Supporting Statement Part-A
Medicare Plan Performance Warning Information
(CMS-10836, OMB 0938-xxxx)

A. BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) is seeking approval for this new collection to collect information to assist in the Agency's response to two reports from the Department of Health and Human Services Office of the Inspector General (OIG) related to how the agency conveys information on plan performance (the reports are described below).

As a payor and regulator of healthcare for more than 63 million Americans, CMS has an essential role in ensuring that high quality care is delivered by the estimated 3,550 Medicare Advantage (Part C) plans and the estimated 1,439 prescription drug (Part D) plans. To ensure the quality of plans and a high level of care for beneficiaries, CMS oversees and monitors the day-to-day performance of health and drug plans. As part of this oversight, CMS also warns and/or penalizes plans when they violate rules.

CMS works to make information about plan quality public, both for public accountability and for beneficiary use when making decisions about health and drug plans. CMS has a responsibility to share information about poor plan performance to help beneficiaries — as well as caregivers and other intermediaries who help them, such as State Health Insurance Assistance Program (SHIP) counselors, brokers, and advocacy groups — make informed choices. This work is vitally important.

B. JUSTIFICATION

B.1 Circumstances Making the Collection of Information Necessary

As required by the Medicare Prescription Drug, Improvement, and Modernization Act (722(a)(3)(A)(i)), Medicare Advantage plans "shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality." Thus, Medicare collects a substantial volume of information about each MA plan. Medicare shares some of this information with the public. The Medicare Advantage Quality Rating System (as defined at 42 CFR § 422.162), is one-way Medicare rates MA plans. Star Ratings information is also shared with the public.

In two recent reports[1], the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) suggested CMS needs to enhance how it conveys this information for both Part C and Part D plans, including sharing more information when plans have serious violations or performance problems.

In a 2018 report, OIG found evidence suggesting that Medicare Advantage beneficiaries were being inappropriately denied services and payments. For example, during 2014-2016, Medicare Advantage Organizations (MAOs) overturned 75 percent of their own denials each year when beneficiaries appealed, and independent reviewers overturned additional denials. OIG also noted that beneficiaries rarely use the appeals process; during 2014-2016, beneficiaries and providers appealed only 1 percent of denials. Furthermore, OIG observed that while CMS' audits identified performance problems related to denials, CMS continues to see these violations every year. OIG recommended CMS "provide beneficiaries with clear, easily accessible information about serious violations by MAOs."

In 2019, OIG issued a second report that studied data and oversight related to Part D pharmacy rejections and coverage denials. When issued for avoidable or inappropriate reasons, such rejections and denials could lead to delays in beneficiary access to needed drugs. OIG found

[1] See "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials" at https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp and "Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs" at https://oig.hhs.gov/oei/reports/oei-09-16-00411.asp.

that when beneficiaries appealed coverage denials at the first level of appeal, they were overturned at least 73% of the time. Additionally, OIG noted that in 2017, CMS cited 53% of Part D contracts for at least one coverage determination process violation that prevented beneficiaries from receiving drugs or led to delays in access to drugs or reimbursement. OIG recommended CMS "provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials."

CMS is conducting this research to respond to OIG's recommendations related to sharing additional information with beneficiaries on plan performance in a clear and accessible format, particularly related to information which may warn or caution beneficiaries about plan performance issues. CMS is seeking to learn more about how beneficiaries, caregivers, and the intermediaries who assist them use and understand the information CMS currently makes (or may make) available, as well as to assess their interest in accessing this information.

B.2 Purpose and Use of Information

The feedback CMS is seeking related to how beneficiaries and caregivers use and understand poor plan performance relates to three main types of information:

- **Audits and denial and appeals letters:** This includes information CMS shares now on annual plan audits as well as sample letters CMS generates related to denials and appeals.
- **Enforcement and compliance information:** This includes information CMS shares now related to enforcement and compliance, including information related to notices of noncompliance, warning letters, sanctions, and civil monetary penalties.
- **Other potential indicators of poor plan performance:** This includes information CMS collects on other indicators of plan performance which CMS may or may not share now, such as complaints, grievances, denials, appeals, and others.

Because of the large volume of information being shared, CMS is planning to collect this information via three separate projects. (The volume of information is equivalent to three 90 minute interviews, and is therefore too large to be shared in a single interview.) CMS intends to

share example information on these topics with a qualitative sample of beneficiaries/caregivers and intermediaries (including SHIP counselors, brokers, and advocates) who assist beneficiaries. Audiences will review existing information CMS makes public on each topic in 1) its current format (which is typically not designed for broad access), and 2) reformatted information created for the purposes of this research. Interviewees will be asked to review and assess the information, including how interested they are in it and how they may use it, including impact on enrollment intentions. They will also provide input on various options to present or share the information, including where or if the information should be made available.

CMS will use this feedback to inform its response to OIG's recommendation that it share additional information on plan performance. Due to the large number of topics CMS is seeking input on, CMS is proposing to conduct this research as a series of individual interviews (IDIs) focused on each of the three topics noted above. The following types of respondents will be included for each topic:

- Medicare beneficiaries, including individuals with a Medicare Advantage Plan or Original Medicare with a Part D prescription drug plan.
- Caregivers or family members of those with a Medicare Advantage Plan or Original Medicare with a Part D prescription drug plan.
- More engaged Medicare beneficiaries (defined as those who seek additional information when selecting a plan and who may be interested in plan performance information), including individuals with a Medicare Advantage Plan or Original Medicare with a Part D prescription drug plan.
- Intermediaries who assist beneficiaries with making decisions about Medicare plans, including SHIP counselors, brokers, and advocacy groups.
- Spanish-speaking Medicare beneficiaries, including individuals with a Medicare Advantage Plan or Original Medicare with a Part D prescription drug plan.
- Spanish-speaking caregivers or family members of those with a Medicare Advantage Plan or Original Medicare with a Part D prescription drug plan.
- Spanish-speaking more engaged Medicare beneficiaries (defined as those who seek additional information when selecting a plan and who may be more interested in plan

performance information), including individuals with a Medicare Advantage Plan or Original Medicare with a Part D prescription drug plan.

Information will be collected via individual interviews that will last 90 minutes.

B.3 Use of Improved Information Technology

Individual interviews will primarily take place in a virtual setting via an online platform that allows for screen sharing. Screen sharing will allow respondents to review and comment on plan warning information. Allowing interviews to take place virtually will reduce the burden of participation. However, to ensure the perspectives are captured of beneficiaries who do not have access to adequate internet or technology, up to n=18 interviews may also be conducted in research facilities to reduce the barrier of technological access. These participants would also take part online, and the protocol would remain identical.

B.4 Efforts to Identify Duplication

CMS is the only Cabinet Department with statutory responsibility for Medicare. Within CMS, responsibility for responding to OIG's concerns about beneficiary communication is being led by the Medicare Drug Benefit and C and D Data Group, which is sponsoring this request. To the best of our knowledge, no other entity within the Federal Government has gathered or is planning to gather similar data. The attached qualitative instruments have been reviewed carefully to avoid potential duplication.

B.5 Involvement of Small Entities

This information collection request does not involve any small businesses.

B.6 Consequences if Information is Collected Less Frequently

OIG has asked CMS to respond to its recommendations. CMS needs to collect data to ensure its response is appropriate. This is a single, point-in-time collection to inform CMS's response.

B.7 Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or,
- Submit proprietary trade secrets, 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.

B.8 Federal Register Notice

The 60-day Federal Register notice was published on 12/15/2022 (87 FR 76626).

No comments were received during the comment period.

The 30-day Federal Register notice was published on 3/10/2023 (88 FR 15036).

B.9 Payments/Gifts to Respondents

This request involves online individual interviews. CMS will provide a stipend of $125 for beneficiaries/caregivers in 90-minute individual interviews. These stipends are necessary to ensure the validity of research findings as potential respondents are likely to be unwilling to

participate in these research activities without receiving compensation for their time. No stipend will be provided to intermediaries.

B.10 Assurance of Confidentiality

Data will be kept private to the extent allowed by law. Individuals contacted as part of this data collection are assured of the confidentiality of their replies under 42 U.S.C. 1306, 20 CFR 401 and 422, 5 U.S.C. 552 (Freedom of Information Act), 5 U.S.C. 552a (Privacy Act of 1974), and OMB Circular A-130.

B. 11 Questions of a Sensitive Nature

There are no questions of a sensitive nature included in these interviews; that is, there are no questions that ask about what is typically considered "sensitive," such as questions about illegal or criminal activities, sexual behavior or orientation, or income.

As a part of the screening process for selecting beneficiary/caregiver participants, our screener will ask for information on race, gender identity and ethnicity. This information is necessary since it is important for CMS to get feedback from diverse audiences and will be used to ensure the study is composed of participants who represent various perspectives. All recruiting is conducted by a third-party vendor (such as Schlesinger Research) who specializes in qualitative recruiting. Vendor records for participants will already include information on race and ethnicity – it will not be collected specifically for this study. The vendor will use its own internal database to recruit and invite participants who have agreed to be contacted for studies such as these.

Participant information is never transferred to an information system where it can be retrieved by a personal identifier by CMS. The recruiting vendor will provide remuneration, using its own data systems. No PII is ever transmitted to CMS, nor is new PII collected specifically for this collection. Our recruiting vendor will already store and own the PII necessary to track remuneration and completions.

No research vendor has been selected to date, but will be selected upon project approval based on project need and cost efficiency to the government.

B.12 Estimates of Annualized Burden Hours and Costs

Individual interviews will be used to collect information from respondents. The annual burden hours requested (561.3 hours) are based on the number of collections we expect to conduct over the requested period for this clearance.

Respondents:

Respondents will consist of three main types of individuals (described below). Respondents across all studies will represent a mixture of gender identities and racial and ethnic backgrounds. Each respondent will take part in a 90-minute session, plus 6-15 minutes for scheduling/screening (there is no screening required for intermediaries; the only qualification is job title). A small number of interviewees (n=18) will also have 15 minutes of travel time because they will participate online at a research facility. We assume, on average, we will need to screen two people to find one qualified respondent, so we have doubled the assumed screening time to 30 minutes to account for that need; scheduling time for intermediaries remains 6 minutes. Each respondent will participate once. Interviews will be conducted in both English and Spanish for beneficiary and caregiver audiences. Intermediary interviews will only be conducted in English.

Research audiences will include the following groups:

"Typical" beneficiaries: Medicare Advantage and Part D enrollees who are enrolling for the first time and/or considering a change in coverage, as well as caregivers or family members who may assist them in selecting a plan. This audience represents "typical" Medicare beneficiaries who are seeking information on coverage options and serves as a benchmark for how to present and frame information on plan performance in a way that is accessible and meaningful for all beneficiaries. We will aim to include beneficiaries of different race/ethnicities,

and include both dual eligible and under-65 disabled populations, and listen for differences along the lines of these variables.

"Engaged" beneficiaries: Medicare Advantage and Part D enrollees who engage in a more extensive or detailed review process before selecting a plan. This audience represents the most likely users of plan warning information. Research with this audience will enable Medicare to understand how to meet this audience's information needs and preferences.

Intermediaries: Those who assist beneficiaries in enrolling in plans or in reviewing Medicare coverage options, including SHIP counselors, brokers, and advocacy groups. These individuals represent frequent users of Medicare information, who also direct others to information sources. Research with this audience will ensure information is accessible and meaningful for these critical users.

Hourly rate:

The estimated annualized costs to respondents is based on Bureau of Labor Statistics (BLS) data from November 2021 ("Average hourly and weekly earnings of all employees on private nonfarm payrolls by industry sector, seasonally adjusted," U.S. Department of Labor, Bureau of Labor Statistics, https://www.bls.gov/news.release/empsit.t19.htm, accessed February 16, 2022). The mean hourly wage for all occupations is $31.23. The employee hourly wage estimates are then adjusted by a factor of 100 percent to account for fringe benefit costs (totaling $62.46 for wage plus fringe benefits). This is a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Annual burden estimates:

Numbers reflect calculated totals for all three research projects described above. All three projects will include three respondent groups. The respondent groups listed below have burden totals across the three groups.

Type of Collection	# of Respondents		Hours per Response	Total Burden Hours	Average Hourly Rate + Fringe	Total Cost
Beneficiaries and Caregivers (English language interviews)						
Screening instrument	156	1	0.5	78	$62.46	**$4,871.88**
Travel to in person facility	12	1	0.25	3	$62.46	**$187.38**
90-minute IDIs	156	1	1.50	234	$62.46	**$14,615.64**
Beneficiaries and Caregivers (Spanish language interviews)						
Screening instrument	84	1	0.5	42	$62.46	**$2,623.32**
Travel to in person facility	6	1	0.25	1.5	$62.46	**$93.69**
90-minute IDIs	84	1	1.50	126	$62.46	**$7,869.96**
Intermediaries						
Scheduling (no screener)	48	1	0.10	4.8	$62.46	**$299.81**
90-minute IDIs	48	1	1.50	72	$62.46	**$4,497.12**
Total	**288**	**1**	**1.95**	**561.3**	**$62.46**	**$35,059.07**

The anticipated burden is 561.3 hours, comprising 90 minutes of interview time per participant, 30 minutes to be scheduled and screened (beneficiaries and caregivers, including additional time for screening since not all will qualify), and 6 minutes to be scheduled for intermediaries. Additionally, 15 minutes is included to account for average travel time to the facility for some participants.

Planned frequency of information collection:

These are one-time data collection activities. Each participant will take part once.

B.12 Estimates of Annualized Respondent Capital and Maintenance Cost

There are no capital or maintenance costs associated with this collection.

B.14 Estimates of Annualized Cost to the Government

The anticipated cost to the Federal Government is approximately $767,713 and is broken out into contract costs and personnel costs of Federal employees.

Contract costs are $755,090 and are comprised of: contractor payments for staff time to conduct and analyze the research, recruitment of participants, participant stipends, transcription, translation, and recordings and electronic remote feeds for offsite viewing.

Personnel costs from Federal employees are $12,623 which includes 10% from GS14.

B.15 Changes in Hour Burden

Not Applicable. This is a new activity.

B.16 Time Schedule, Publication, and Analysis Plan

Data from individual interviews will be collected and analyzed over a 12-month period, conducted as three separate four-month periods (one period for each of the three research topics). For each topic, we anticipate one month to plan the research, two months to field the research, and one month to analyze and report on findings. We will repeat this process three times for each of the unique topics we are investigating: “Audits and Existing Letters for Denials and Appeals;” “Enforcement and Compliance Information;” and “Desired Content Related to Poor Plan Performance.”

Feedback will inform CMS’s response to OIG and planned sharing of information. CMS may publish or distribute select findings from the research in its response to OIG, to explain its decision-making process to interested stakeholders, or to advance scientific knowledge on how

best to share this kind of plan warning information. No information released will include publicly identifiable information, including first names of research respondents or organizations they work for.

B.17 Exemption for Display of Expiration Date

CMS does not seek this exemption. The Expiration Date and OMB control number will be displayed at the top of every survey.

B.18 Exceptions to Certification Statement 19

There are no exceptions taken to item 19 of OMB Form 83-1.

LIST OF ATTACHMENTS:

- **Attachment A:** Beneficiary Screener
- **Attachment B:** Caregiver Screener
- **Attachment C:** Beneficiary and Caregiver Guide: Audits and Existing Letters for Denials and Appeals
- **Attachment D:** Intermediary Guide: Audits and Existing Letters for Denials and Appeals
- **Attachment E:** Beneficiary and Caregiver Guide: Enforcement and Compliance Information
- **Attachment F:** Intermediary Guide: Enforcement and Compliance Information
- **Attachment G:** Beneficiary and Caregiver Guide: Desired Content Related to Poor Plan Performance
- **Attachment H:** Intermediary Guide: Desired Content Related to Poor Plan Performance