

Supporting Statement Part A
Medicare Coverage of Items and Services for Coverage with Evidence
Development (CMS-10697; OMB 0938-1387)

I.

This is a reinstatement package. In general, in order for an item or service to be covered under Medicare, it must meet the standard described in section 1862(a)(1)(A) of the Act – that is, it must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The statute, however, also contains express exceptions that authorize payment for other items and services that may not meet the reasonable and necessary standard. Some examples are coverage for hospice care, certain vaccines to prevent illness, and specific preventive or cancer screening services. Under existing regulations at 42 CFR § 411.15(o), Medicare does not cover experimental or investigational devices, except for certain Category B devices.

When the available evidence is insufficient to demonstrate that the items and services are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member under section 1862(a)(1)(A) of the Act, CED has been used to support evidence development for certain items and services that are likely to show benefit for the Medicare population. CED relies primarily on the statutory exception in section 1862(a)(1)(E) of the Act, which effectively permits Medicare payment for items and services that are reasonable and necessary to carry out research conducted pursuant to section 1142 of the Act. Items and services that are not reasonable and necessary to carry out that research are excluded. As noted above, participation in a CED trial is voluntary, and beneficiaries are protected by separate regulations including those at 45 CFR Part 46 related to the protection of human research subjects.

CED has been a pathway whereby, after a CMS and AHRQ review, Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. CMS and AHRQ established CED based on section 1862(a)(1)(E) of the Act in 2006 and have used the NCD process to provide public notice and to obtain the public’s input. The term “national coverage determination” is defined in section 1862(l)(6)(A) of the Act as a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Act. In general, NCDs are national policy statements published to identify the circumstances under which particular items and services will be considered covered by Medicare. NCDs serve as generally applicable rules to ensure that similar claims for items or services are covered in the same manner. Oftentimes, an NCD is written in terms of defined clinical characteristics that identify a population that may or may not receive Medicare coverage for a particular item or service.

Since CMS started covering items and services in the context of CED clinical studies almost two decades ago, the timing of evidence development and the stages of the technology development lifecycle have evolved. Over the past few years, innovative technologies have come on the market earlier in the technology development lifecycle and reached the market

with a limited or developing evidence base for coverage purposes. CMS has received inquiries for coverage of new technologies that are early in the product lifecycle, which means the clinical evidence is just starting to accumulate. New technologies often lack sufficient clinical evidence to support broad national coverage under section 1862(a)(1)(A) of the Act.

In general, CMS relies heavily on health outcomes data before proposing an NCD. Early in the product lifecycle there is usually evidence about whether the product is safe and may produce the intended result (for example, a laboratory measurement, radiographic image, physical sign or other measure). For drug trials, the FDA requires that surrogate endpoints be reasonably likely to predict clinical benefit for accelerated approval but requires validated surrogate endpoints for full approval. Surrogate outcomes are not direct measures of clinical benefit, and there is often little evidence at this point regarding health outcomes (for example, mortality, disease progression, quality of life). When premarket, pivotal clinical study data are collected to support an application to FDA for marketing authorization, they provide clinical evidence for a defined population enrolled in the study.

These pivotal clinical study data, however, may not be generalizable to the Medicare population if Medicare beneficiaries are insufficiently represented. Medicare beneficiaries have been historically underrepresented in pivotal studies due to age, access, disability status, multiple comorbidities, and concurrent treatments. When there is little or limited evidence, CMS may not have enough information to make a favorable NCD due to gaps in research about health outcomes. Thus, coverage under CED can expedite earlier beneficiary access to new items and services while ensuring that systematic patient safeguards, including assurance that items and services are provided to clinically appropriate patients, are in place to reduce the risks inherent to new technologies or to new applications of older technologies. In addition, the CED framework can support manufacturers that are interested in working with CMS to generate additional evidence that is appropriate for Medicare beneficiaries and that may demonstrate improved health outcomes in the Medicare population to support more expeditious national Medicare coverage.

CMS has issued a total of 27 NCDs requiring CED over the last two decades to provide Medicare beneficiary access to promising items and services that could not otherwise be covered under section 1862(a)(1)(A) of the Act. CED requirements may be satisfied by several different study types, including randomized controlled trials, pragmatic clinical trials, single-arm registry-based studies, and studies making secondary use of real-world data (RWD). To date, CMS has approved over 128 CED studies and five national registries to facilitate evidence development for these CED NCDs. Forty-two of these studies have generated evidence across 14 topics covered under CED. Three CED NCD topics have had the CED requirement removed following an NCD reconsideration and have received national coverage. Over the last several years, CMS actively collaborated with AHRQ to update the general criteria for CED studies, originally described in the 2014 CED guidance document, to ensure the criteria are up to date and continue to maintain rigorous evidentiary standards. In November 2022, in order to better inform the CED process, AHRQ released a final report on “The Analysis of Requirements for Coverage with

Evidence Development (CED).”¹ The AHRQ report was first released in draft form in September 2022 and the public had an opportunity to provide comment on the draft report.

The AHRQ report served as the basis for discussion at the February 13-14, 2023, Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting. CMS convened the MEDCAC to examine the general requirements for clinical studies submitted for CMS coverage under CED. The MEDCAC panel consisted of a variety of experts on the topic and included an industry representative and patient advocate. MEDCAC guest panel members included representatives from FDA, AHRQ and NIH.

The February 2023 MEDCAC evaluated the CED criteria to assure that studies informing CED are assessed using consistent, feasible, transparent and methodologically rigorous criteria. The MEDCAC advised CMS on whether the criteria are appropriate to ensure that studies approved to inform CED decisions will produce informative evidence that CMS can rely on when making future reasonable and necessary determinations.²

In June 2023, CMS published a proposed CED guidance document³ for public comment with updated CED criteria based on the November 2022 AHRQ Report, and February 2023 MEDCAC. The public had 60 days to provide comments on the draft guidance document.

On August 7, 2024, CMS released an updated CED guidance document⁴ to address the factors CMS considers in making NCDs, the principles governing the application of CED, and the clinical study standards for CED. The final CED guidance document allows for a range of fit-for-purpose study designs to satisfy CED requirements. Provided that the study design, analysis plan, and data sources are appropriate to the research question, manufacturers may submit CED studies for CMS review that incorporate RWD. As noted above, RWD study submissions are a subset of CED study protocol submissions. For example, there are eight RWD protocols that CMS has provisionally approved to date pending NCD finalization. Over the next three years, CMS anticipates receiving three to seven RWD CED study protocols per year.

CMS is requesting OMB approval for this collection of information.

II.

This Paperwork Reduction Act (PRA) package is for Coverage with Evidence Development (CED). As noted above, CMS has utilized the CED pathway since 2006 under 1862(a)(1)(E) of the Act. Early on, there were only 2 CED National Coverage Determinations (NCDs) that required data collection in registries, all of which had publicly available data collection forms. Currently, there are over 120 approved CED studies involving complex data collections, most of which are proprietary to the study sponsor.

¹ <https://effectivehealthcare.ahrq.gov/products/coverage-evidence-development/research-report>

² Additional information on the MEDCAC can be found at <https://www.cms.gov/medicare-coverage-database/view/medcac-meeting.aspx?medcacid=79&year=all&sortBy=meetingdate&bc=15>.

³ <https://www.cms.gov/files/document/proposed-ced-guidance-6-22-2023.pdf>

⁴ <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38>

There is no specific submission form required for a CED clinical study submission. We note that CMS may publish guidance, including templates, to provide information to manufacturers or other study sponsors to assist them in creating study protocols to satisfy CED requirements (for example, guidance on developing RWD study protocols). Any approved CED study submission should satisfy each of the criteria “1 –17” provided in the CMS Coverage with Evidence Development guidance document.

Criteria (1) – (17) in the Coverage with Evidence Development guidance document state:

1. **Sponsor/Investigator:**

The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.

2. **Milestones:**

A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to ensure timely completion of the CED process.

3. **Study Protocol:**

The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.

4. **Study Context:**

The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.

5. **Study Design:**

The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.

6. **Study Population:**

The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in

premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors. At a minimum, this includes attention to the intended population's racial and ethnic backgrounds, gender, age, disabilities, important comorbidities, and, dependent on data availability, relevant health related social needs. For instance, more than half of Medicare beneficiaries are women so study designs should, as appropriate, consider the prevalence in women of the condition being studied as well as in the clinical trial and subsequent data reporting and analyses.

7. Subgroup Analyses:

The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically-relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.

8. Care Setting:

When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.

9. Health Outcomes:

The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and the health outcomes it is thought to predict.

10. Objective Success Criteria:

In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.

11. Data Quality:

The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.

12. Construct Validity:

Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control),

health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.

13. Sensitivity Analyses:

Sponsors/investigators will demonstrate robustness of results by conducting pre-specified sensitivity testing using alternative variable or model specifications as appropriate.

14. Reporting:

Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with incomplete results).

15. Sharing:

The sponsors/investigators commit to making study data publicly available by sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.

16. Governance:

The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.

17. Legal:

The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely-debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).

III.

A. Justification

1. Need and Legal Basis

Sections 1862(a)(1)(A) and 1862(a)(1)(E) of the Act (42 U.S.C. 1395y) state:

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1861(ddd)(1)), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section.

Recent NCDs have relied on section 1862(a)(1)(E) and 1142 of the Act in order to support clinical research that addresses evidence gaps. In these instances, the item or service was promising but the evidence was insufficient to conclude that the item or service is reasonable and necessary under section 1862(a)(1)(A) of the Act. Clinical registries offer an important means of robust data collection for certain items and services following FDA market authorization. Submission of data to clinical registries has since been required for transcatheter aortic valve replacement (TAVR; NCD Manual §20.32), left atrial appendage closure (LAAC; NCD Manual §20.34), and others. Nonetheless, CMS recognizes that CMS-approved registries may not be necessary to address all evidentiary deficiencies; in 2015 and 2017 we finalized CED NCDs that allowed clinical studies that rely on analysis of administrative claims (Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis, NCD Manual §150.13; Leadless Pacemakers, NCD Manual §20.8.4).

Section 1142 of the Act

Section 1142 of the Act describes the authority of AHRQ to conduct and support research on outcomes, effectiveness, and appropriateness of services and procedures to identify the most effective and appropriate means to prevent, diagnose, treat, and manage disorders and other health conditions. That section includes a requirement that the Secretary assure that AHRQ research priorities under Section 1142 appropriately reflect the needs and priorities of the Medicare program.

The coordination of AHRQ priorities under section 1142 with the needs and priorities of the Medicare program is accomplished through direct collaboration between AHRQ and CMS. Consistent with section 1142, AHRQ supports clinical research studies that meet specific scientific standards, reviews all CED NCDs, endorses those trials that CMS determines address the CED questions for CED studies, and recommends changes to the CED guidance document when necessary.

2. Information Users

CMS uses the 17 criteria listed in the 2024 CED guidance document to ensure that the submitted CED study has a high degree of likelihood to generate the data and evidence needed to support Medicare coverage. It is important that the submitted CED study is of high quality because the data and evidence generated from CED study can be used for the following:

- Results from studies may inform medical decision-making and improve patient care.
- Data and results published in the medical literature may be used by CMS to inform an NCD reconsideration.
- Data from registries can be used by researchers to advance the field specific to the NCD.

For example, criterion 12 states “Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.”

Satisfaction of this criterion minimizes the risk of confounding factors influencing study results, and thus contributes to informed decision-making and improved patient care. Moreover, results from methodologically appropriate studies optimizes the probability that CED studies are published in the medical literature and may be used by CMS to inform NCD reconsiderations.

Criterion 7 states “The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.”

Satisfaction of this criterion ensures that results from a CED study informs CMS what subpopulation will be benefit from this item or service and if the results can be generalized

to the Medicare beneficiary population. This will assist CMS in ensuring that clinical and health care practices are, for the Medicare beneficiary population, fair and equitable, thus improving the health of the Medicare beneficiary population as a whole.

3. Use of Information Technology

Electronic submissions (i.e., e-mail with attachments) are preferable. CMS also accepts hard copies.

4. Duplication of Efforts

CMS CED studies are not regulated by any other Federal agency. Therefore, there is no duplication of effort and similar information is unavailable.

CMS uses different evaluation criteria than FDA. Generally, FDA makes marketing authorization decisions based on whether the relevant statutory standard for safety and effectiveness is met, while CMS generally makes NCDs based on whether an item or service is reasonable and necessary for the diagnosis or treatment of an illness or injury for individuals in the Medicare population. CMS collaborates with FDA and shares information.

5. Small Businesses

CED NCD requirements apply to all firms, institutions or individuals involved in conducting clinical studies for items and services to support Medicare coverage, regardless of the size of the organization. Some manufacturers and study sponsors may be small businesses.

6. Less Frequent Collection

In general, submitters send only one study protocol. When needed, the Coverage and Analysis Group (CAG) works interactively and iteratively with CED study sponsors to revise the protocol so that it satisfies all requirements for approval. Occasionally, there are approved information collections through registries for specific CED NCDs (e.g., TAVR and TMVR). In such cases, CMS may formally contract with the owner of the registry to purchase registry data. When the CED clinical study is complete, CMS may use claims data, the clinicaltrials.gov study report, and/or peer-reviewed publications to evaluate whether the evidence provided by the clinical study is sufficient to support Medicare coverage.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register Notice was published xx/xx/2025.

The 30-day Federal Register Notice was published xx/xx/2025.

9. Payments/Gifts to Respondents

Although Medicare coverage of items and services identified in a CED study is dependent upon approval of the submission, no payments or gifts will be given to respondents to encourage their participation.

10. Confidentiality

The documents submitted to CMS may contain proprietary and trade secret information. CMS will retain the protections in §405.215, Confidential Commercial and Trade Secret Information. We note that section 502(c) of the Act broadly prohibits the disclosure of trade secret and confidential commercial or financial information -- information exempt from public disclosure by the Freedom of Information Act (FOIA) 5 U.S.C. 552(b)(4) outside the Department. This prohibition is found in the devices and regulatory inspections provisions of the Social Security Act and is not limited to device-related information. This disclosure prohibition also applies to information reported or otherwise obtained by the Department during inspection activities and other activities. This prohibition is interpreted to allow information sharing within the U.S. Department of Health and Human Services only.

11. Sensitive Questions

The information to be submitted to CMS does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Burden Estimates (Hours & Wages)

CMS approved 34 CED studies between 2019-2024. Non-approved CED studies constitute approximately 10% of studies submitted to CMS. We also review study protocol changes for previously approved CED studies (approximately seven updated protocols per year). Therefore, we estimate the total number of study protocol submissions (approved and not approved) is 80 for 2019-2024.

CMS estimates the hour burden associated with this collection of information to be the following:

Number of submissions: Since January 1, 2019, CMS has received approximately 80 CED studies, averaging about 13 studies per year.

Annual hour burden: We estimate that for 13 submissions per year, the total time to be expended by all potential study sponsors is estimated to be 1,300 hours (100 hours per

submission). Five full-time equivalents (FTEs) average 20 hours to write and submit a protocol for each study. Resources required for writing a protocol for purposes of submitting it to CMS for Medicare coverage includes technical, scientific, and financial experts. The 5 FTEs may include, medical doctors, statisticians, a data manager, a project manager, and an executive administrative assistant.

To derive average costs: We used data from the U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm) for all salary estimates (See Table 1). The burden associated with this activity is the time and effort it would take a study sponsor requesting Medicare coverage of a CED study to prepare their submission.

Table 1 Using May 2023 National Occupational Employment and Wage Estimates in US to Estimate the Cost

Occupation title (Occupation code)	2023 Mean wage (per hour)	Hourly wage includes 100% in fringe benefits	Hours	Estimate cost
Physicians (29-1210)	\$126.85	\$253.70	30	\$7611.00
Statisticians (15-2041)	\$52.50	\$105.00	30	\$3150.00
Database Administrators (15-1240)	\$54.67	\$109.34	20	\$2186.80
General and Operations Managers (11-1021)	\$62.18	\$124.36	10	\$1243.60
Executive administrative assistant (43-6011)	\$35.42	\$70.84	10	\$708.40
Total Cost				\$14899.80

In estimating costs to the public (sponsor), we used the Bureau of Labor Statistics May 2023 estimate of \$126.85 + 100% in fringe benefits for estimated hourly wage of \$253.70 for Physicians (occupation code 29-1210), \$52.50 + 100% in fringe benefits for estimated hourly wage of \$105.00 for Statisticians (15-2041), \$54.67 + 100% in fringe benefits for estimated hourly wage of \$109.34 for Database Administrators (15-1240), \$62.18 + 100% in fringe benefits for estimated hourly wage of \$124.36 for General and Operations Managers (11-1021), \$35.42 + 100% in fringe benefits for estimated hourly wage of \$70.84 for an executive administrative assistant (occupation code 43-6011). We estimate the cost to be \$14,899.80 per study, for 13 potential CED studies, the cost to sponsors will be \$193,697.40 for one year.

Number of	Hours per	Annual hour	Cost per	Annual cost
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responses	response	burden	response	burden
13	100	1,300	\$14,899.80	\$193,697.40

13. Capital Costs

We do not anticipate additional capital costs.

14. Cost to Federal Government

CMS estimates that 5 FTEs, GS12-15 are required to process and review each CED submission (including amendments). This amounts to a yearly total of \$1,283,247 based on a cost of \$ 256,649.42 per position which is the agency’s projected average cost of an FTE including benefits*.

*<https://www.federalpay.org/employees/centers-for-medicare-and-medicaid-services>. Centers for Medicare & Medicaid Services Salaries of 2022 AVERAGE SALARY is \$128,324.71 plus 100% in fringe benefits.

15. Changes to Burden

Wage information was updated with the most recent information available from the Bureau of Labor Statistics (2023, published in 2024). The burden hours decreased from 1,500 to 1,300. The per study cost changed from \$12,105.40 to \$14,899.80.

16. Publication/Tabulation Dates

Upon CMS approval of a CED study, we will post the study title, sponsor name, National Clinical Trial number, and CMS approval date on the CMS website. The link to the CMS website for Coverage with Evidence Development is <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development>.

17. Expiration Date

CMS will display the PRA expiration date on the Coverage with Evidence Development website (<https://www.cms.gov/medicare/coverage/evidence>).

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.