162):

1. Provides analytic support and information to the Administrator and the Executive Council needed to establish Agency goals and directions.
2. Performs environmental scanning, identifying, evaluating, and reporting emerging trends in health care delivery and financing and their interactions with Agency programs.
3. Designs and conducts research and evaluations of health care programs, studying their impacts on beneficiaries, providers, plans, States and other partners and customers, designing and assessing potential improvements, and developing new measurement tools.

2. Information Users

MCBS data users can assess the impact of major policy innovations and health care reform on Medicare beneficiaries (pre and post implementation). They can monitor delivery of services, sources of payment for Medicare covered and non-covered services, beneficiary cost sharing and financial protection, and satisfaction with and the access to health care services. Analysts can relate the dynamics of future aging patterns to age-specific rates of use of health care services. MCBS data also allow accurate measurement of total health care expenditures for enrollees and changes in private health insurance benefits (including long-term care insurance). The capacity to follow individuals into and out of nursing homes and hospitals provides analysts the opportunity to estimate the total cost of episodes of illness and level and type of system interventions including home health care.

Analysts are able to assess the aggregate cost of short stays and long stays in nursing homes, and of combined hospital/nursing home stays. In addition, the MCBS data can be used to forecast the need and settings for selected chronic disease care and the total need for long-term care services by examining trends in the use of health care services, linked with morbidity, disability and mortality data. (A detailed analysis plan is included as Attachment II. This plan discusses the analytic potential of the data and presents studies and data uses that exceed the budgetary and staffing limitations of the MCBS.)

The comprehensive nature of the MCBS makes its data appealing to a broad spectrum of users. There are three separate categories of data users.

1. Within CMS. Survey results have been and will continue to be used by the CMS' Office of Research, Development, and Information. ORDI is using the information collected to examine access to health care, including the preparation of a mandated Report to Congress. The survey detects any changes that may occur with the implementation of the Medicare Modernization Act and monitors any changes over time to access, availability and cost of medical care for Medicare enrollees. In addition to monitoring access to health care, ORDI uses both the household and the facility components of MCBS to assess the use of influenza and pneumonia vaccinations, to compare the use and cost of prescribed medication in both outpatient community and facility settings and to determine the impact of the Qualified Medicare Beneficiary program. ORDI uses the managed care supplement to the MCBS to compare fee-for-service with alternative delivery systems and assess beneficiary satisfaction and access to alternative delivery systems. Also, MCBS provides information on health promotion and preventive techniques from the core instrument. Additional information on these areas can be obtained by the development of supplements.

Analysis of the facility component also allows CMS to examine expenditures that are covered by Medicaid, the shifts between private pay and Medicaid, and the cost implications for both Medicare and Medicaid in the areas of spending down assets and spousal impoverishment.

Use of the MCBS provides the opportunity to quantify and establish baseline measures for several of the objectives in the CMS action plan, specifically, to involve the beneficiaries in defining their health care needs by aggregating and using data for continuous policy and process improvement, and to assess outreach and information to the beneficiaries on programs, services and health care choices.

The Office of External Affairs uses the MCBS to track beneficiaries' knowledge and sources of information about Medicare. The Office of Financial Management and Office of Clinical Standards and Quality use immunization data to track whether CMS is meeting GPRA objectives. The Center for Drug & Health Plan Choices uses the MCBS demographic data to support its web based beneficiary health projection resource tool.

2. Other Governmental / quasi-governmental, outside CMS. The MCBS is a major source of information for the Medicare Payment Advisory Commission (Med PAC) to monitor access to health care and beneficiary financial protection. The MCBS data have been routinely included in Med PAC's Annual Reports and data collected by the MCBS have been used both in descriptive statistics and simulation.

The MCBS is also a major source of information for the Congressional Research Service (CRS) to monitor access to health care. CMS staff has worked closely with CRS staff in collecting and processing the MCBS data to publish a CRS article on the role of supplemental health insurance (O'Sullivan, Lee, and Yang, 1996) and using the cost and use data to develop a model of spending for Medicare covered and non-covered services.

Several other agencies that have developed a partnership in using MCBS data include the Congressional Budget Office, Public Health Service, Centers for Disease Control and Prevention, National Institute of Mental Health, National Institute on Aging, and Advisory Council on Social Security. Foundations such as Kaiser, R W Johnson, and the Commonwealth Fund also use MCBS data for policy analyses.

3. Other researchers. Data are available to academic researchers through data use agreements. Topics of their research include: chronic disease, effects of Medicare drug coverage, racial and ethnic disparities in service use, use of preventive services, underuse of medications, hospital readmission, body mass and aging, assistance with activities of daily living, obesity, quality of care, medication use in nursing homes, alcohol use, home care, veterans' care, disability trends, treatments for dementia, depression, beneficiary knowledge, effects of the Part D coverage gap, informal assistance, use of durable medical equipment, falls, depression, and self-management for chronic disease. These are just a few examples of actual uses of MCBS data for policy research.

3. Use of Information Technology

The MCBS takes full advantage of advances in survey techniques by conducting a survey that is administered completely electronically. Respondents living in the community are administered a personal, face to face interview using computer-assisted personal interviewing (CAPI). Though respondents residing in long-term care facilities are not administered a personal, face-to-face interview, the CAPI instrument is used in interviewing the designated facility staff proxy. CAPI, which functions with programmed edit checks, reduces respondent burden by minimizing the potential for double reporting and inconsistent responses. CAPI enables the interviewer to move through complex skip patterns quickly, which reduces respondent burden by shortening the interview and eliminating the need for call backs to correct errors. CAPI greatly increases the efficiency of the questionnaire during the interview in the following ways:

1. CAPI tailors the sequence of questions to the responses of the interviewee, resulting in few – if any – interviewer skip errors. The natural flow of the interview is maintained even when the pattern of questions is complex.
2. CAPI automatically provides “fills”, or word choices within questions. One keystroke can insert “you”, “he”, or “she”, as appropriate, for the duration of the interview. The sample person’s name, date of the last interview, and other items can also be filled as needed.
3. CAPI maintains rosters or lists created during the interview, such as household members, health insurance plans, medical conditions, providers, visit dates, prescription drugs, and people who help with daily activities. These rosters can be used to structure questions, e.g., cycling through a series of doctor visits and checking for missing information. Interviewers can select items from a roster, add items, or correct them. Rosters are carried over from one interview to the next.
4. CAPI edits entries for range and consistency. The interviewer can make corrections immediately. Information missing from a previous round can be inserted in the questionnaire.
5. CAPI allows instantaneous calculations to be made, such as the amount remaining to be paid on a medical bill after totaling several payments.
6. Interviewers use the computer to electronically transmit completed cases to the central office over the telephone.

CAPI has strategic implications for survey design and planning, some of which are not easily predicted. CAPI strongly influences the shape of the questionnaire itself: It can be more complex, more tailored to the characteristics of respondents, with more cross-references and rosters, and have more error checks. MCBS does not require a signature from the respondent(s).

4. Duplication of Efforts

During the development and initial administration of the MCBS, a number of people inside and outside the Federal government were consulted. This consultation included issues of design, content, and statistical methodology and analysis. None of the people contacted were aware of duplicative information, nor were they aware of any other survey that

duplicates the efforts of MCBS. In addition, both CMS and its data collection contractor have undertaken exhaustive reviews of the literature and other data sources. In no instance have we identified another source of data, which would be an effective substitute for the MCBS. Continuing interagency collaboration insures against the likelihood of duplicative data collection processes now and in the future.

5. Small Businesses

Most of the data collected for the MCBS will be from individuals in households. However, in any given round about 1,100 sample persons will reside in government-sponsored, non-profit, and for-profit institutions such as nursing and personal care homes. Some of these institutions qualify as small businesses. All data collected on sample persons in these institutions will be collected from small businesses, their employees serve as proxies for each sample person in their care.

Interviewers in long-term settings make every effort to determine, for each type of question, which staff members are most able to answer them. The data collection procedures are designed to minimize the burden on all respondents, with skip instructions so that respondents will be asked only questions that apply to them. Facility respondents are not asked to answer questions of which they are not likely to have ready knowledge, such as attitudes and perceptions. Finally, the MCBS questionnaire mirrors the Minimum Data Set questions where applicable, to further reduce respondent burden.

All enrollees will be selected from the Medicare Enrollment Database and sample persons residing in nursing homes will be randomly distributed. Therefore, the burden for the collection of this information will be proportional to the size of nursing homes (on average), thereby reducing the burden on small nursing homes.

6. Less Frequent Collection

Only a continuous survey can fully meet CMS' information needs for operating the Medicare program. And, address many of the limitations of existing databases for collecting information on the elderly and disabled including the oldest old portion of the population (85+). Large changes in the Medicare delivery system and program itself have been occurring with increasing frequency, e.g., The Medicare Prescription Drug, Improvement, and Modernization Act. While such extensive changes as contained in MMA are the exception rather than the rule, adjustments to the Medicare program continue to remain an ongoing part of the program administration. Only a continuous survey will produce the data that support accurate evaluation of the effects of all such changes.

By re-interviewing the same respondents and replenishing the sample annually, the MCBS will continue to support longitudinal as well as cross-sectional analyses. Longitudinal data provide the material for models that analyze quantitative change over time. Longitudinal data are needed for causal analysis, such as the relationship between legislative and program changes and their effects on enrollees, providers, and costs. Longitudinal data can also help clarify the relationship between changes in health status and functioning and levels of health

care service use and expenditures (i.e., temporal ordering for analysis).

Research on survey methodology shows that as the length of time between community interviews grows, there is a marked decline in the quality of the data reported (Cohen and Burt, 1985; Cohen and Cohen, 1986). The literature seems to support spacing interviews for a continuous survey of medical care use up to four months apart. The Current Medicare Survey employed a one month recall period, the 1977 NMCES an average of three months, and the 1987 NMES an average of four months. In the first round of interviewing, the sample person in the community is provided with a calendar and asked to record all visits to health care providers, expenditures and to retain all statements including private insurance and Medicare statements/bills. Thus after the initial round, the recall period for the MCBS is since the time of the last interview. Making MCBS community rounds any farther apart would significantly jeopardize the quality of the results, because of the strong potential for recall problems with the elderly. In addition, less frequent data collection may negate the opportunity to obtain additional information by using supplements; more time spent on repetition of the core items might not allow time for the inclusion of proposed supplements questions to assess legislative and program changes.

7. Special Circumstances

None of the special circumstances listed by OMB apply to the MCBS.

8. Federal Register/Outside Consultation

A 60-day Federal Register Notice was published on May 28, 2010. A copy of the notice is included as (Attachment 1), and can be found on Page 30030 of the FR Notice. Since this collection is not new, we have not gone out to solicit outside consultation; however, during the 60-day Federal Register Notice the public is free to comment. No public comments were received.

9. Payments/Gifts to Respondents

The MCBS does not provide payments or gifts as incentives to respond. The most important incentive we use is to persuade the respondent that his or her participation is a service to the future of Medicare. We use standard refusal conversion techniques, letters, and newsletters.

10. Confidentiality

The cover letter to the respondent and a handout presented at the beginning of the interview contain the following disclosure statement:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0568. The time required to complete this information collection is estimated to average 1.5 hour per response, including the time to review

instructions, search existing data resources, gather the data needed, and complete and review the information collection. Additionally, a randomly selected 10 percent of the respondent population (per round) are contacted for a validation interview averaging 10 minutes. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

(Attachment 3) is a copy of the advance letter and MCBS brochure and introduction to the MCBS sheet for the household.

This is a person-based survey. The cover letter to the respondent contains a reference to the Privacy Act of 1974, as amended. A handout sheet (provided to the household respondent at the door and the nursing home administrator and proxy respondents) contains a statement of confidentiality consistent with the Privacy Act of 1974 and the Paperwork Reduction Act of 1995. In fielding selected supplements, e.g., Income and Assets, an additional hand-out sheet is provided explaining the purpose of the supplement and restating the Privacy Act. Interviewer training stresses the importance of maintaining confidentiality. The household interviewer's manual specifically addresses this and it is part of the training for the interviewers (both household and nursing home). Procedures have been established to maintain and insure confidentiality. These include computer security procedures (password protection for each interview and interviewer), electronic mail submission and next of kin consent forms for following nursing home people (discharged residents).

In addition, the administration of the facility component is preceded by a statement that CMS will collect only the information necessary to perform the system's functions. Any data published will exclude information, which might lead to the identification of specific individuals (e.g., ID number, claim numbers, and location codes). CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to the individual privacy or other personal or property rights of the individual.

All MCBS survey staff directly involved in MCBS data collection and/or analysis activities are required to sign confidentiality agreements. Furthermore, all MCBS patient-level data are protected from public disclosure in accordance with the Privacy Act of 1974, as amended.

11. Sensitive Questions

None of the data to be obtained by this study are considered to be sensitive.

12. Burden Estimates (Hours & Wages)

Table B-12 shows estimates of the annual respondent burden. The annual burden for the MCBS is based on three interviews per respondent. We currently estimate that our annual burden will be 58,450 hours for the survey. A community interview should take roughly an

hour and a half to complete and a facility interview roughly an hour.

Table B-12: Estimates of the Annual Respondent Burden

	Time per Response	Number of Interviews	Expected Number of Completed Per Round	Burden Hours
Community Rounds 61-63				
-Fall Rd Supplemental Interview	1.0 hour	1	5,250	5,250
-Fall Round Continuing Interview	1.5 hour	1	9,250	13,875
-Winter Round Interview	1.5 hour ¹	1	13,900	18,900
-Summer Round Exit Interview	15 minutes	1	3,000	750
-Summer Rd Continuing Interview	1.5 hour	1	10,600	15,900
Validation per 10% of Population	10 minutes	3	1,550	775
Facility Rounds 61-63	1.0 hour	3	1,000	3,000

Total Annual				58,450
Total Estimate for Rounds 59-67 (3 Years)				175,350

Note: 1. During the Winter Round interview the Round 62 supplemental panel and the Round 63 exiting panel time per response is 1.5. This is a result of a utilization start and end point that deviates from the standard Continuing Interview reference point. The regular reference point is "from the last interview. The Round 62 supplemental panel (4,800 completes) use January 1 as the start date in the Winter Round. The Round 63 exiting panel (3,000 completes) use December 31 as the end date in the Winter Round.

The MCBS survey methodology is designed to reduce burden on the survey respondents in the community and facility setting. In the community setting logical skip patterns and rotating supplements limit the time per response. In the facility setting, questionnaire flow designed around likely respondents in addition to reduction in data collection rounds help reduce burden.

13. Capital Costs

All costs associated with this effort are reported in Items 12 and 14.

14. Cost to Federal Government

The estimated cost to the government for collecting these data includes the Westat contract, and direct CMS expenses for labor and travel.

The estimated cost for the planning, sampling, data collection and analysis for the MCBS in each year is: (The following estimated costs per Fiscal Year are approximated amounts based on the current MCBS contract and include the cost associated with conversion from a DOS based platform to a Windows based platform.)

FY 2010: Data collection and analysis	\$15,200,000
FY 2011: Data collection and analysis	\$15,600,000
FY 2012: Data collection and analysis	\$16,000,000

These costs include all labor hours, materials and supplies, reproduction, postage, telephone charges and indirect costs.

CMS personnel involved in MCBS include approximately 9.5 FTEs broken out by pay grade in Table B-14.

Table B-14: CMS Personnel

<u>Grade</u>	<u>FTE</u>	<u>2010 Annual Salary</u>	<u>Cost to Government</u>
GS12 step 1	1.0	\$74,872	\$74,872
GS13 step 6	6.0	\$103,872	\$623,232
GS14 step 5	1.5	\$119,238	\$178,857
GS15 step 3	1.0	\$132,009	<u>\$132,009</u>
			\$1,008,970

CMS staff costs are approximately \$1,008,970. In addition, staff travel is budgeted for \$2,000. The MCBS releases its documentation on CD Rom thus eliminating its printing budget. Thus, in-house CMS cost will be \$1,010,970.

15. Changes to Burden

In 2008 the Facility component methodology was adjusted to extend the recall period for the September to December round from four months to eight months. This decision was driven by a need to address a budget reduction in research. After the best analysis at the time concluded cost savings would be meaningful and data quality wouldn't diminish, this methodological change was instituted. From 2008 through 2011 the Facility component was collected twice per year, from January through April and September through December.

In the spring of 2011 our post collection analysis began indicating that the methodological change instituted in the Facility collection frequency was having a negative impact on data quality and the cost savings were not as substantial as anticipated. Having an eight month recall period was causing detectable gaps in our resident history timeline, thus losing valuable utilization reporting. The anticipated decrease in burden was only being postponed by a data collection round as the same amount of data still needed to be collected.

We propose to return the Facility component methodology to its pre-2008 frequency. There will be three data collection rounds: January through April; May through August; and September through December. These rounds will mirror those cleared for our Community component. Burden on business will increase due to the increase in frequency of visits; however, the added interview round from May through August will be offset by the reduction in duration of the September through December round.

16. Publication/Tabulation Dates

A number of published methodological studies have been conducted (Attachment 2). In addition, data files will continue to be prepared over the course of the survey, see Table B-16.

Table B-16: Schedule for information collection and dissemination

05/01/2010	Data collection begun for MCBS Round 57.
09/01/2010	Data collection begun for MCBS Round 58.
10/01/2010	Public Use File available for 2009 Access to Care series.
12/01/2010	Public Use File available for 2008 Cost and Utilization series.
01/01/2011	Data collection begun for MCBS Round 59.
05/01/2011	Data collection begun for MCBS Round 60.
09/01/2011	Data collection begun for MCBS Round 61.
10/01/2011	Public Use File available for 2010 Access to Care series.
12/01/2011	Public Use File available for 2009 Cost and Utilization series.
01/01/2012	Data collection begun for MCBS Round 62.
05/01/2012	Data collection begun for MCBS Round 63.
09/01/2012	Data collection begun for MCBS Round 64.
10/01/2012	Public Use File available for 2011 Access to Care series.
12/01/2012	Public Use File available for 2010 Cost and Utilization series.
10/01/2013	Prepare clearance package for Rounds 67 – 75.
01/01/2013	Data collection begun for MCBS Round 65.
05/01/2013	Data collection begun for MCBS Round 66.

There are two special reports being issued on an annual basis by CMS, Health and Health Care of the Medicare Population: Data from the Medicare Current Beneficiary Survey and Characteristics and Perceptions of the Medicare Population: Data from the Medicare Current Beneficiary Survey. These reports or “chartbooks” contain a comprehensive set of statistical tables describing the Medicare population in terms of its demographic and socioeconomic

characteristics, use of and expenditures on health care, perceived health and functional status, and access to and satisfaction with health care. The tables, which were created from Access to Care and Cost and Use files released to the public, are intended as references for persons interested in using MCBS data to analyze the health and health care of the Medicare population.

CMS has disseminated these chartbooks to federal and state governmental agencies, for profit companies, nonprofit organizations, and academic institutions. The data in these tables are being updated as new files become available, and are released to the public in the two series of chartbooks. In addition to providing statistics from the annual MCBS releases, the chartbooks can be used to follow trends and measure change in the Medicare population. Subsequent chart books have illustrated the types of longitudinal analysis that can be performed with MCBS data.

Annual updates to the two chartbooks are available for the following years. (For years were the chartbooks are still unavailable an asterisk is used as a denotation and an estimated date of completion follows.)

Health and Health Care of the Medicare Population: Data from the MCBS
1992 – 2006, 2007* (December 2010), 2008* (December 2011), and 2009* (December 2012)

Characteristics and Perceptions of the Medicare Population: Data from the MCBS
1995 – 2007, 2008* (August 2010), 2009* (August 2011), and 2010* (August 2012)

17. Expiration Date

CMS would like an exemption from displaying the expiration date as the collection of the MCBS is an ongoing endeavor. Therefore, an expiration date is not practical.

18. Certification Statement

There are no exceptions to this certification statement.