Supporting Statement, Part A
Collection of Diagnostic Data 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). Most recently, 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 capitation 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. 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 16 million Medicare beneficiaries who are enrolled in MAOs, and Part D risk adjustment payments applicable to the prescription drug benefit are applied to approximately 36 million beneficiaries. CMS makes prospective monthly payments that are risk adjusted to MAOs and Part D sponsors for each enrollee in an MAO. The purpose of risk adjustment is to pay plan sponsors accurately based on the health status and diagnoses of their Medicare enrollees. CMS risk adjusts beneficiary-level payments for enrollees in MAOs, certain demonstration organizations, Program of All-inclusive Care for the Elderly (PACE) organizations, and Part D sponsors.

As a result, CMS updates and maintains several CMS-HCC (Hierarchical Condition Category) risk adjustment models: a Part C aged/disabled model, an End-Stage Renal Dialysis (ESRD) model, and a model used to pay PACE organizations; further, each of these models is comprised of several segments for subpopulations such as low-income, 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. CMS requires MAOs to submit five data elements which include the Health Insurance Claim (HIC) Number, Diagnosis code, Service from Date, Service through Date, and Provider Type.

Additional payment related projects include, the independent verification and validation of Plan bid data and Medical Loss Ratio 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.) implement system infrastructure development activities legislatively mandated for the MA and MA-PD program, and 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 is to have the least burdensome data submission requirements necessary for accurate payment and appropriate program oversight. We believe that diagnostic data provide the most reliable approach to ensuring that payment calculations are accurate. In the absence of these data, we would not be able to accurately determine the beneficiary's health (risk) status. We further believe that our

limited data set requirement minimizes the burden of data collection and management, while maintaining the accuracy of payment related calculation. Also, by focusing on a small number of critical data elements the ability of MAOs to collect and submit accurate, timely and complete data for the purpose of payment calculations will be optimized. Our overall premise is that in order to fulfill the statutory requirements of the Act, we will need to continue to collect the diagnostic data elements listed below from MAOs.

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)(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	§1854(a)(6)(A)(i) 1854(b)(3)
Risk adjustment in Part D bidding	§1860D-11(b)(2)(B)
Risk adjusted stabilization fund payments	§1858(e)(4)(B)(ii)

2. Information Users

Risk adjustment allows CMS to pay plans for the risk of the beneficiaries they enroll, instead of an average amount for Medicare beneficiaries. 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 annually in advance of submission. MAOs currently have a choice between four connectivity options: CONNECT:DIRECT, File Transfer Protocol (FTP),Gentran, and TIBCO MFT Internet Server which became a new option for 2013. If MAOs decide to use TIBCO MFT as their connection option, then they are responsible for phasing in the new option and phasing out Gentran.

In addition, the ICD-10-related implementation date occurred October 1, 2014, as announced in final rule CMS-0040-F issued on August 24, 2012. This final rule is available at http://www.cms.gov/Medicare/Coding/ICD10/Statute_Regulations.html on the Centers for Medicare & Medicaid Services (CMS) website. On October 1, 2014, medical coding in U.S. health care settings changed from ICD-9-CM to ICD-10. The transition required business and systems changes for MAOs and throughout the health care industry. ICD-9-CM codes are no longer accepted for services provided on or after October 1, 2014. ICD-10 codes are not accepted for services prior to October 1, 2014. The ICD-10-CM (diagnoses) codes are to be used by all providers in all health care settings. Each ICD-10-CM code is 3 to 7 characters, the first being an alpha character (all letters except U are used), the second character is numeric, and characters 3-7 are either alpha or numeric (alpha characters are not case sensitive), with a decimal after the third character. The ICD-10-PCS codes are for use only on hospital claims for inpatient procedures. ICD-10-PCS codes are not to be used on any type of physician claims for physician services provided to hospitalized patients. These codes differ from the ICD-9-CM procedure codes in that they have 7 characters that can be either alpha (non-case sensitive) or numeric. The numbers 0 - 9 are used (letters O and I are not used to avoid confusion with numbers 0 and 1), and they do not contain decimals.

3.1.a. Data Collection

MAOs currently have a choice between four connectivity options to submit their data to CMS: CONNECT:DIRECT, File Transfer Protocol (FTP), Gentran, and TIBCO MFT Internet Server which became a new option for 2013. If MAOs decide to use TIBCO MFT as their connection option, then they are responsible for phasing in the new option and phasing out Gentran.

Once an MAO submits Risk Adjustment data to CMS, they must submit the data in either the RAPS format or via Direct Data Entry (DDE).

3.1.b. Data Submission

CMS worked extensively with the industry to develop a minimum required data set for risk adjustment in order to reduce the reporting burden. The risk adjustment minimum data set contains 5 key data elements:

- Health Insurance Claim Number (HIC Number)
- ICD-9-CM Code/ICD-10 (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)

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

As of 2012, MAOs must submit data to CMS in the RAPS format. Beginning in late 2012, a Health Risk Assessment (HRA) Indicator was added to the RAPS format. Previously, organizations could also submit data using standard fee for service claims. Only two plans were submitting under formats other than RAPS, however. Working with CMS these two plans were able to convert to the RAPS format in two months. Hospital inpatient, hospital outpatient, and physician risk adjustment data must be submitted to CMS at least quarterly but may also be submitted weekly, bi-weekly, or monthly.

The base 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

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 through June 30th of the following year. Risk adjustment payments are reset in January each year to reflect new rates and risk scores.

Mid-Year

The Mid-Year submission deadline is the first Friday in March of each payment year. It represents the calendar year dates of service period from January 1st through December 31st of the year prior to the payment year. Payments are updated each July to reflect the mid-year risk adjustment update.

Reconciliation

The Final submission deadline is the last day of January in the year following the payment year. It represents the final reconciliation data for dates of service from January 1st through December 31st of the year prior to the payment year. Final reconciled payments are made in August of 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 to 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 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 July 22, 2016 (81 FR 47807). Comments were received. The comments and our response is attached to this package.

9. Payment/Gifts to Respondents

Filing an encounter form or claim 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 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. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

Bureau of Labor Statistics (BLS) Occupation Title	BLS Occupation Code	Mean Hourly Wage ($/hr)	Mean Annual Wage ($/hr)
Computer and Information Systems Managers	11-3021	$67.79	$141,000

We are adjusting our employee hourly wage estimates by a factor of 100 percent which 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.

12.2. Burden Estimates

The burden associated with reporting risk adjustment data depends upon two factors, the amount of data that must be reported and the percentage of data that is reported using automated vs. manual processes. The amount of data that must be reported is a function of the number of diagnoses that will be reported per beneficiary and the number of reports that will be filed per beneficiary.

As the frequency distribution of the number of beneficiary diagnoses per year demonstrates in the table below, 44% of beneficiaries have 6 or fewer significant diagnoses reported per year that are used in risk adjustment. The below table illustrates the beneficiary diagnosis submission frequency that occurred in 2014.

MA Beneficiary Diagnosis Submission Frequency (As of 2014)			
Number of Beneficiary Diagnoses per Year	Frequency	Cumulative Frequency	Percent of Beneficiaries
0	1,265,487	1,265,487	7.93%

MA Beneficiary Diagnosis Submission Frequency (As of 2014)			
1	692,867	1,958,354	4.34%
2	928,157	2,886,511	5.81%
3	1,069,587	3,956,098	6.70%
4	1,074,685	5,030,783	6.73%
5	1,008,279	6,039,062	6.32%
6	930,149	6,969,211	5.83%
7	846,923	7,816,134	5.30%
8	766,317	8,582,451	4.80%
9	691,728	9,274,179	4.33%
10	626,529	9,900,708	3.92%
11	563,867	10,464,575	3.53%
12	508,696	10,973,271	3.19%
13	459,206	11,432,477	2.88%
14	414,830	11,847,307	2.60%
15	373,423	12,220,730	2.34%
16	338,590	12,559,320	2.12%
17	306,202	12,865,522	1.92%
18+	3,100,232	15,965,754	19.42%
Total	15,965,754	N/A	100.00%

*This source of this data is the Risk Adjustment Processing System.

We know that 7.93% of beneficiaries had no significant diagnoses reported in Service Year 2013, meaning that at least 7.93% of MA enrollees had no risk adjustment data reported that year.

12.3. Summary of Annual Burden Estimates

The estimated annual electronic processing cost per each Risk Adjustment file is $0.68 per the 2016 CAQH Index Report (http://www.caqh.org/sites/default/files/explorations/index/report/2016-caqh-index-report.pdf). Thus, the total estimated cost of transaction is $9,611,215 when multiplying $0.68 by the total number of Risk Adjustment diagnoses cluster submissions for 2014 (14,134,139). Each diagnoses cluster can contain up to 10 diagnoses. When dividing by the total number of diagnoses submitted by 10, 141,341,392, we arrive at 14,134,139 diagnosis clusters. We divided the total estimated cost of transactions by the total number of respondents in 2014 to get the annual cost to a respondent which results in $11,735.30 per plan. The table below provides more details on these calculations.

Risk Adjustment Data Submission Burden 2014			
			NOTES
A	TOTAL NUMBER OF RESPONDENTS IN 2014	819	819 is the number of MA, MAPD, PDP, PACE contracts, and Cost Plans.
B	TOTAL NUMBER OF MEDICARE BENEFICIARIES ENROLLED IN MEDICARE	39,594,637	Number of Medicare managed care enrollees in Part C, Part D, PACE, Cost HMOs/CMPs,

	MANAGED CARE PLANS PER YEAR IN 2014		HCPPs, and MMPs
C	AVERAGE NUMBER OF BENEFICIARIES PER PLAN	48,345	(B) divided by (A)
D	TOTAL NUMBER OF RISK ADJUSTMENT DIAGNOSIS SUBMISSIONS IN 2014	141,134,392	
E	TOTAL NUMBER OF RISK ADJUSTMENT CLUSTER SUBMISSIONS IN 2014	14,134,139	Based on annual submission of Risk Adjustment diagnosis clusters in 2014 (D) divided by 10[1]
F	AVERAGE NUMBER OF CLUSTER SUBMISSIONS PER MA PLAN	17,258	Average Risk Adjustment records per beneficiary per year (E) divided by (A)
G	AVERAGE NUMBER OF TRANSACTIONS PER HOUR	2,226,328	Estimated average processing volume per hour
H	AVERAGE COST PER ELECTRONIC TRANSACTION	$.68	Based on $.68 per transaction, per CAQH index report from 2016[2]
I	TOTAL COST OF ANNUAL TRANSACTIONS	$9,611,215	(E) multiplied by (H)
J	AVERAGE COST PER BENEFICIARY	$.24	(I) divided by (B)
K	ANNUAL COST TO A PLAN	$11,735.30	(I) divided by (A)

10 RAPS diagnoses clusters per RAPS submission

2016 CAQH Index. *A Report of Healthcare Industry Adoption of Electronic Business Transactions and Cost Savings*. Retrieved from: http://www.caqh.org/sites/default/files/explorations/index/report/2016-caqh-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

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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 expected to be approximately $9.4 million for FY2017.

15. Program and Burden Changes

This iteration does not propose any program changes or burden adjustments.

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

- 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

The expiration date will be displayed on www.csscoperations.com which contains Risk adjustment

documentation and references for the plans as well as help desk and technical assistance.

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.