Supporting Statement, Part A
Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments
CMS-10062, OMB 0938-0878

Background and Summary

In the Balanced Budget Act of 1997 (BBA), Congress created the Medicare+Choice (M+C or Part C) program in order to expand the types of private entities eligible to contract with Medicare and to address some perceived flaws in the risk-contracting program. Congress subsequently refined the M+C program through the Balanced Budget Refinement Act of 1999 (BBRA) and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). Under the Medicare Prescription Drug Benefit, Improvement and Modernization Act of 2003 (MMA), Congress restructured the M+C program into the Medicare Advantage (MA) program and added an outpatient prescription drug benefit, Part D.

The 1997 BBA and later legislation required CMS to adjust per-beneficiary payments with a risk adjustment methodology using diagnoses to measure relative risk due to health status instead of just demographic characteristics such as age, sex, and Medicaid eligibility. The purpose of risk adjustment is to pay plan sponsors accurately based on the health status and diagnoses of their Medicare enrollees. Risk adjustment using diagnoses provides more accurate payments for Medicare Advantage Organizations (MAO), with higher payments for enrollees at risk for being sicker, and lower payments for enrollees predicted to be healthier.

Part C risk adjustment payments are applied to more than 21million Medicare beneficiaries who are enrolled in MAOs. Part D risk adjustment payments applicable to the prescription drug plan payments are applied to approximately 44 million beneficiaries in the MA and Fee-for-Service (FFS) programs. CMS makes prospective monthly payments that are risk adjusted to MAOs and Part D sponsors for each enrollee in an MAO. CMS also risk adjusts beneficiary-level payments for enrollees in certain demonstration organizations and, the Program of All-inclusive Care for the Elderly (PACE) organizations.

As a result, CMS updates and maintains several CMS-HCC (Hierarchical Condition Category) risk adjustment models: a Part C aged/disabled model, three End-Stage Renal Dialysis (ESRD) models, and a model used to pay PACE organizations; further, each of these models is comprised of several segments for subpopulations such as low-income (full and partial dual eligibles), disabled, aged, and institutionalized beneficiaries. Similarly, for Part D, CMS must develop and maintain several risk adjustment models to adjust payment based on the expected plan liability for prescription drug expenditures of their Medicare-enrolled population, measured by the demographics and health status of that population.

Note that implementing regulations at 42 CFR 422.310 specify two data formats for risk adjustment data: (1) comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data) and (2) data in abbreviated formats. The subject of this PRA package is collection of data in the abbreviated format known as RAPS data, named for the Risk Adjustment Processing System (RAPS). Encounter data collection is addressed in a separate PRA package.

For data submissions to CMS in the abbreviated format called the RAPS format (Risk Adjustment Processing System), CMS requires MAOs to submit six data elements which include the Member ID, Diagnosis Cluster, Service from Date, Service through Date, Provider Type, and Risk Assessment Code (whether or not the source of diagnoses is plan enrollee risk assessments that are equivalent to Annual Wellness Visit health risk assessment).

Additional payment related projects include, the independent verification and validation of Plan bid data and Medical Loss Ratio (MLR) reporting mandated by the Affordable Care Act (ACA). In addition, under the MMA, a bidding system was instituted for Parts C and D with a significant role for risk adjustment. Thus, independent of enrollment and payment, risk adjustment now plays a significant role simply because it is central to the bidding process. Under the MMA, risk adjustment is used to standardize bids. Plans bid on the average beneficiary, referred to as a "standardized" bid for a beneficiary with a 1.0 risk score. This enables comparison of Part C and D bids against a baseline (average) standard, even though every plan will have different enrollee characteristics and benefit packages and will therefore have different costs.

In summary, the risk adjustment process is comprised of the following major activities: 1.) support of the annual development and implementation of the risk adjustment model, 2.) implement payment policy changes that impact the risk adjustment Part C and Part D payment models and Risk Adjustment System (RAS), and 3.) operate and maintain system infrastructure activities legislatively mandated for the MA and MA-PD program, and 4.) support the bidding process to accurately calculate costs for a beneficiary with a 1.0 risk score.

A. Justification

1. Legal Basis and Needs

The BBA constituted the first legislative mandate for health status risk adjustment. Section 1853 (a)(3) of the Social Security Act as enacted by Section 4001 of Subtitle A of the BBA required the Secretary to implement a risk adjustment methodology that accounted for variations in per capita costs based on health status and other demographic factors for payment to Medicare+Choice (now MA) organizations. The new methodology was to be effective no later than January 1, 2000. The BBA also required that M+C organizations submit data for use in developing risk adjusted payments.

The BBA stated that for purposes of risk adjustment inpatient hospital data were to be submitted for discharges occurring after July 1, 1997, while other data (e.g., hospital outpatient and physician data) were to be submitted after July 1, 1998. No organization was required to submit data before January 1, 1998. Following passage of the BBA, CMS promulgated the Medicare+Choice Regulation (42 CFR 422). This regulation references the requirement for M+C organizations to submit outpatient as well as inpatient hospital encounter data.

In December 2000, section 603 of BIPA amended §1853(a)(3)(C) of the Act (previously amended by §511 of the BBRA) by specifying that CY 2003 payments would only be adjusted 10 percent by the new risk adjustment method. Therefore, under BIPA CMS continued to apply the transition percentages that were already in effect for CY 2000- 2002: 90 percent demographic adjustment and 10 percent risk payment.

BIPA further stipulated that the risk adjustment methodology for 2004 and succeeding years should be based on data from both inpatient hospital and ambulatory settings. BIPA also altered the risk adjustment phase-in schedule that had been set in the BBA. The new phase-in schedule for the health status aspect of risk adjustment became: in 2004, 30% health status or "risk" payment with 70% of payment still based on the demographic-only method; in 2005, 50% risk and 50% demographic payment; in 2006, 75% risk/25% demographic; and 100% risk payment in 2007. Note that the risk model includes factors for demographic characteristics of enrollees while adding health status measures; it does not eliminate demographic factors from risk adjustment. In the MMA, Congress maintained its former commitment to risk adjusted managed care payments by mandating risk adjusted payment for both Parts C and D.

CMS' fundamental goal for the abbreviate format RAPS data is to require collection of the minimum data necessary for accurate risk-adjusted payment. We believe that diagnostic data provide the most reliable approach to measuring health status, as required by statute. In the absence of these data, we would not be able to accurately determine the beneficiary's health (risk) status.

The following table summarizes the key functions for data collection for risk adjustment under the Social Security Act as amended by the BBA, BBRA, BIPA, and most recently the MMA.

Table 1. The Roles of Risk Adjustment and Authorizing Legislation

Function	Authorizing legislation (The Social Security Act)
Risk adjusted Part C payment	§1853(a)(1)(C), 1853(a)(1)(I),1853(a)(3)
Data Collection	§1853(a)(3)(B)
Publishing Part C risk factors	§1853(b)(1)(B)
Risk adjusted Part D payment	§1860D-15(a)(1)(A)
Data collection	§1860D-15(c)(1)(C)
Publishing Part D risk factors	§1860D-15(c)(1)(D)
Risk adjustment in Part C bidding (used in determination of benchmarks and premiums	§1854(a)(6)(A)(i) 1854(b)(3)
Risk adjustment in Part D bidding	§1860D-11(b)(2)(B)

2. Information Users

Risk adjustment allows CMS to pay plans for the health risk of the beneficiaries they enroll, instead of paying an identical average amount for each enrollee. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs. Risk adjustment is used to adjust bidding and payment based on the health status and demographic characteristics of an enrollee. Risk scores measure individual beneficiaries' relative risk and the risk scores are used to adjust payments for each beneficiary's expected expenditures. By risk adjusting plan bids, CMS is able to also use standardized bids as base payments to plans.

Table 1 above also summarizes the purposes for which the diagnostic data will be used. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS-HCC and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan.

3. Information Technology

The risk adjustment data is collected 100% electronically. Risk adjustment data are processed through the Risk Adjustment Processing System (RAPS). A summary of the data collection/submission process are as follows.

3.1. Risk Adjustment Data Collection/Submission Overview

MAOs use an electronic connection between the organization and CMS to submit risk adjustment data and to receive information and transaction and system reports in return. Submitters must sign an Electronic Data Interchange (EDI) agreement in advance of submission. MAOs currently have a choice between four connectivity options: CONNECT:DIRECT, Secure File Transfer Protocol (SFTP), Gentran, and TIBCO MFT Internet Server.

In addition, the ICD-10-related implementation date occurred October 1, 2015 as announced by CMS on its ICD-10 webpage at https://www.cms.gov/Medicare/Coding/ICD10/ in final rule CMS-0040-F-issued on July 31, 2014. For the MA program, RAPS data submissions using ICD-9-CM codes were no longer accepted for services provided on or after October 1, 2015. ICD-10 codes are not accepted in RAPS for services prior to October 1, 2015. The ICD-10-CM (diagnoses) codes are to be used by all providers in all health care settings.
MAOs currently have a choice between four connectivity options to submit their data to CMS: CONNECT:DIRECT, Secure File Transfer Protocol (SFTP), Gentran, and TIBCO MFT Internet Server.

MAOs submit RAPS data records to the front-end risk adjustment system (FERAS), which is part of the RAPS system.

3.1.a. Data Submission

In 2002, CMS worked extensively with the industry to develop the abbreviated RAPS format for risk adjustment data submission. The RAPS data layout introduced beginning with the 2004 payment year contains 6-key data elements:

- Member ID
- ICD-CM-10 Code (Diagnosis Cluster* for Each Enrollee Diagnosis
- Submitted) Service from Date
- Service through Date

Provider Type (hospital inpatient-principal diagnosis, hospital inpatient-other diagnoses, hospital outpatient, physician)

- Risk Assessment-Code, whether or not the source of diagnoses is plan enrollee risk assessments that are equivalent to Annual Wellness Visit health risk assessment.

*Each diagnosis cluster is stored as a unique cluster associated with an enrollee's Member ID.

Beginning in late 2012, a Health Risk Assessment (HRA) Indicator was added to the RAPS format. Hospital inpatient, hospital outpatient, and physician risk adjustment data should be submitted to CMS at least quarterly but may also be submitted weekly, bi- weekly, or monthly.

The data collection period for submission of risk adjusted payment data is the calendar year prior to the payment year. In previous years, RAS has limited the addition/deletion of diagnosis codes from claims to only six years from the current submission year. The reporting periods (i.e., Data Submission Schedule) are:

Initial

CMS' first run to calculate beneficiary risk scores occurs in the fourth quarter of the calendar year prior to the payment year to determine the initial risk adjustment scores to be applied to prospective payments for first six months (typically January through June) of the applicable payment year. The Initial submission deadline is the first Friday in September prior to the payment year. It represents the 12-month date of service period that extends from July 1st of a given year (the year prior to the data collection period) through June 30th of the following year (the year of the data collection period).

Mid-Year

The mid-year run occurs in the first quarter of the payment year. It is used to make prospective payments for the next six months (typically July-December) of the applicable payment year, and to update the risk scores created during the initial payment model run using more current data. The payment system adjusts payments for those beneficiaries whose scores have changed since the initial payment model run. The adjustment is made to both the prospective and retrospective (back to January) payments.

The Mid-Year submission deadline is the first Friday in March of each payment year. It represents the calendar year dates of service for the data collection period of the given payment year (January 1st through December 31st of the year prior to the payment year).

Final Reconciliation

The final reconciliation run occurs following the end of the payment year and is subsequently applied to payment for that payment year. It uses all of the complete diagnosis data (with complete submission run-out) from the data collection period (the year prior to the payment year) to create the final (and most accurate) risk adjustment score for the payment year. It retrospectively adjusts payments made in the initial and mid-year runs for members whose scores have changed based on the applicable risk adjustment diagnoses submitted by the Medicare Advantage organization.

The Final submission deadline is no earlier than the last day of January in the year following the payment year.

4. Duplication/Similar Information

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Business

The data submission process is designed to accommodate a wide variety of users. Thus, it maximizes advantages to the small business community by reducing the number of required data elements, providing for multiple enrollee sizes, and allowing for multiple connectivity options and submission formats.

6. Collection Frequency

CMS requires MAOs to collect hospital inpatient, hospital outpatient, and physician risk adjustment data and recommends that MAOs submit diagnostic data at least quarterly to CMS. This timeframe is used to encourage timely data submissions from MAOs which allows for effective system processing by CMS. This also allows for accurate calculation of the risk scores that are used in the payment calculation to MAOs and is also used for risk adjustment payment reconciliation. Each quarter's submission represents approximately one quarter of the data that the organization will submit over the course of the data collection period (12 months). MAOs are also allowed the option of submitting data more frequently such as weekly, bi-weekly, or monthly. There has been no change in collection frequency since the last PRA approval.

7. Special Circumstances

There are no special circumstances with respect to 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 secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on 09/25/2019 (84 FR 50453).

The Centers for Medicare and Medicaid Services (CMS) received one comment from an MAO supporting the continued use of the RAPS system to collect diagnosis data from MAOs. Specifically, the commenter stated that they believed that the RAPS system allows CMS to capture information that the agency can use to inform its payment decisions. The comment did not suggest changes to the Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments. CMS appreciates the support from the commenter. Should further consultation be required, CMS shall contact the commenter to discuss RAPS data collection.

The 30-day notice published in the Federal Register on 03/02/2020 (85 FR 12303).

No comments were received.

9. Payment/Gifts to Respondents

Filing a risk adjustment form itself does not result in payments or gifts to respondents, and many conditions must be met before risk adjusted payment is actually made. However, submitting data for risk adjustment is a required condition of risk adjustment payment under Parts C and D.

10. Confidentiality

The data are protected and kept confidential under System of Record (SOR) # 09–70–0508, entitled "CMS Risk Adjustment Suite of Systems (RASS), HHS/CMS/CM" (August 17, 2015; 80 FR 49237).

We also note that any electronic claims or encounter data sent from providers (hospitals and physicians) to the MAO are HIPAA-covered transactions.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimate (Wages & Hours)

12.1. Summary of Annual Burden Estimates

The figure used to calculate the annual burden represent the average number of risk adjustment diagnoses clusters submitted during CY 2016 thru 2018. We evaluated risk adjustment diagnosis submissions over three years (2016, 2017, and 2018) and came up with an average annual diagnoses count of 1, 117,388,349. When dividing the average number of diagnoses 1,117,388,349 submitted by 10, we arrive at 111,738,834 diagnosis clusters. The RAPS Inbound Record Layout is designed so that each diagnoses cluster can

contain up to 10 diagnoses. According to the 2018 CAQH Index, A Report of Healthcare Industry Adoption of Electronic Business Transactions and Cost Savings (Retrieved from: https://www.caqh.org/sites/default/files/explorations/index/report/2018-index-report.pdf), providers spend three minutes on average submitting electronic transactions. We used this processing time to determine the burden hours for submitting RAPS data.

Number of Clusters	Burden/Cluster	Total Burden Hours
111,738,834	3 minutes (or .05)	5,586,942 Hrs

To derive the cost burden , we used data from the Council of Affordable Quality Healthcare, Inc (CAQH) Index. In the 2018 CAQH Index titled "*A Report of Healthcare Industry Adoption of Electronic Business Transactions and Cost Savings"* the industry cost for each electronic claim submission is reported as $1.54 (Retrieved from: https://www.caqh.org/sites/default/files/explorations/index/report/2018-index-report.pdf). As a result, we multiplied the number of diagnoses clusters, 111,738,834 by the claim submission cost of $1.54 to come to a total of $172,077,804. This calculation as well as the total annual hourly burden is listed below.

Financial Costs

111,738,834 diagnosis clusters X $1.54 cost per transaction = $ $172,077,804 total cost

Cost Comparison from previous PRA Package:

Current Costs:	$172,077,804
- Previous Costs:	$ 9,611,215
=Difference	$162,466,589

Risk Adjustment Data Submission Burden			
			NOTES
A	TOTAL NUMBER OF RESPONDENTS IN 2018	761	761 is the number of MA, MAPD, PDP, PACE contracts, and Cost Contracts.
B	AVERAGE NUMBER OF RISK ADJUSTMENT DIAGNOSIS SUBMISSIONS	1,117,388,349	Based on annual submission of Risk Adjustment data diagnoses in 2016, 2017, and 2018
C	AVERAGE NUMBER OF RISK ADJUSTMENT CLUSTER SUBMISSIONS	111,738,834	Based on annual submission of Risk Adjustment diagnosis clusters in 2016, 2017, and 2018. (D) divided by 10[1]

D	AVERAGE TIME TO SUBMIT DIAGNOSIS CLUSTER	.05 (or 3 Minutes)	Average time it takes to submit a risk adjustment diagnosis cluster – 3 minutes or 3/60 equals .05 Based on average of 3 minutes-per transaction, per CAQH index report from 2018[2]
E	COST PER ELECTRONIC TRANSACTION	$1.54	Based on $1.54 per transaction, per CAQH index report from 2018[2]
F	TOTAL ANNUAL TRANSACTION HOURS	5,586,942	(E) multiplied by (F) (Divided by 60 to convert minutes to hours)
G	TOTAL ANNUAL BURDEN COST	$172,077,804	(E) multiplied by (H)

[1] 10 RAPS diagnoses clusters per RAPS submission

[2] 2018-CAQH Index. *A Report of Healthcare Industry Adoption of Electronic Business Transactions and Cost Savings*. Retrieved from: https://www.caqh.org/sites/default/files/explorations/index/report/2018-index-report.pdf

13. Capital Costs

We do not anticipate significant start-up costs for any new MAOs submitting data. CMS further believes that the connectivity option will equalize the data submission costs regardless of enrollee size.

The capital and operational costs for this data collection that may be incurred by MAOs should be part of their customary and reasonable business practices. Health plans must receive diagnostic data from providers in order to manage the services provided to their enrollees, so they already collect these data. The demographic score is the default score used if no data is submitted by MAOs. In addition, the data are necessary for making risk adjusted payments in accordance with Congressional mandates.

CMS has developed a data collection approach that requires the MAO to submit a minimal number of data elements that are readily available from the different provider settings (hospital inpatient, hospital outpatient, and physician).

14. Cost to Federal Government

The costs to the Federal Government for data collection can best be described as the total costs of acquiring and preparing the required data for MAO payment calculation. Calculation of the precise costs for all processes involved in the data collection is not feasible for the purposes of the Paperwork Reduction Act without conducting a costly study. It is also difficult to disaggregate efforts and resources used for risk adjustment data collection and preparation from other MA payment processes and data collection efforts. Therefore, aggregate costs have been estimated taking into consideration programming, software, training, tapes, overhead costs, etc. CMS's total cost for operating and maintaining risk adjustment data collection is approximately $6.5 million for FY2019.

15. Program and Burden Changes

This iteration proposes burden adjustments to the currently approved burden which reflects data from 2014 and 2015 to reflect data that is reflective of years 2016, 2017, and 2018. Since the previous approval, the number of annual respondents has decreased from 819 to 761, the number of diagnosis clusters increased significantly and the annual hours have increased from 40,650 total hours to 5,586,942 total hours. The total annual cost burden has increased from $9,611,215 to $172,077,804. The increases are due to the increase in the number of diagnoses being submitted (which results from increases in MA enrollment) as well as an increase in the electronic cost of claims submission from $.68 to $1.54.

16. Publication and Tabulation Dates

The purpose of this data collection is to support the development and refinement of risk adjusted rates for beneficiaries who are members of MAOs. Available publication and tabulation dates are:

- Annual publication of the risk adjustment factors that result from the data for plans and other interested entities in the Advance Notice of Methodological Changes for Medicare Advantage (MA) Payment Rates and the Announcement of Medicare Advantage Payment Rates (every March-April).

    a. This information can be found at the following link: Announcements and Documents - https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html
    b. Throughout the year, MAOs receive reports from CMS that communicate activity for enrolled beneficiaries. Reports that are generated provide results of several edit checks regarding enrollment and payment data. If there are any issues related to data submitted, an error report is generated and distributed to the MAOs for review and corrective action. MAOs receive other reports that present summary-level data and detailed information regarding individual diagnoses. Management reports are also generated to assist MAOs with ongoing data collection and submission.

17. Expiration Date

CMS displays the OMB Control number and expiration date on all forms as necessary.

18. Certification Statement

CMS has no exceptions to Item 19, “Certification for Paperwork Reduction Act Submissions,” of OMB Form 83-I.

B. Statistical Methods

CMS will not use statistical methods to collect these data. In order to make accurate payment, CMS needs to collect 100% of the relevant diagnostic data that are used in the risk adjustment models.