Supporting Statement for the Paperwork Reduction Act of 1995

Part A. Justification

QIC Demonstration Evaluation Contractor (QDEC): Analyze Medicare Appeals to Conduct Formal Discussions and Reopening's with DME Suppliers and Part A Providers

(CMS-10633, OMB 0938-1348)

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Centers for Medicare & Medicaid Services

Center for Medicare (CM)

Medicare Enrollment and Appeals Group (MEAG)

Division of Appeals Operations (DAO)

7500 Security Boulevard

Baltimore, MD 21244

Table of Contents

Supporting Statement – Part A

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Background

Medicare processes over one billion fee-for-service (FFS) claims a year. These claims go through hundreds of edits to determine if the claim is proper and can be paid, either through an automated system or through manual review. Claims that fail an edit, or audit, are denied or returned to the Durable Medical Equipment (DME) supplier or Part A provider.

Section 1869 of the Social Security Act sets the process for adjudicating FFS claims under Medicare Parts A and B. When a party is dissatisfied with the payment decision by a Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) on a claim, the party is entitled to appeal through the Medicare claims appeals process. The 2nd level of the Medicare FFS appeals process, also known as reconsiderations, is performed by Qualified Independent Contractors (QIC).

Consistent with the current statutory and regulatory framework for the FFS claim appeals process, the QICs only engage in an on-the-record review with no opportunity currently for the QIC to educate the supplier, or for the appellant to present oral testimony, before the QIC makes a reconsideration decision.

Section 402(a)(1)(F), U.S.C.§ 1395-1(a)(1)(F), of the Social Security Amendments of 1967 permits the Secretary to "determine whether, and if so which type of, fixed price or performance incentive contract would have the effect of inducing the greatest degree effective, efficient, and economical performances of agencies and organizations making payment under agreements or contracts with the Secretary for health care and services under health programs established by the Social Security Act." Pursuant to this authority, the Centers for Medicare & Medicaid Services (CMS) is implementing the **Formal Telephone Discussion Demonstration and Reopening's Process** (the Demonstration). The
Demonstration began on January 1, 2016 and will continue through December 31, 2021.

The Demonstration is designed to improve the efficiency of Medicare's five-level appeals system for fee-for-service (FFS) claims, which currently is experiencing a backlog, by improving the quality of future claim submissions. The Demonstration provides DME suppliers and Part A providers with the opportunity to engage in a telephone discussion of appealed claims with the QIC and to gain an understanding of critical documentation that could result in a favorable claim outcome.

The Demonstration is being implemented in multiple phases:

- In Phase I, which started on January 1, 2016, the Demonstration was implemented in two of the four DME MAC jurisdictions, Jurisdictions C and D, and focused on oxygen supplies and diabetic testing supplies.
- In Phase II, which started on October 31, 2016, CMS extended the coverage of the Demonstration to nearly all DME service categories.[1]
- In Phase III, which started on November 1, 2018, Demonstration activities were expanded to the remaining two DME MAC jurisdictions, Jurisdictions A and B.
- In Phase IV, CMS furthered expand the Demonstration activities to Part A claims. This expansion will initially be implemented in the Part A East QIC Jurisdiction, including Part A MAC Jurisdictions H, J, K, L, M, and N.

In the Demonstration, the QIC provides education through a formal telephone discussion process to improve participating DME suppliers' and Part A providers' understanding of the reasons for claim denials. The evaluation's objective is to determine whether telephone-based engagement with the QIC will improve DME suppliers' and Part A providers' understanding of the cause of Level 2 appeal denials, and over time, whether this increases submission of accurate and complete claims at the MAC level.

The evaluation results will help CMS assess whether the scope of the Demonstration is to be expanded, and determine the utility of permanently adding a telephone discussion to the QIC reconsideration level if, for example, it is associated with a decrease in Level 2 claims appeals or an increase in the submissions of accurate and complete claims at the MAC level, or similar findings that CMS considers to be substantively important.

The mixed methods evaluation of the Demonstration will use both quantitative and qualitative techniques to analyze the outcomes and impact of the Demonstration. The evaluation will:

(1) focus specifically on outcomes of the intervention including satisfaction with the discussions, the rate of claims denials, and the number of claims that go through appeals Levels 2 and 3, and contextual information about the usefulness of the telephone discussions to suppliers who participate in them;
(2) seek to determine whether further engagement with the QIC by DME suppliers and Part A providers improves understanding of the reasons for claim denials; and

1 Certain service categories were excluded from the Demonstration to avoid overlap with other initiatives (e.g., Prior Authorization for Power Mobility Devices [PMDs] and the Settlement Conference Facilitation process [SCF]).

(3) support CMS in assessing the QIC's effectiveness in meeting a number of criteria established by CMS, including how satisfied DME suppliers and Part A providers participating in the formal telephone discussion process were with specific educational activities used by the QIC during the discussions (e.g., how well the QIC explained applicable regulations, policies, and reasons for denial associated with a given appeal).

Based on findings triangulated from both qualitative and quantitative data analyses, the contractor will develop recommendations for CMS. The results of the evaluation and contractor recommendations will allow CMS to make informed policy decisions regarding the effectiveness of the Demonstration and whether or not it should become a permanent part of the appeals process.

Primary and secondary data will inform the evaluation.

Secondary data consist of DME claims submitted by DME suppliers and Part A providers, appeals to claim denials, and DME supplier and Part A provider characteristics. Specifically, we will analyze claims extracted from the Common Working File, appeals and appeal decisions extracted from the Medicare Appeals System and the ViPS Medicare System, and DME supplier and Part A provider characteristics (e.g., non-profit status, tenure with CMS) extracted from the Provider Enrollment, Chain, and Ownership System DME Competitive Bidding Implementation Contractor.

Primary data will be collected to evaluate the Demonstration from the perspective of DME suppliers and Part A providers who participate in the formal telephone discussions and reopening's process. Two primary data collection activities will assess experiences and satisfaction with the Demonstration:

- A web-based supplier survey administered to suppliers and providers who participated in a formal telephone discussion, and
- A series of key informant interviews with suppliers who participated in a formal telephone discussion.

These are described next.

Supplier Web-Based Survey. The team will administer a web-based customer satisfaction survey to a random sample of no more than 2,544 DME suppliers and 2,544 Part A providers that participated in a formal telephone discussion. The survey will be administered on a monthly basis to DME suppliers and Part A providers that participated in a formal telephone discussion during the previous month. Because many suppliers regularly participate in the Demonstration each month, it is likely that some will receive a survey invitation more than once in a given calendar year. However, we will not send a survey to a specific individual two months in a row. Survey data will be used to assess the QIC's performance and to inform the broader evaluation of how well the Demonstration is meeting its intended goal of reducing appeals submission by changing DME supplier and Part A provider behavior that results in more accurate claims submission, from the perspective of participants. Specifically, we will analyze survey responses to understand satisfaction with activities performed by the

QIC to determine if some aspects of the Demonstration are more successful than others and to understand what could be improved. Tabulated and trended results for all survey items will be made available to CMS in semi-annual and annual reports. The web-based survey instrument and recruitment materials for DME suppliers appear in Attachment A: Web-Based Survey Instrument and Recruitment Materials, Appendix A and Appendix B. The web-based survey instrument and recruitment materials for Part A providers appear in Attachment A: Web Based Survey Instrument and Recruitment Materials, Appendix C and Appendix D.

Key Informant Interviews. The IMPAQ team will conduct qualitative key informant interviews each year with 100 randomly selected DME suppliers and 100 randomly selected Part A providers who participated in Demonstration. Findings from key informant interviews will be used to evaluate the overall effectiveness of the Demonstration. Fifty DME suppliers and 50 Part A providers will be selected from Survey responses that indicate dissatisfaction with one or more aspects of the formal telephone discussion. A second set of key informant interviews will be conducted with 50 DME suppliers and 50 Part A providers selected at random from telephone discussion participants. Topics discussed in the interviews will include: How well the QIC explained and led the formal telephone discussion process; whether the formal discussion met interviewees' expectations; what aspects of the formal telephone discussion and reopening's processes worked well; and, what aspects of the formal discussion and reopening's processes could have worked better. Key informant protocols and recruitment materials for DME suppliers appear in Attachment B: Key Informant Interview Instrument and Recruitment Materials, Appendix A and Appendix B. Key informant protocols and recruitment materials for Part A providers appear in Attachment B: Key Informant Interview Instrument and Recruitment Materials, Appendix C and Appendix D.

CMS has selected IMPAQ International, LLC and its partner, Palmetto GBA (the IMPAQ team), as the **QIC Demonstration Evaluation Contractor (QDEC)** to conduct the evaluation of the Demonstration. The Demonstration project is conducted by telephone, initiated from the QIC's offices.

Justification

1. Need and Legal Basis

The **Formal Telephone Discussion Demonstration and Reopening's Process** is authorized under Section 402(a)(1)(F), U.S.C.§ 1395b-1 of the Social Security Amendments of 1967. Primary and secondary data are needed to understand the effectiveness of the Demonstration in improving DME suppliers' and Part A providers' understanding of claims denial during Level 2 of the appeals process and facilitating more accurate claim submission over time. Primary data are necessary to determine, from the perspective of participating DME suppliers and Part A providers, the quality of the formal telephone discussions, satisfaction with the formal telephone discussion process, and the effect of the formal telephone discussions on submitting accurate claims. These data will inform an evaluation of the demonstration's effectiveness in achieving more accurate claims submissions, and thus reducing the number of claims CMS must process each year. This could potentially reduce Federal resources expended to process claims.

2. Information Users

All information collected through the evaluation of the Formal Telephone Demonstration and reopening's Process will be used by CMS through the QDEC (IMPAQ International and its partner, Palmetto GBA) to conduct analyses of satisfaction with the formal telephone discussions, and determine whether further engagement with the QIC improves understanding of the reasons for claim denials.

CMS will use the results of the evaluation to make informed policy decisions regarding the effectiveness of this demonstration and whether or not the demonstration should become a permanent part of the appeals process. Ultimately, if the information shows that DME suppliers and Part A providers were able to submit more accurate claims on the first pass, and a reduced number of claims are put through the appeals process, the Federal government could realize cost savings.

3. Use of Information Technology

The QDEC will collect all survey information electronically through a web-based platform. This includes opinions and assessments regarding satisfaction with the formal telephone discussion process, and suggestions for possible improvements. Voxco survey software will be used to program and administer the monthly web-based survey. Web-based surveys enable respondents to complete the survey at a time of their choosing and allow the project team to monitor survey response rates in real time and send customized reminder e-mails. Voxco allows the project team to electronically program the survey instrument including skip-pattern logic, to minimize respondent error and burden. Respondent signatures are not required, as submission of survey responses indicate consent.

Key informant interviews will be conducted by telephone, and with participant consent, recorded via voice-over internet protocol software. Interviews will cover motivations for participating in the formal telephone discussion process, their expectations and perceived quality of the formal telephone discussions, and aspects that worked well/could be improved upon. Recordings will be stored securely on a FISMA-compliant enclave.

4. Duplication of Efforts

The web-based survey and key informant interviews will collect key information that CMS believes is not captured elsewhere. This information collection does not duplicate any other effort and the information cannot be obtained from any other source. DME suppliers and Part A providers who participate in the formal telephone discussion demonstration are not surveyed about the Demonstration under any other activities, aside from the proposed information collection activities.

5. Small Businesses

Some of the DME suppliers and Part A providers that participate in the formal telephone discussion process may be employed by small businesses. As part of primary data collection efforts, these small businesses may be invited to respond to the web-based survey and/or 30 minute key informant interview. The survey and key informant interview instruments have been designed to minimize the burden on all respondents and will not have a significant impact on small businesses or other small entities.

6. Less Frequent Collection

If the web-based survey and key informant interviews were not conducted, CMS would be unable to capture supplier perspectives on the quality and effectiveness of the Formal Telephone Discussions and reopening's Demonstration. Because DME suppliers and Part A providers are key stakeholders in the appeals process, their experiences, satisfaction, and opinions must be collected to evaluate the overall Demonstration and assess the QIC's performance.

The frequency of data collection (monthly surveys and annual key informant interviews) is necessary to execute the evaluation design, which allows for monthly, semi-annual, and annual reporting of the QIC effectiveness. It is important to capture DME suppliers' and Part A providers' experiences throughout the course of the QIC's annual period of performance, and as soon as possible after they participate in the formal telephone discussions. Monthly web based survey data collection will allow ongoing assessment of the quality of the Demonstration, with the ability to detect issues that might emerge during specific points of time throughout the year.

7. Special Circumstances

None of the special circumstances applies to this data collection effort. It is not expected that DME suppliers or Part A providers will participate in a formal telephone discussion more frequently than quarterly; thus, they will not be invited to complete a web-based survey more than quarterly.

8. Federal Register/Outside Consultation

The 60-Day Federal Register notice was published in the Federal Register on 07/01/2020 (85 FR 39568).

No comments were received.

The 30-Day Federal Register notice was published in the Federal Register on 09/24/2020 (85 FR 60169).

No additional outside consultation was sought. The web-based survey was pilot tested with nine suppliers randomly selected prior to OMB approval, in September 2016. The average response time was 8 minutes, with a range of 4 to 10 minutes. Minor grammatical revisions were made to the instrument to improve clarity.

9. Payments/Gifts to Respondents

No payments or gifts will be provided to participants of the information collection activities.

10. Confidentiality

It is the QDEC's policy to efficiently protect all information and data, in whatever media they exist, in accordance with applicable Federal and state laws and contractual requirements. All program participants will receive unique identification codes, which will be stored separately from personally identifying information.

Surveys. The surveyed DME suppliers and Part A providers will be assured that their responses will be kept private to the extent permitted by law. Survey data will be stored on the QDEC's FISMA- compliant server that is protected by a firewall that monitors and evaluates all attempted connections from the Internet. Personal information (name, telephone number, and e-mail address) on each survey response will be maintained in a separate data file apart from the survey data so that individuals outside of the project team cannot link specific responses to individual respondents. Once the contract is completed, all sensitive data pertaining to each survey respondent will be destroyed. The entire survey database will be encrypted so that any data stored will be further protected. Finally, access to any data with identifying information will be limited only to contractor staff directly working on the survey. Survey findings will be presented at a level of aggregation such that it will not be possible to link specific responses to individual respondents.

Key Informant Interviews. DME suppliers and Part A providers interviewed by research team members will be assured that their responses will be kept private to the extent permitted by law. All findings in any published reports or briefings will be presented at the aggregate level, so that it is not possible to link comments to particular individuals. Similarly, interview notes or recordings will not be shared with CMS staff or anyone else outside the study team. Audio recording files will be stored in a FISMA-compliant secure server. If any notes are recorded on laptop computers, such notes will be stored in a SQL Server database located in the contractor's access-controlled server room.

11. Sensitive Questions

No information of a sensitive nature will be collected.

12. Burden Estimates

Exhibit A-1 shows the estimated annualized burden hours for the respondents to participate in this study. Each month, a random sample of no more than 212 DME suppliers and 212 Part A providers who participated in a formal telephone discussion in the prior month will be selected across all jurisdictions and asked to complete a web-based survey. Annually, this will total 2,544 DME suppliers and 2,544 Part A providers invited to complete the survey. The brief survey will take approximately 10 minutes to complete (0.167 hour). Key informant interviews with DME suppliers and Part A providers will last about 30 minutes (0.5 hour). The total annual burden is estimated at 949.7 hours.

Exhibit A-1: Estimated Annualized Burden Hours

Data Collection Activity	Number of Respondents	Frequency of Response	Average Time per Respondent	Burden Hours
DME Suppliers Web-Based Survey	2,544	1	0.167	424.85
DME Suppliers Key Informant Interview	100	1	0.5	55050
Part A Providers Web-Based Survey	2,544	1	0.167	424.85
Part A Providers Key Informant Interview	100	1	0.5	5050
TOTAL	**5,288**	1	Varies by Activity	**949.7**

Exhibit A-2 shows the annualized cost to respondents for the hour burdens for data collection. Labor rates and associated costs are based on Bureau of Labor Statistics data. For DME suppliers and Part A providers, the mean hourly wage is $55.57/ hour using the occupation "Managers, all others" taken from the United States Department of Labor, Bureau of Labor Statistics, "Occupational Employment and Wages May 2018."[2] We used the wage for the occupational group listed above as the basis for the labor rates for DME supplier and Part A provider senior billing managers/supervisors, who are the individuals participating in formal telephone discussions and who will be surveyed and interviewed. These rates represent salaries plus fringe benefits and do not include the cost of overhead. An overhead rate of 110 percent is used to account for these costs. Therefore, the full-burdened hourly wage rate of DME suppliers and Part A providers is $116.69. The total annualized cost is estimated at $110,820.50.

Exhibit A-2: Estimated Annualized Cost

Data Collection Activity	Burden Hours	Average Hourly Wage Rate	Cost of the Hour Burden
DME Suppliers Web-Based	424.85	$116.69	$49,575.75
Survey DME Suppliers Key Informant	50	$116.69	$5,834.50
Interviews Part A Providers Web-Based	424.85	$116.69	$49,575.75
Survey Part A Providers Key Informant	50	$116.69	$5,834.50
Interviews **TOTAL**	**949.7**	$116.69	**$110,820.50**

13. Capital Costs

There are no direct costs to respondents other than that of their time of participation. There will be no start-up or ongoing financial costs incurred by respondents. There are no record keepers.

14. Cost to Federal Government

Exhibit A-3 shows the cost to the Federal Government for carrying out this information collection effort is approximately $145,116.89 for the first year and $122,736.00 per year through the end of the project, which is the cost associated with primary data collection activities for the evaluation.

Exhibit A-3: Annualized Cost to the Government

Data Collection Activity	Cost of the Hour Burden
Web-based Survey Instrument Design (one-time only)	$6,935.13
Web-based Survey Instrument Testing (one-time only)	$8,509.71

2 https://www.bls.gov/oes/2018/may/oes119199.htm

Web-based Survey Implementation (annual)	$89,436.72
Subtotal Survey	**$104,881.56 Year 1 $89,436.72/year, Year 2-6**
Key Informant Interviews Instrument Design (one-time only)	$6,935.13
Key Informant Interviews Implementation (annual)	$33,300.20
Subtotal Interviews	**$40,235.33 Year 1 $33,300.20/year, Year 2-6**
TOTAL	**$145,116.89 Year 1 $122,736/year, Year 2-6**

15. Changes to Burden

CMS will conduct the demonstration in all jurisdictions. Estimated Annualized Burden Hours (Exhibit A-1 above) increases from 473.3 hours to 949.7 due to the addition of the Part A provider respondents. Estimated Annualized Cost (Exhibit A-2 above) increases to $110,820.50 because of the addition of the Part A provider respondents and the cost estimate is updated with the most recent mean hourly wage data from the United States Department of Labor, Bureau of Labor Statistics.

16. Publication/Tabulation Dates

Tabulations and analyses of web-based surveys will be published in monthly, semi-annual, annual, and final reports to the Agency. Exhibit A-4 shows the schedule of publication.

Exhibit A-4: Table of Publication Dates: 2016 - 2022

Item Number	Deliverable Description	Delivery Date
109	Semi-Annual Report of Findings Regarding the Effectiveness of the Discussions Demonstration and Lessons Learned	April 15th and October 15th annually
110	Monthly and Annual Report of QIC's Effectiveness in Meeting Award Fee Objectives	Last business day of each month, Annual Report Due on January 31st for the prior year's activities.
115	Ad Hoc Reports	As requested
119	Annual Report of Findings	April, 2018, 2019, 2020, 2021, 2022

The contractor will analyze web-based survey data collected monthly using descriptive statistics to estimate suppliers' overall satisfaction with the formal telephone discussions process. Analyses will include simple question-level response frequencies, and the creation of a satisfaction index combining responses to five Likert-style items into one satisfaction measure. The contractor will use thematic qualitative analyses to identify common themes and patterns about formal telephone discussions process successes, challenges, and recommendations for improvement that emerge during key informant interviews.

17. Expiration Date

The expiration date and OMB control number will appear on the first page of the instrument (top-right corner).

The PRA disclosure statement will be included in the footer on the first page of the instrument.

18. Certification Statement There are no exceptions.