SUPPORTING STATEMENT PART A
Collection of Risk Adjustment Data from MA Organizations,
Section 1876 Cost HMOS/CMPS, Section 1833 HCPPS, MMPS, and PACE Organizations
CMS-10340, OMB 0938-1152

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 MA organizations, with higher payments for enrollees at risk for being sicker, and lower payments for enrollees predicted to be healthier.

On December 30, 2011, CMS first received OMB approval to collect risk adjustment data, or data on each item or service delivered to enrollees of MA plans offered by Medicare Advantage organizations as defined at 42 CFR 422.4. Medicare Advantage organizations currently obtain this data from providers. We collect this information using standard HIPAA transaction forms and code sets. Typically these data would be collected by MA organizations and other entities for general business activities such as claims payment, coordination of benefits, eligibility and enrollment, and quality improvement activities. Pursuant to 42 CFR 422.4 and 422.310, each MA organization must submit encounter data to CMS that is used to determine the risk adjustment factors for payment as well as to update the risk adjustment model, calculate Medicare Disproportionate Share Hospital (DSH) percentages, for Medicare coverage purposes, and for quality review and improvement activities.

CMS has also begun collecting risk adjustment data using similar formats for each item or service delivered to enrollees of section 1876 Cost HMOs/CMPs, section 1833 HCPPs, PACE organizations, and MMPs. Additional uses for the data include verifying the accuracy and validity of the costs claimed on Cost Reports. For PACE organizations, risk adjustment data would serve the same purposes it does related to the MA program and would be submitted in a similar manner. For MMPs, risk adjustment data serves the same purposes it does related to the MA program and is submitted using the ASC X12N 837/005010, NCPDP, and 837-D Dental formats. This also includes the collection of Medicaid data.

The currently approved title for this information collection request is, “Collection of Encounter Data from Medicare Advantage Organizations.” This iteration proposes to revise the title to

read, “Collection of Risk Adjustment Data from MA Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 HCPPS, MMPS), and PACE Organizations.”

We have revised the CSSC Operations Submitter Application Instruction and CSSC Operations Submitter Authorization Forms (see the attached Crosswalk). Our currently approved burden estimates have been revised as a result of these changes. In addition, the Institutional, Professional, and DME companion guides have been added to this package since the system processes all institutional, professional, and DME claims. We are also requiring MA management to complete a PRS Contract and Contact Verification Form to approve their contract jurisdiction. We have clarified the submission timeframes in section 6 of this Supporting Statement based on the release of the reconciliation reports. The burden for these claims is built into the cost of effort for a plan per year that is calculated in section 15 of this Supporting Statement.

A. Justification

1. Legal Basis and Needs

Section 1853 of the Act requires CMS to make advance monthly payments to a Medicare Advantage (MA) organization for each beneficiary enrolled in an MA plan offered by the organization for coverage of Medicare Part A and Part B benefits. Section 1853(a) (1) (C) of the Act requires CMS to adjust the monthly payment amount for each enrollee to take into account the health status of MA plan enrollees. Under the CMS-Hierarchical Condition Category (HCC) risk adjustment payment methodology, CMS determines risk scores for MA enrollees for a year and adjusts the monthly payment amount using the appropriate enrollee risk score.

Under section 1853(a)(3)(B) of the Act, MA organizations and other entities are required to ‘‘submit data regarding inpatient hospital services . . . and data regarding other services and other information as the Secretary deems necessary’’ in order to implement a methodology for ‘‘risk adjusting’’ payments made to MA organizations. Risk adjustments to payments are made in order to take into account ‘‘variations in per capita costs based on [the] health status’’ of the Medicare beneficiaries enrolled in an MA plan offered by the organization. Submission of data on inpatient hospital services has been required with respect to services beginning on or after July 1, 1997. Submission of data on other services has been required since July 1, 1998.

While we initially required the submission of comprehensive data regarding services provided by MA organizations, including comprehensive inpatient hospital risk adjustment data, we subsequently permitted MA organizations to submit an ‘‘abbreviated’’ set of data. We currently collect limited risk adjustment data from MA organizations, primarily diagnosis data under OMB control number 0938-0878 (CMS-10062). The current information request of OMB control number 0938-1152 (CMS-10340) requires MA plans to submit more comprehensive data regarding services provided by MA organizations. Therefore, the overall burden of the current information request is expected to be higher than the burden of OMB control number 0938-0878 (CMS-10062). The currently approved package states an estimated 34,433 total transaction hours for the industry. We are currently proposing 19,479 current hours

which is a decrease of 14,954 total hours. Although the total annual transaction hours have decreased, the cost of annual transaction hours has increased from the $1,136,289 in the currently approved package to a proposed total cost of annual transaction hours of $523,184,582. Therefore, the proposed total annual cost to a respondent is $757,141. This is due to the average increase of encounter diagnoses submissions (769,389,091) from 2015 through 2017 as well as the average cost increase of an electronic transaction of $0.68.

From calendar years 2000 through 2006, the application of risk adjustment to MA payments was ‘‘phased in’’ with an increasing percentage of the monthly capitation payment subjected to risk adjustment. Prior to calendar year 2000, and in diminishing proportion from 2000-2006, CMS also adjusted monthly capitation payments based on “demographic” factors such as age, disability status, gender, and institutional status. Beginning with calendar year 2007, 100 percent of payments to MA organizations have been risk-adjusted. Given the increased importance of the accuracy of our risk adjustment methodology, we amended § 422.310 in August of 2008 to authorize the collection of data from MA organizations regarding each item and service provided to an MA plan enrollee. Collection of such data would allow CMS to incorporate the Medicare Advantage utilization in the development of the risk adjustment models for the Medicare Advantage program.

A similar rationale applies to PACE organizations which are also paid under section 1853 of the Social Security Act (see section 1894(d) of the Act).

Section 1876 Cost HMOs/CMPs are paid reasonable costs actually incurred under the authority in section 1876(h)(3) of the Act. Section 1833 HCPPs are paid reasonable costs under the authority in section 1833(a)(1)(A) of the Act. Reasonable costs are further defined in section 1861(v) of the Act. CMS has the authority to require Cost HMOs/CMPs to submit risk adjustment data under 42 CFR 417.568(b)(1) which requires submission of “adequate cost and statistical data that can be verified by qualified auditors,” and 42 CFR 427.576(b)(2)(iii) which requires “[a]ny other information required by CMS” for purposes of final cost-settlement of payment amounts due. CMS also has the authority to require HCPPs to submit risk adjustment data under 42 CFR 417.806(c) to access “records of the HCPP...that pertain to the determination of amounts payable for covered Part B services furnished its Medicare enrollees” and 42 CFR 417.871(b)(2)(iii) to require “other data as specified by CMS” for purposes of final cost-settlement of payment amounts due. In short, in addition to the other stated purposes for collection of risk adjustment data, with respect to section 1876 Cost HMOs/CMPs and section 1833 HCPPs, additional data submission requirements included in this encounter collection data will assist us in verifying the accuracy and validity of the costs claimed on Cost Reports.

We are also requiring that accountable MA management approve their contract jurisdiction before any pharmacy reconciliation reports are submitted to them by completing a PRS Contract and Contact Verification form. This data is collected electronically and on an annual basis. The change is set out in sections 12 and 15 of this Supporting Statement.

<u>Current Uses</u>

Now that risk adjustment data for MA enrollees are available, CMS has beneficiary-specific information on the utilization of services by MA plan enrollees. These data can now be used to develop and calibrate the CMS–HCC risk adjustment models using MA patterns of diagnoses and expenditures. These models will be used to risk adjust payment to beneficiaries enrolled in Medicare Advantage plans. As stated in Title 42, CFR, § 422.4 (RIN 0938-AN06) and 42 CFR § 422.310 (RIN 0938-AN06), , we clarified that CMS' uses of these data may include disclosure to CMS contractors or other agents that perform activities or analyses on CMS' behalf in connection with authorized use of the data. As stated in the existing regulation at § 422.310, there are five specified purposes of the data: (1) to determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c); (2) to update risk adjustment models; (3) to calculate Medicare DSH percentages; (4) to conduct quality review and improvement activities; and (5) for Medicare coverage purposes. We restructured paragraph (f) to identify the purposes for which CMS may use and release risk adjustment data and to impose certain conditions on any release of that data. CMS revised paragraph (f) to add four purposes of the data, as paragraphs (f)(1)(vi) through (ix), for which CMS may use risk adjustment data submitted by MA organizations. These uses are stated as: (1) to conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research; (2) for activities to support the administration of the Medicare program; (3) for activities conducted to support program integrity; and (4) for purposes permitted by other laws.

Legal Authority

The following table summarizes the key functions for data collection for risk adjustment and the authorizing legislation under the Social Security Act as amended by the BBS (Public Law 105-33), BBRA (Public Law 106-113), BIPA (Public Law 106-554), and most recently the MMA (Public Law 108-173) and the current regulations.

Roles of Risk Adjustment/Encounters and Authorizing Legislation/Regulations

Function	**Authorizing legislation**
Risk adjusted Part C payment	1853(a)(1)(G)
Risk adjusted Part D payment	1860D-15(a)(1)
Data Collection	1853(a)(3)(B), 1860D-
Establishment of risk methodology and factors	1853(a)(3)
Publishing Part C risk factors	1853(b)
Publishing Part D risk factors	1860D-15(c)(1)(D)
Risk adjustment in Part C bidding (used in determination of benchmarks and premiums) and Computation of average per capita	1854(a)(6)(A)(i) 1854(b)(3)
Calculating Medicare DSH percentages, Medicare coverage purposes	1886(d)(5)(F)(vi)
Quality review and improvement activities	1852(e)
Payment to §1876 Cost HMOs/CMPs and Reasonable Cost	1876(h)(3) and 1861(v)

Submission of Risk Adjustment Bids and Premiums	1860(D)-11(b)
Risk Adjusted Stabilization Fund Payments	1858(e)(4)(B)(ii)
Payment to §1833 HCPPs and Reasonable Cost	1833(a)(1)(A) and
Payment to PACE organizations	1894(d)
Medicare and Medicaid Innovation	1115A [42 U.S.C.
Risk Adjustment Data	Title 42 – Chapter 4 – Subchapter B – Part 422

2. Information Users

CMS uses the risk adjustment data to develop individual risk scores for risk adjusted payment under Part C. As required by law, CMS also establishes the risk adjustment methodology and annually publishes the risk adjustment factors for MA organizations 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). Risk adjustment data in particular is used to calibrate the CMS-HCC risk adjustment models using MA patterns of diagnoses, utilization, and expenditures. Starting with Payment Year (PY) 2016, CMS performed a blend of Risk Adjustment Processing Data, Encounter Data, and Fee-For-Service as data sources applied to the CMS-HCC and RxHCC models. The blending ratio used in PY2016 was 90% Risk Adjustment Processing Data and 10% Encounter Data. In addition, CMS performed a blend of 75% Risk Adjustment Processing Data and 25% Encounter Data for PY2017 and a blend of 85% Risk Adjustment Processing Data and 15% Encounter Data for PY2018.

More information on these blends can be found in the Advance Notice of Methodological Changes for Medicare Advantage (MA) Payment Rates and the Announcement of Medicare Advantage Payment Rates (every March-April) at the following link: Announcements and Documents - https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html

While determining the risk adjustment factors used to adjust payments and establishing a risk adjustment model appropriate for the MA program are the paramount reasons for collecting MA risk adjustment data, there are other important uses of the data that will improve other key functions undertaken by CMS. Data is used for the calculation of Medicare Disproportionate Share Hospital (DSH) payments. CMS collects inpatient stay information for the Medicare managed care enrollees. In particular, we collect the admission date, discharge date, Health Insurance Claim Number (HICN), and Medicare hospital number/CCN.

Further, we also use the data for quality review and improvement activities. For example, MA risk adjustment data may be used in the development and calculation of quality measures for MA organizations.

Other uses for the data include geographical acuity studies, utilization trends and detection of abuse as defined in the False Claim Act.

Additional uses for the data include verifying the accuracy and validity of the reasonable costs claimed on Cost Reports submitted by section 1876 Cost HMOs/CMPs and section 1833 HCPPs. CMS only requires submission of risk adjustment data for items/services for which such plans claim costs on their CMS Cost Reports. These submissions are important because they will assist us in calibrating the Part C and Part D risk adjustment models. Additionally, in the absence of risk adjustment data for cost plan enrollees, risk scores for them under Part D would be inaccurate. (Many cost plan enrollees, both section 1876 Cost HMO/CMP and section 1833 HCPP enrollees, are enrolled in Part D – either through their section 1876 Cost HMO/CMP, or another Part D sponsor.) Finally, should cost plan enrollees later join a Part C plan, risk adjusted payments to that new Part C plan would be inaccurate in the absence of cost plan risk adjustment data.

We also restructured paragraph § 422.310 (f) to identify the purposes for which CMS may use and release risk adjustment data and to impose certain conditions on any release of that data. CMS revised paragraph (f) to add four purposes of the data, as paragraphs (f)(1)(vi) through (ix), for which CMS may use risk adjustment data submitted by MA organizations. These uses are stated as: (1) to conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research; (2) for activities to support the administration of the Medicare program; (3) for activities conducted to support program integrity; and (4) for purposes permitted by other laws.

Finally, as stated in the regulation at § 422.310, we use the data for Medicare coverage purposes. For example, we can use risk adjustment data for the determination of whether day limits have been exhausted and, if not, how many such days are left.

3. Use of Information Technology

The risk adjustment data is collected 100% electronically. Risk Adjustment data is processed through the Customer Support Front End System (CSFES). A summary of the data collection/submission process is as follows:

Risk Adjustment Data Collection/Submission Overview

CMS has built a suite of systems and is now operating and maintaining, the Risk adjustment data Systems (RAS), to collect and price risk adjustment data for items and services provided to beneficiaries enrolled in MA organizations, PACE organizations, Cost HMOs/CMPs and HCPPs, as well as MMPs and PDEs. The RAS consists of the following new functionalities:

- capability to receive, edit and process risk adjustment data,
- transaction reporting
- an operational data store,
- risk adjustment data pricing, and
- risk adjustment data analysis and reporting system.

MA organizations and other entities use an electronic connection between the organization and CMS to submit risk adjustment data and to receive information in return. CMS collects the data electronically from MA organizations via the HIPAA compliant standard Health Care Claims transactions for professional data (currently using implementation guide ASC X12N 837/005010X222 *with* Errata for ASC X12N 837/05010X222A1), institutional data (currently using implementation guide ASC X12N 837/005010X223 *with* Errata for ASC X12N 837/05010X223A2), Durable Medical Equipment (DME) (currently using implementation guide ASC X12N 837/005010X223 *with* Errata for ASC X12N 837/05010X223A2), Risk Adjustment Processing system (RAPS) data, National Council for Prescription Drug Programs (NCPDP) data**,** Prescription Drug Event (PDE) data, and dental data. Submitters must sign an Electronic Data Interchange (EDI) agreement in advance of their submission. MA organizations and other entities have a choice between three connectivity options: CONNECT:DIRECT, File Transfer Protocol (FTP) and Gentran. It is also required that accountable MA management approve their contract jurisdiction before any pharmacy reconciliation reports are submitted to them by completing a PRS Contract and Contact Verification form. This data is collected electronically on an annual basis. In addition, CMS has provided specific training and communications to the industry regarding risk adjustment data submission under these standards. These communications can be found at www.csscoperations.com. CMS' instructions to the industry include companion guides for institutional, professional, and DME claims to be used in conjunction with the associated 837 Implementation Guides.

The information collection effort includes a data collection instrument that is updated every three years to validate accountable MA management (i.e. Survey or form).

4. Duplication of Efforts

The information collection requirements are not duplicated through any other effort and the information cannot be obtained from any other source. In the case of cost plans, we will obtain data from the FFS claims processing system and add it to risk adjustment data submitted by cost plans for their cost plan enrollees to ensure correct computation of risk scores for these enrollees.

For section 1876 Cost HMOs/CMPs and section 1833 HCPPs, CMS will only require submission of risk adjustment data for items/services for which such plans claim costs on their CMS Cost Reports or for items/services not reimbursed by FFS Medicare.

5. Small Businesses

The collection of information has a minimal impact on small businesses or other small organizational entities since the applicants must possess an insurance license and be able to accept risk. Generally, state statutory licensure requirements effectively prevent small organizations from accepting the level of risk needed to provide the medical benefits required in the MMP and Medicare Advantage program.

For cost plans (both section 1876 Cost HMOs/CMPs and section 1833 HCPPs), the average

enrollment is over 24,000 Medicare enrollees per cost plan and cost plan sponsors have substantial enrollment in the form of commercial membership (section 1876 Cost HMOs/CMPs) or other employer group members (section 1833 HCPPs).

6. Collection Frequency

We have clarified the submission timeframes here based on the release of the reconciliation reports (collection of data is annual) and on our experience with Prescription Drug Event and Risk Adjustment Data. All claim types, including hospital inpatient, hospital outpatient, and physician risk adjustment data would be required to be submitted according to a specific schedule that is based on the size of the MA (or other entity) contract. The schedule in the following table is for encounter data submissions

Number of Medicare Enrollees	Minimum Submission Frequency
Greater than 100,000	Weekly
50,000 – 100,000	Bi-weekly
Less than 50,000	Monthly

PACE organizations and section 1876 Cost HMOs/CMPs and section 1833 HCPPs have similar options and requirements.

CMS publishes the final submission deadlines that are applicable for risk adjustment in an annual HPMS memorandum.

MA organizations and other entities are encouraged to submit data more frequently.

7. Special Circumstances

As discussed above in section 6 of this Supporting Statement, reporting may be more often than quarterly. Additionally, the reported data are protected and kept confidential under System of Record (SOR) # 09-70-0506 and 09-07-0508.

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

- 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; or
- 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.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on August 5, 2016 (81 FR 51916). One comment submission was received and is attached to this package along with our response.

CMS has revised the package subsequent to the publication of the 60-day Federal Register notice. Changes have been made to the CSSC Operations Submitter Application Instruction and CSSC Operations Submitter Authorization Forms. Our currently approved burden estimates have not been revised as a result of these changes.

For the CSSC Operations Submitter Application Instruction Form, currently approved connectivity options state that submitters must establish a connection to the Front-End System through CMSNet provided by Ability network. In this iteration we propose to update the language to reflect that submitters can now establish connection through any CMS approved Network Service Vendor (NSV).

For the CSSC Operations Submitter Authorization Form, currently approved instructions state that the completed form may be submitted online, printed and faxed, or scanned and sent via email address for processing. In this iteration we propose to update the language to reflect that the form may only be submitted online or scanned and sent via email. The form can no longer be printed and faxed.

The 30-day notice published in the Federal Register on December 2, 2016 (81 FR 87034). We did not receive any comments.

9. Payments/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 Notice (SORN) #09-70-0506 (June 17, 2014; 79 FR 34539) and 09-07-0508 (August 17, 2015; 80 FR 49237).

We also note that any electronic claims or risk adjustment data sent from providers (hospitals and physicians) to MA, MMPs, and PACE organizations and cost plans are HIPAA-covered transactions. The HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. The Security Rule (45 CFR Part 160 and Subparts A and C of Part 164) specifies a series of administrative, physical, and technical safeguards for covered entities to use to assure the confidentiality, integrity, and availability of

electronic protected health information.

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 Estimates (Hours & Wages)

12.1 Wage Estimates

The purpose of this data submission request is to support the payment of Medicare Advantage for beneficiaries who are members of Part C plans and to verify the accuracy and validity of the reasonable costs claimed on Cost Reports submitted by section 1876 Cost HMOs/CMPs, section 1833 HCPPs, and MMPs. CMS only requires submission of risk adjustment data for items/services for which such plans claim costs on their CMS Cost Reports. These submissions are important because they will assist us in calibrating the Part C and Part D risk adjustment models. Additionally, in the absence of risk adjustment data for cost plan enrollees, risk scores for them under Part D would be inaccurate. (Many cost plan enrollees, both section 1876 Cost HMO/CMP and section 1833 HCPP enrollees, are enrolled in Part D – either through their section 1876 Cost HMO/CMP, or another Part D sponsor.) Finally, should cost plan enrollees later join a Part C plan, risk adjusted payments to that new Part C plan would be inaccurate in the absence of cost plan risk adjustment data.

The burden placed on MA, MA-PD plans and MMPs (contracts), PACE organizations and cost plans (section 1876 Cost HMOs/CMPs and section 1833 HCPPs) associated with submitted risk adjustment data is predicated upon the following factors: (1) the amount of data that must be submitted; (2) the number of plans submitting data; and (3) the time required to complete the data processing and transmission transactions.

Based on the Collection Frequency, all claim types, including hospital inpatient, hospital outpatient, and physician risk adjustment data are required to be submitted according to a specific schedule that is based on the size of the MA (or other entity) contract. The schedule in the following table is for encounter data submissions and outlines cost based on submission frequency. Based on 2016 data, the annual cost to a respondent results in $757,141 per plan. For a plan submitting on a weekly basis, the cost to a respondent results in $14,560; a plan submitting on a bi-weekly basis, the cost to a respondent results in $29,121; a plan submitting on a monthly basis, the cost to a respondent results in $63,095.

Number of Medicare Enrollees	Minimum Submission Frequency	Cost
Greater than 100,000	Weekly	$14,560
50,000 – 100,000	Bi-weekly	$29,121
Less than 50,000	Monthly	$63,095

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 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 (calculated at 100 percent of salary), and the adjusted hourly wage.

National Occupational Employment and Wage Averages

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Computer Systems Analyst	15-1121	44.05	44.05	88.10

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily 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 Requirements and Annual Burden Estimates

The burden associated with data reporting 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 submitted is a function of the number of beneficiaries per contract and the number of services provided per encounter.

12.2.1 CMS EDI Agreement

Agreement Form: The MA organizations and other entities complete the EDI agreement forms to establish an electronic connection between the organization and CMS to submit risk adjustment data and to receive information in return. Submitters must sign an EDI agreement in advance of submission. MA organizations and other entities would have a choice between three connectivity options: CONNECT: DIRECT, File Transfer Protocol (FTP), and Gentran.

For new plans, we estimate that it will take approximately 5 minutes (0.083 hr) at $88.10/hr for a computer systems analyst to complete the EDI agreement form process for one MA plan. In aggregate we estimate 57 hours (691 managed care contracts x 0.083 hr) at a cost of $5,021.70 (57 hr x $88.10/hr) or $7.27 per contract. (See Table 2, below.) In 2016, there were a total of 691 managed care contracts. This number was obtained from the CMS Health Plan Management System (HPMS) and includes MA Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 HCPPS, MMPS, and PACE Organizations.

12.2.2 Submitter Application and Instructions

Application and Instructions: This form is required to be completed if Medicare Advantage plans or third party submitters wish to request to receive a Submitter Identification number from CMS. This submitter ID obtained from the application process allows either party to submit plan

data to CMS.

For new plans, we estimate that it will take approximately 5 minutes (0.083 hr) at $88.10/hr for a computer systems analyst to complete the Submitter Application process for one MA plan. In aggregate we estimate 57 hours (691 managed care contracts x 0.083 hr) at a cost of $5,021.70 (57 hr x $88.10/hr) or $7.27 per contract. (See Table 2, below.)

12.2.3 Submitter Authorization

Authorization Form: This form is required to be completed for Medicare Advantage plans or third party submitters to be authorized to submit their risk adjustment data to CMS.

For new plans, we estimate that it will take approximately 15 minutes (0.25 hr) at $88.10/hr for a computer systems analyst to complete the Submitter Authorization form for one MA plan. In aggregate we estimate 173 hours (691 managed care contracts x 0.25 hr) at a cost of $15,241.30 (173 hr x $88.10/hr) or $22.06 per contract. (See Table 2, below.)

12.2.4a Connect: Direct Application – RAPS

Application Form: This form is required to be completed for Medicare Advantage plans or third party submitters to be authorized to gain access to the Connect: Direct application. This will allow the MA plans to submit their risk adjustment data directly to the CMS RAPS application. There are separate forms for the Encounter, PDE, and MMP applications.

For new plans, we estimate that it will take approximately 7 minutes (0.116 hr) at $88.10/hr for a computer systems analyst to complete a Connect: Direct Application form for one MA plan. In aggregate we estimate 80 hours (691 managed care contracts x 0.116 hr) at a cost of $7,048.00 (80 hr x $88.10/hr) or $10.20 per contract. (See Table 2, below.)

12.2.4b Connect: Direct Application – Encounter Data

Application Form: This form is required to be completed for Medicare Advantage plans or third party submitters to be authorized to gain access to the Connect: Direct application. This will allow the MA plans to submit their risk adjustment data directly to the CMS Encounter application. There are separate forms for the RAPS, PDE, and MMP applications.

For new plans, we estimate that it will take approximately 7 minutes (0.116 hr) at $88.10/hr for a computer systems analyst to complete a Connect: Direct Application form for one MA plan. In aggregate we estimate 80 hours (691 managed care contracts x 0.116 hr) at a cost of $7,048.00 (80 hr x $88.10/hr) or $10.20 per contract. (See Table 2, below.)

12.2.4c Connect: Direct Application – PDE

Application Form: This form is required to be completed for Medicare Advantage plans or third party submitters to be authorized to gain access to the Connect: Direct application. This will allow the MA plans to submit their risk adjustment data directly to the CMS PDE application.

There are separate forms for the RAPS, Encounter, and MMP applications.

For new plans, we estimate that it will take approximately 7 minutes (0.116 hr) at $88.10/hr for a computer systems analyst to complete a Connect: Direct Application form for one MA plan. In aggregate we estimate 80 hours (691 managed care contracts x 0.116 hr) at a cost of $7,048.00 (80 hr x $88.10/hr) or $10.20 per contract. (See Table 2, below.)

12.2.4d Connect: Direct Application - MMP

Application Form: This form is required to be completed for Medicare Advantage plans or third party submitters to be authorized to gain access to the Connect: Direct application. This will allow the MA plans to submit their risk adjustment data directly to the CMS MMP application. There are separate forms for the RAPS, Encounter, and PDE applications.

For new plans, we estimate that it will take approximately 7 minutes (0.116 hr) at $88.10/hr for a computer systems analyst to complete a Connect: Direct Application form for one MA plan. In aggregate we estimate 80 hours (691 managed care contracts x 0.116 hr) at a cost of $7,048.00 (80 hr x $88.10/hr) or $10.20 per contract. (See Table 2, below.)

Please note that this form only needs to be completed once in the lifetime of every MA plan.

12.2.5 PRS Contract and Contact Verification Form

Verification Form: We are also requiring that accountable MA management approve their contract jurisdiction before any pharmacy reconciliation reports are submitted to them by completing the PRS Contract and Contact verification form. This data is collected electronically and on an annual basis. The information collection effort includes a data collection instrument that is updated annually to validate accountable MA management (i.e. Survey or form). Collection of this data will prevent breach of confidentiality for beneficiaries.

We estimate that it will take approximately 5 minutes (0.083 hr) at $88.10/hr for a computer systems analyst to complete the EDI agreement process for one MA plan. In aggregate we estimate 57 hours (691 managed care contracts x 0.083 hr) at a cost of $5,021.70 (57 hr x $88.10/hr) or $7.27 per contract. (See Table 2, below.)

Please note that this form only needs to be completed once in the lifetime of every MA plan.

12.2.6a CMS 837 Institutional Companion Guide

The CMS Encounter Data 837-I Companion Guide addresses how MA organizations and other entities conduct Institutional claims Health Information Portability and Accountability Act (HIPAA) standard electronic transactions with CMS. The CMS EDS supports transactions adopted under HIPAA, as well as additional supporting transactions described in the guide.

We estimate that it will take approximately 455 minutes (7.5 hr) at $88.10/hr for a computer systems analyst to read the CMS 837 Institutional Companion Guide for one MA plan. In

aggregate we estimate 5,182.5 hours (691 managed care contracts x 7.5 hr) at a cost of $456,578 (5,182.5 hr x $88.10/hr) or $660.75 per contract. (See Table 2, below.)

12.2.6b CMS 837 Professional Companion Guide

The CMS Encounter Data 837-P Companion Guide addresses how MAOs and other entities conduct Professional claims Health Information Portability and Accountability Act (HIPAA) standard electronic transactions with CMS. The CMS EDS supports transactions adopted under HIPAA, as well as additional supporting transactions described in the guide.

We estimate that it will take approximately 405 minutes (6.75 hr) at $88.10/hr for a computer systems analyst to read the CMS 837 Professional Companion Guide for one MA plan. In aggregate we estimate 4,664.25 hours (691 managed care contracts x 6.75 hr) at a cost of $410,920 (4,664.25 hr x $88.10/hr) or $594.68 per contract. (See Table 2, below.)

12.2.6c CMS 837 DME Companion Guide

The CMS Encounter Data 837-P Companion Guide addresses how MAOs and other entities conduct DME claims Health Information Portability and Accountability Act (HIPAA) standard electronic transactions with CMS. The CMS EDS supports transactions adopted under HIPAA, as well as additional supporting transactions described in the guide.

We estimate that it will take approximately 290 minutes (4.83 hr) at $88.10/hr for a computer systems analyst to read the CMS 837 DME Companion Guide for one MA plan. In aggregate we estimate 3,337.53 hours (691 managed care contracts x 4.83 hr) at a cost of $294,036 (3,337.53 hr x $88.10/hr) or $425.52 per contract. (See Table 2, below.)

12.2.6d Risk Adjustment Data Submission

As stated the electronic, HIPAA compliant standard Health Care Claims transactions for professional data (currently using implementation guide ASC X12N 837/005010X222 *with* Errata for ASC X12N 837/05010X222A1), institutional data (currently using implementation guide ASC X12N 837/005010X223 *with* Errata for ASC X12N 837/05010X223A2), DME (currently using implementation guide ASC X12N 837/005010X223 *with* Errata for ASC X12N 837/05010X223A2) and for RAPS, NCPDP, Dental and PDEs is used as the format for encounter submissions. This also includes the collection of Medicaid data from MMPs. There are no additional forms for performing risk adjustment data submission.

The estimated annual electronic processing cost per each Risk Adjustment file is $0.68 per the 2016 Council for Affordable Quality Healthcare (CAQH) Index Report (http://www.caqh.org/sites/default/files/explorations/index/report/2016-caqh-index-report.pdf). The CAQH Index, formerly known as the U.S. Healthcare Efficiency Index, is the only industry source monitoring the annual progress of the commercial healthcare industry toward full adoption of electronic transactions and estimating potential for additional cost savings. The report is based on data representing calendar year 2015. The report provides detail on adoption

and cost of those transactions for which there was adequate data to estimate industry benchmarks.

Thus, the total estimated cost of transactions is $523,184,582 when multiplying $0.68 by the average number of Encounter diagnoses submissions for 2015, 2016, and 2017 (769,389,091). We divided the total estimated cost of transactions by the total number of respondents in 2016 to get the annual cost to a respondent which results in $757,141 per plan. See Table 1 for details.

Table 1 - Encounter Data Submission Burden

			NOTES
A	TOTAL NUMBER OF RESPONDENTS IN 2016	691	691 is the number of managed care contracts from 2016
B	TOTAL NUMBER OF MEDICARE BENEFICIARIES ENROLLED IN MEDICARE MANAGED CARE PLANS PER YEAR IN 2016	18,854,626	Number of Medicare managed care enrollees in Part C, Part D, PACE, Cost HMOs/CMPs, HCPPs, and MMPs
C	AVERAGE NUMBER OF ENCOUNTER DIAGNOSIS SUBMISSIONS	769,389,091	Based on annual submission of Encounter data diagnoses in 2015, 2016, and 2017
D	AVERAGE NUMBER OF BENEFICIARIES PER PLAN	27,286	(B) divided by (A)
E	AVERAGE NUMBER OF ENCOUNTER DATA SUBMISSIONS PER MA PLAN	1,113,443	Average Encounter Data records per MA plan per year (C) divided by (A)
F	AVERAGE NUMBER OF ENCOUNTER DATA SUBMISSIONS PER BENEFICIARY	41	(C) divided by (B)
G	AVERAGE NUMBER OF ENCOUNTER DATA TRANSACTIONS PER HOUR	136,591	Estimated average processing volume per hour
H	AVERAGE COST PER ELECTRONIC TRANSACTION	$.68	Based on $.68 per transaction, per CAQH index report from 2016[1]
I	AVERAGE COST PER BENEFICIARY	$27.75	(L) divided by (B)
J	TOTAL ANNUAL TRANSACTION HOURS	5,632	(C) divided by (G)

[1]

K	ANNUAL COST TO A RISK ADJUSTMENT PLAN	$757,141	(L) divided by (A)
L	TOTAL COST OF ANNUAL TRANSACTIONS	$523,184,582	(C) multiplied by (H)

5,632.8 total hours (769,389,091 transactions x 1 hr/136,591 transactions).

12.3 Summary of Annual Burden Estimates

A factor that contributes to the burden estimate for submitting risk adjustment data depends upon the time and effort necessary to complete data transaction activities, including completing and submitting the submitter application, submitter authorization form, the Connect: Direct parameters form, and the CMS EDI agreement. These forms all apply to Medicare Advantage plans or third party submitters that wish to request to receive a Submitter Identification number from CMS. This submitter ID obtained from the application process allows either party to submit plan data to CMS. Since our regulations require plans/sponsors to submit risk adjustment data to CMS that can be linked at the individual level to Part A and Part B data in a form and manner similar to the current processes for risk adjustment and prescription drug event data, the data transaction timeframes will be based on risk adjustment (Part C) and prescription drug industry experiences. Moreover, our risk adjustment data submission format will only support electronic formats. Also, plans that submit PDE data must complete and submit the PRS contract and contact verification form as required so that accountable MA management approve their contract jurisdiction before any pharmacy reconciliation reports are submitted to them. This data is collected electronically and on an annual basis. The information collection effort includes a data collection instrument that is updated annually to validate accountable MA management (i.e. Survey or form). The burden associated with each RAPS, Encounter, PDE, and MMP form is displayed in Table 2.

Table 2:- Summary of Annual Burden Estimates for Forms

Requirement	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden (hours)	Hourly Labor Cost	Cost per Respondent ($)	Total Cost ($)
CMS EDI Agreement *(see section 12.2.1, above)*	691	1	691	0.083 (5 minutes)	57	$88.10/hr	7.27	5,022
Submitter Application and Instructions *(see section 12.2.2, above)*		1	691	0.083 (5 minutes)	57	$88.10/hr	7.27	5,022
Submitter Authorization Form *(see section 12.2.3, above)*		1	691	0.25(15 minutes)	173	$88.10/hr	22.06	15,241
Connect: Direct Applications for RAPS *(see section 12.2.4a, above)*		1	691	0.116 (7 minutes)	80	$88.10/hr	10.20	7,048
Connect: Direct Applications for Encounter Data *(see section 12.2.4b, above)*		1	691	0.116 (7 minutes)	80	$88.10/hr	10.20	7,048
Connect: Direct Applications for PDE *(see section 12.2.4c, above)*		1	691	0.116 (7 minutes)	80	$88.10/hr	10.20	7,048
Connect: Direct Applications for MMP *(see section 12.2.4d, above)*		1	691	0.116 (7 minutes)	80	$88.10/hr	10.20	7,048
PRS Contract and Contact Verification Form *(see section 12.2.5, above)*		1	691	0.083 (5 minutes)	57	$88.10/hr	7.27	5,022
CMS 837 Institutional Companion Guide *(see section 12.2.6a, above)*		1	691	7.5 Hrs	5,182.5	$88.10/hr	660.75	456,578

Requirement	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden (hours)	Hourly Labor Cost	Cost per Respondent ($)	Total Cost ($)
CMS 837 Professional Companion Guide *(see section 12.2.6b, above)*		1	691	6.75 Hrs	4,664.25	$88.10/hr	594.67	410,920
CMS 837 DME Companion Guide *(see section 12.2.6c, above)*		1	691	4.83 Hrs	3,337.53	$88.10/hr	425.52	294,036
Risk Adjustment Data Submission (see section 12.2.6d, above)		1,113,443	769,389,091	8.15 Hrs	5,633	$0.68/ Transaction	757,141	523,184,582
Total	**691**	**1,113,454**	**769,396,692**	**varies**	**19,480**	**varies**	**758,906.61**	**524,404,615**

13. Capital Costs

We do not anticipate significant start-up costs for any new MA, MMP, PACE, and Cost plan organizations, and other entities submitting data. The capital and operational costs for this data collection that may be incurred by MA organizations should be part of their customary and reasonable business practices. Health plans are required to use the 5010 format for electronic transactions with the submission of ICD-10 data. Also, these entities have sufficient capital assets in place to address reporting risk adjustment data.

MA organizations and other entities have reworked the 5010 to an appropriate outbound file format and certain fields may need to be reformatted according to the MA Risk adjustment data specifications. MA organizations and other entities may choose to participate in our risk adjustment data technical assistance program for which they are only responsible for the cost of travel. MA organizations and other entities have interfaced with our new front end, and have the capability to send CMS more data and resolve more errors. MA organizations and other entities have participated in testing to ensure a clean transmission to CMS and internal testing to ensure inbound data maps to the outbound data correctly prior to the time they begin to send data to CMS. They have tested and certified claims of each type. We expected the cost of these activities to be less than $10,000. The cost to purchase each standard ANSI ASC X12N format from the Washington Publishing Company at http://www.wpc-edi.com/ is currently $525. We also expected that plans needed to add about .5 FTE for responding to reports received from the Risk adjustment data System and other manual interventions. This is based on the average plan size. The number of FTEs that a plan needed to add varies depending on the size of the plan and the number of claims received. We expect that the addition of .5 FTE will cost approximately $25,000. This is based on a salary of $50,000.

For cost plans – both section 1876 Cost HMOs/CMPs and section 1833 HCPPs – although there may be start- up costs, as we have said, we reimbursed the full reasonable cost under our authority in 42 CFR 417.550, including those reasonable start-up costs incurred in 2011. For cost plans this represents

less than $10,000/plan. As there were 11 HCPPs and 20 Cost HMOs/CMPs, this would amount to, at most, $310,000 – which costs are all also captured below, under Costs to the Federal Government.

For MA and PACE organizations, note that any administrative and/or capital costs incurred will be recouped through the bidding process.

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 MA organization 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, technical assistance, tapes, overhead costs, etc. CMS's total cost for implementing risk adjustment data collection is expected to be approximately $25.01 million. Costs to the Federal Government also include reasonable costs CMS reimbursed to Cost plans under our authority in 42 CFR 417.550.

	Cost ($)
Software Development	20 million
Technical Support	4 million
FTE	700,000
Cost plan start-up costs	310,000
Total	25.01 million

15. Program and Burden Changes/Adjustments

The currently approved title is, “Collection of Encounter Data from Medicare Advantage Organizations.” This iteration proposes to revise the information collection request title to read, “Collection of Risk Adjustment Data from MA Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 HCPPS, MMPS), and PACE Organizations.”

We have revised the CSSC Operations Submitter Application Instruction and CSSC Operations Submitter Authorization Forms (see the attached Crosswalk). Our currently approved burden estimates have not been revised as a result of these changes. The changes are below:

- For the CSSC Operations Submitter Application Instruction Form, currently approved connectivity options state that submitters must establish a connection to the Front-End System through CMSNet provided by Ability network. In this iteration we propose to update the language to reflect that submitters can now establish connection through any CMS approved Network Service Vendor (NSV).

- For the CSSC Operations Submitter Authorization Form, currently approved instructions state that the completed form may be submitted online, printed and faxed, or scanned and sent via email address for processing. In this iteration we propose to update the language to reflect that the form may only be submitted online or scanned and sent via email. The form can no longer be printed and faxed.

  Previous submissions had lumped all of the information collections under one ICR. To improve reader understanding and to better manage future iterations, we propose to break out all of the information collections into separate ICRs. For instance, in section 12 we have outlined each ICR and its burden on the respondents.

While the number of respondents has been adjusted by +8 due to the increase in MA plans (from 683 currently approved) to 691 (proposed), our total time calculation estimate has decreased by -13,847 hours (14,954 hr - 28,800 hr). This net reduction includes -28,800 hours under the Risk Adjustment Data Submission ICR along with +13,847 hours for the remaining ICRs. This net reduction is based off of the currently approved total transaction hours of 34,433. A net reduction of 28,800 hours being proposed results in 5,632 total transaction hours. In addition, the other ICRs account for 13,847 remaining hours. Thus, the total proposed hours are 19,479.

Requirement	Currently Approved Hours	Proposed Hours (2017)	Difference
CMS EDI Agreement *(see section 12.2.1, above)*	0	57	+57
Submitter Application and Instructions *(see section 12.2.2, above)*	0	57	+57
Submitter Authorization Form *(see section 12.2.3, above)*	0	173	+173
Connect: Direct Applications for RAPS *(see section 12.2.4a, above)*	0	80	+80
Connect: Direct Applications for Encounter Data *(see section 12.2.4b, above)*	0	80	+80
Connect: Direct Applications for PDE *(see section 12.2.4c, above)*	0	80	+80
Connect: Direct Applications for MMP *(see section 12.2.4d, above)*	0	80	+80
PRS Contract and Contact Verification Form *(see section 12.2.5, above)*	0	57	+57
CMS 837 Institutional Companion Guide *(see section 12.2.6a, above)*	0	5,182	+5,182
CMS 837 Professional Companion Guide *(see*	0	4,664	+4,664

The following attachments have been added to this package:

Institutional, Professional, and DME companion guides have been added to this package since the system processes all

institutional, professional, and DME claims. The burden for these claims is built into the cost of effort for a plan per year that is calculated in section 12 of this Supporting Statement, listed as $757,141. DME claims for risk adjustment data is a smaller portion of Part B claims and therefore the process to create the data in the same format is reduced.

We are also requiring that accountable MA management approve their contract jurisdiction before any pharmacy reconciliation reports are submitted to them by completing a PRS Contract and Contact Verification Form. We have clarified the submission timeframes in section 6 of this Supporting Statement based on the release of the reconciliation reports. This information collection effort includes a data collection instrument that is updated annually to validate accountable MA management (i.e. Survey or form).

16. Publication/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.

18. Certification Statement

CMS has no exceptions to Item 19, “Certification for Paperwork Reduction Act Submissions” of OMB Form 83-1.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.