SUPPORTING STATEMENT PART-A
Collection of Encounter Data from MA Organizations, Section 1876 Cost HMOs/CMPs, MMPs, and PACE Organizations (CMS-10340, OMB 0938-1152)

Background and Summary

On December 30, 2011, CMS received OMB approval to collect health care data on each item or service delivered to enrollees of the MA program. Pursuant to 42 CFR 422.310, each MA organization must submit to CMS the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. Typically, these data are collected by MA organizations, PACE organizations, 1876 Cost Plans, and Medicare-Medicaid Plans (MMPs) for general business activities such as claims payment, coordination of benefits, eligibility and enrollment, and quality improvement activities and include beneficiary diagnosis information.

CMS collects encounter data for beneficiaries enrolled in MA organizations, section 1876 Cost Health Maintenance Organizations (HMOs)/Competitive Medical Plans (CMPs), Programs of All-inclusive Care for the Elderly (PACE) organizations, and MMPs. For PACE organizations and MMPs, encounter data serves essentially the same purposes as it does for the MA program (for Part C and Part D risk adjustment). To 1876 Cost Plans that offer Part D coverage, CMS makes risk adjusted, capitated monthly payments for Part D.

MA organizations, Part D organizations, 1876 Cost Plans, MMPs and PACE organizations must use a CMS approved Network Service Vendor to establish connectivity with the CMS secure network for operational purposes. Once connectivity is established, these entities must submit required documents to CMS's front-end contractor to obtain security access credentials. The forms used in this process are covered under this package.

To date, the Encounter Data Processing System (EDPS) has been unable to accept dental encounters unless they are submitted on one of the two formats that have been used since the inception of encounter data collection: professional encounters (837P) and institutional encounters (837I). The currently approved package is being revised to enable MA Organizations to submit data on routine dental services to CMS in the industry standard dental claim format, 837D. Through consultation with the CMS Chief Data Officer and industry subject matter experts, claim format 837D has been identified as the least burdensome and most complete format for dental service submission as it is the industry standard and already used for Medicare Medicaid Plan demonstration dental submissions.

CMS has updated Submission Forms to allow MAOs to submit data in the 837-D format; these Forms are attached to this PRA. Similar form changes were submitted and approved under a Non-Substantive PRA update earlier in 2023. There is no additional burden for the MAOs to

complete this form. The burden to submit the dental encounters is documented in Section 12 of this document.

A. Justification

1. Legal Authority

Section 1853 of the Social Security Act, hereafter referred to as "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 account for 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 uses the appropriate enrollee risk score to adjust the monthly payment amount.

Section 1853(a)(3)(B) of the Act directs CMS to require MA organizations and eligible organizations with risk-sharing contracts under 1876 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 and other entities. Risk adjustments to enrollee monthly 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.

Under section 1894(d) of the Act, CMS must make prospective monthly capitated payments to PACE organizations in the same manner and from the same sources as payments to organizations under section 1853. Section 1894(e)(3)(A)(i) requires in part that PACE organizations collect data and make available to the Secretary reports necessary to monitor the cost, operation, and effectiveness of the PACE program.

For 1876 Cost Plans that offer Part D coverage, CMS makes risk adjusted, capitated monthly payments to these plans for Part D that are calculated using the encounter data submitted by Cost Plans. Cost Plans may voluntarily submit encounter data to CMS.

Medicare-Medicaid Plans (MMPs) are subject to the same requirements as MA Special Needs Plans (SNPs) unless CMS uses the demonstration authority to waive these requirements. CMS has not waived data submission requirements for MMPs related to data collection under MA. Therefore, MMPs are also required to submit encounter data to CMS under section 1853(a)(3)(B) of the Act and 42 CFR 422.310.

2. Current Uses

CMS uses encounter data to develop individual risk scores for risk adjusted payment to MA organizations, PACE organizations, and MMPs. Starting with Payment Year (PY) 2016, CMS began to blend risk scores calculated with Risk Adjustment Processing Data and Medicare Fee-For-Service (FFS) data with risk scores calculated with encounter data and FFS data, for risk scores calculated under both the CMS-HCC and the RxHCC models. In PY 2022, we will move to calculating risk scores under both the CMS-HCC and the RxHCC models using 100 percent of the risk score calculated using encounter data and FFS data.

For 1876 Cost Plans, encounter data is used to calculate Part D risk scores. Additionally, if Cost Plan enrollees switch to MA coverage, encounter data collected from Cost Plans would be used to calculate MA risk scores.

As stated at 42 CFR 422.310(f)(2), CMS may release the minimum data it determines is necessary for one or more of the purposes listed under 42 CFR 422.310(f) to other HHS agencies, other Federal executive branch agencies, States, and external entities in accordance with the restrictions outlined in this section of the CFR.

To date, other government entities and several external researchers have been granted access to encounter data. Users include several components within CMS and HHS, as well as entities such as the Department of Justice, and the Medicare Payment Advisory Commission. Specific uses include program integrity, quality measurement, public health emergency response, and innovation and demonstration programs.

This package includes the forms that must be completed to establish a secure connection to submit data to CMS. In order to submit files to CMS, the user must be enrolled by the front-end contractor. As part of this enrollment process, users complete the Submitter Authorization Form (if applicable), Electronic Data Interchange (EDI) agreement,
Connect:Direct form (if applicable), and Submitter/Receiver Application. CMS and its contractor use the information in the forms as part of this enrollment process.

3. Use of Information Technology

The risk adjustment encounter data is collected 100 percent electronically.

A summary of the data collection/submission process is as follows:

Risk Adjustment Encounter Data Collection/Submission Overview

CMS has a front-end system to receive MA encounter data. The MA encounter data are further processed in a back-end system called the Encounter Data Processing System (EDPS). Together, this suite of systems is referred to as the CMS Encounter Data System (EDS). The EDS receives

data from MA organizations, 1876 Cost Plans, MMPs, and PACE organizations, processes the data by applying a series of automated edits, assesses each record to produce an FFS-equivalent price, and stores the data.

All organizations required to submit encounter data use an electronic connection between the organization and CMS to submit encounter data and to receive information in return. CMS collects the data from MA organizations, 1876 Cost Plans, MMPs and PACE organizations in the X12N 837 5010 format for professional, DME, institutional, and dental services or items provided to MA enrollees.

Submitters must sign a Submitter Authorization Form, Electronic Data Interchange (EDI) agreement, and Submitter/Receiver ID application in advance of their submission. The forms are available electronically on the CSSC Operations website (http://www.csscoperations.com/). The Submitter Authorization Form and the EDI agreement can be printed, completed and scanned or mailed. The Submitter/Receiver ID application can be submitted through the website. Submitters have a choice between three connectivity options: Connect:Direct, File Transfer Protocol (FTP) and TIBCO MFT.

4. Duplication of Efforts

Section 1876 Cost HMOs/CMPs are allowed to have providers submit claims directly to Medicare Administrative Contractors for adjudication and payment directly from the Medicare FFS program; therefore, 1876 Cost HMOs/CMPs may not have the claims data for all items/services covered under their policies. The 1876 Cost Plans submit encounter data only for services that are reimbursed by their organization. The encounter data submitted by 1876 Cost Plans is not duplicative of data that CMS has from other means or programs.

For MA organizations, PACE organizations, and Medicare-Medicaid Plans (MMPs), the information collection requirements are not duplicated through any other current national effort and the service-level information for Medicare beneficiaries enrolled in MA, PACE, or Medicare-Medicaid Plans is not available through other data sources.

The forms required to establish connectivity are not duplicative of other forms for CMS connectivity. They are the only source of information provided by organizations to validate submitters and establish a secure connection to submit data.

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 1876 Cost Plan, PACE, MMP, and MA programs.

6. Collection Frequency

All encounter data is submitted according to a specific schedule that is based on the size of the MA organization, PACE organization, 1876 Cost Plan or MMP. The schedule in the following table is for encounter data submissions by all entities submitting data. Organizations are encouraged to submit data more frequently than the minimum submission frequencies below.

Table 1. Recommended Frequency of Submission for MA Encounter Data

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

If the data is collected less frequently, MA organizations, PACE organizations, 1876 Cost Plans, and MMPs may have challenges submitting their data prior to the annual deadline. The current schedule is recommended to minimize system burden for both organizations submitting encounter data and CMS.

7. Special Circumstances

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 Federal Register notice published in the Federal Register on TBD (88 FR 83946).

Two comments were received. The first had to do with getting information when the supplemental dental services are managed by a vendor. Our guide was updated to inform that CMS expects the MA organization to obtain the information from the vendor and provide it to CMS.

The other comment suggested timeframes for implementation and requesting guidance. The response addressed both and no other updates were required.

The 30-day Federal Register notice published in the Federal Register on TBD (89 FR).

9. Payments/Gifts to Respondents

Submitting an encounter or any form in this PRA package does not result in payments or gifts to respondents, and many conditions must be met before risk adjusted payment is actually made.

10. Confidentiality

The data are protected and kept confidential under System of Record Notice (SORN) #09700506 (June 17, 2014; 79 FR 34539).

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

The burden associated with collecting encounter data includes the resources required to submit encounter data records as well as the resources required to establish connectivity and review guidance. Establishing connectivity is necessary for first-time submitters registering to submit

data or for new contracts or MA organizations, Part D organizations, Cost Plans, PACE organizations, or MMPs that are switching third party submitters.

Specific estimates of the annual cost and hours burden on MA organizations and other entities of submitting risk adjustment encounter data are based on five factors: (1) the number of encounter data records submitted in the most recent submission year; (2) the estimated cost of processing an electronic transaction; (3) the estimated time (in minutes) of processing an electronic transaction; (4) the estimated adjusted hourly wages for a computer systems analyst; and (5) the labor time required of a computer systems analyst to complete connectivity forms and related activities and to review submission guidance. We provide a detailed explanation of the changes from our previous estimates below in section 15. Program and Burden Changes/Adjustments.

We are modifying these estimates in section 15 to reflect the addition of data collection using the 837D. We based these modifications on expected volume increases and the associated labor cost increases. Volume estimates are derived using current Medicare Medicaid Program demonstrations dental encounter submissions.

12.1 Burden Estimates for Submitting Encounter Data

Assumptions for each of the three factors directly related to the encounter data being submitted are described below.

(1) Number of Encounter Data Records. In 2022, MA organizations, Cost Plans, MMPs and PACE organizations submitted 1,467,645,179 encounter data records. It should be noted that this is the total number of records submitted and includes both rejected and accepted data.

(2) Estimated Cost of Processing an Electronic Record. The estimated annual electronic processing cost per encounter data record is $1.85 according to the 2022 Council for Affordable Quality Healthcare (CAQH) Index Report (https://www.caqh.org/sites/default/files/2022-caqh-indexreport%20FINAL%20SPREAD%20VERSION.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 the potential for additional cost savings from adoption of electronic transactions. The report is based on data representing calendar year 2022. The report provides details on electronic transaction adoption and on the cost of those transactions for which there was adequate data to estimate industry benchmarks.

(3) Estimated Time Required to Process an Electronic Record. The estimated time required to process an electronic transaction is based on the 2019 CAQH Index Report as well (https://www.caqh.org/sites/default/files/explorations/index/report/2019caqhindex.pdf?token=SP6YxT4u). The estimated time per record of two minutes was not updated in the 2022 CAQH.

Using the assumptions above, the total estimated cost of transactions is $ 2,715,143,581 when the industry standard of $1.85 per transaction is multiplied by the number of encounter data submissions for 2022 (1,467,645,179). We divided the total estimated cost of transactions by the total number of respondents in 2022 (900) to get the average annual cost to a respondent which results in $3,016,826 per MA organization or other entity.

The estimated burden of hours required is based on the CAQH estimate of two minutes per transaction, which amounts to 48,921,506 hours for 1,467,645,179 transactions. The average annual burden in hours per entity is 54,357.

12.2 Burden Estimates for Establishing Connectivity to Submit Encounter, Risk Adjustment, and PDE Data

Over the past three years, we have seen an average of 81 new organizations requiring connectivity to submit data each year. New organizations must complete a series of forms and a certification process (or testing of system connectivity) in order to submit data to CMS' Front-End System. Once connectivity has been established, an organization does not need to revisit the connectivity process unless the organization wishes to change its existing connectivity option or make other changes to how the organization will connect to CMS systems to submit encounter data. The resources to establish connectivity are estimated below. The Part D and MMP submitters impacted by the update to the Connect:Direct form have established connectivity and therefore are only providing a new dataset name for a new report that will only be issued for PDEs submitted for benefit year 2023.

Assumptions for each of the factors related to establishing connectivity and reviewing guidance related encounter data submission are described below.

(1) Estimated Labor Cost per Hour. To derive average wage costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 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 median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 2. National Occupational Employment & Wage Averages, Computer Systems Analyst

Occupation Title	**Occupation Code**	**Median Hourly Wage ($/hr)**	**Fringe Benefit ($/hr)**	**Adjusted Hourly Wage ($/hr)**
Computer Systems Analyst	15-1211	$49.15	$49.15	$98.30

(2) Estimated Time Required to Establish Connectivity. The table below presents estimates of the number of new submitters and the time required to complete the forms and activities related to establishing connectivity. Note that during the most recent three years used to determine the average number of new submitters, none of the submitters needed to complete the Connect:Direct form, which is why there are no burden hours or cost for this form.

Table 3. Estimated Time Required to Establish Connectivity, by Form and Number of Submitters

Form/Activity	Median Hourly Wage ($/hr)	Est. Time Required to Complete Form	Est. Number of New Submitters	Estimated Burden Hours	Estimated Cost
EDI Agreement	$98.30	5 minutes	201	16.8	$1,651
Submitter Application and Instructions	$98.30	8 minutes	19	2.5	$246
Submitter Authorization Form	$98.30	10 minutes	181	30.2	$2,969
Connect: Direct Form	$98.30	10 minutes	0	0	$0
Complete Certification	$98.30	1 month	3	120	$11,796
TOTALS all forms/activities				169.5	$16,662

12.2.1 CMS EDI Agreement

Submitters complete the EDI agreement forms to establish an electronic connection between the organization and CMS to submit ~~to submit~~ MA and Part D data and to receive information in return. Submitters must sign an EDI agreement in advance of submission. Submitters have a choice between three connectivity options: Connect:Direct, File Transfer Protocol (FTP), and TIBCO MFT. The form is completed once when a new organization enters the program, and as stated above, this process is not required to be updated annually. The updated form is included in this PRA package with the redlined version.

12.2.2 Submitter Application and Instructions

This form is completed if submitters request a Submitter Identification number from CMS. This submitter ID allows either party (Medicare Advantage organizations, other entities, or third-party

submitters) to submit data to CMS. The form is completed when a new organization enters the program or when an organization changes the entity used to submit data on its behalf.

12.2.3 Submitter Authorization

This form is required to be completed for submitters to be authorized to submit encounter data, dental encounter data, RAPS data, or PDE data to CMS.

12.2.4 Connect: Direct Application

This form is required to be completed for submitters to be authorized to gain access to the Connect: Direct application. This allows the submitters to submit their data directly to the CMS front end system. There are separate forms for the Encounter, PDE, and MMP applications. The estimates are for new organizations completing a Connect:Direct application, regardless of data type. Existing Part D and MMP submitters will need to provide a new dataset name for the new report but the existing dataset names for the other reports will continue to be the same.

12.3 CMS Encounter Data Submission & Processing Guide

In 2017, CMS undertook an effort to consolidate, update, and streamline our operational website (www.csscoperations.com) that provides instructions for submission of encounter data as well as several resources such as edit code look up tools. As part of that effort, CMS reviewed all documents and links on the website and took into account feedback from stakeholders regarding the ability to find information related to encounter data submission quickly and in one source. CMS determined that a single updated source of information for submission of encounter data and a streamlined website would reduce burden on submitters.

The Encounter Data Submission and Processing Guide (hereafter referred to as the Guide) contains the most relevant information from the Institutional, Professional, and DME Companion Guides in a user-friendly, single document with appendices. A Guide has been created for the initial submission of dental supplemental services encounter data. The Guide will be updated on an on-going basis to reflect current requirements and system edits.

We estimate that it will take approximately 16 hours at $103.40/hour for a computer systems analyst to review the Guide for a single contract. The total number of hours for all 900 MA organizations, Cost Plans, MMPs and PACE organizations amounts to 14,400 total hours and a total cost of $1,415,520.

Table 4. Estimated Cost of Reviewing Encounter Data Submission Guidance

Activity	Median Hourly Wage ($/hr)	Estimated Time Required	Estimated Number of Contracts	Estimated Burden Hours	Estimated Cost
Review Encounter Data Submission and Processing Guide	$98.30	16 hours	900	14,400	$ 1,415,520

12.4 Total Estimated Annual Cost and Hours Burden to Organizations of Submitting Encounter Data

The total annual estimated cost and hours burden is summarized below.

Estimated Cost
Total Annual Estimated Cost of Submitting Records = $2,715,143,581
Total Annual Estimated Cost of Forms/Activity related to Establishing Connectivity = $16,662
Total Annual Estimated Cost of Reviewing Submission Guide = $1,415,520 Total
Annual Estimated Cost of Encounter Data = $2,716,575,763

Estimated Hours
Total Annual Estimated Hours Burden of Submitting Records = 48,921,573 hours
Total Annual Estimated Hours Burden related to Establish Connectivity = 170 hours
Total Annual Estimated Hours of Burden of Reviewing Submission Guide = 14,400 hours
Total Annual Estimated Hours of Burden Related to Encounter Data Submission = 48,936,143

13. Capital Costs

There are no significant maintenance or start-up costs that are directly associated with this effort. Any administrative and/or capital costs incurred will be recouped through the bidding process. The number of Part C contracts per year is 900 in 2022. These entities have sufficient capital assets in place to address reporting encounter data. MA organizations, 1876 Cost Plans, PACE organizations and MMPs also have sufficient capital assets in place to address encounter data reporting. MAOs who will submit dental service encounters to CMS are already submitting encounters to CMS and the 837D form is currently the industry standard for dental claims, suggesting no significant start-up costs directly associated with this effort.

14. Cost to Federal Government

CMS's total annual cost for encounter data collection activities using the Encounter Data System was $18.1 million in FY23 (11/20/2023).

Table 4. Estimated Costs to Federal Government

	Cost ($)
Infrastructure (or other direct costs)	$ 16.5 million
FTE	$1.6 million
Total	$18.1 million

15. Program and Burden Changes/Adjustments

15.1 Dental Encounter Data Submissions

Dental services are a supplemental benefit that are not required coverage in the Medicare Advantage program. Contracts who offer these benefits are required to submit encounters for the dental services provided. The program burden estimates associated with the collection of supplemental dental service encounter data are based on the current submission of dental service encounter data by the Medicare-Medicaid Plans (MMPs).

15.2 Burden Estimates for Submitting Dental Encounter Data

MAOs do not currently submit encounter data for supplemental dental services to CMS. MMPs do currently submit encounter data for dental services to using the 837D format. MMPs are capitated financial alignment models where Medicare and Medicaid cooperate to provide access to seamless, integrated care for covered dual-eligible beneficiaries. CMS calculated burden for MA Organization submission of dental services using MMP data to estimate the expected volume of dental encounters.

Three factors were estimated to derive an expected burden for submitting supplemental dental services: volume of submissions, cost of processing submissions, and time for processing submissions.

1. MA Dental Submissions: Expected MA dental submission estimates are based on the average dental encounters for a beneficiary in the MMP program, controlled for the higher total overall utilization in the MMP program, and scaled to the overall utilization in MA. To do this, the average per-beneficiary MMP dental total is multiplied by the ratio of MMP to MA utilization for an average of .36 dental encounters per MA beneficiary. Multiplied by the total 2022 MA population of 22,533,746, this results in an expected 8,010,607 dental encounters.

2. Estimated Cost of Processing a Dental Electronic Record: The estimated annual electronic processing cost per dental encounter data record is $1.63 according to the 2022 Council for Affordable Quality Healthcare (CAQH) Index Report (https://www.caqh.org/sites/default/files/2023-05/2022-caqh-index-report.pdf). The CAQH Index is an industry source monitoring the annual progress of the commercial healthcare industry toward full adoption of electronic transactions and estimating the potential for additional cost savings from adoption of electronic transactions.
3. Estimated Time Required to Process an Electronic Record: The time estimated to process an electronic dental encounter data record is consistent with professional medical encounters at 2 minutes per transaction.

Using the assumptions above, the total estimated cost of transactions using the industry standard of $1.63 per transaction multiplied by the 8,010,607 estimated dental encounter data submissions is $13,057,289.

The estimated burden of hours equals 267,020 hours for 8,010,607 transactions. 267,020 hours multiplied by the 2022 hourly rate of $98.30 is $26,248,066.
The total burden for dental service submission is $39,305,355, equal to the encounter transaction total $13,057,289 + the encounter labor cost total $26,248,066. This represents a 1.4% increase to the previous projected total of $2,716,653,376.

16. Publication/Tabulation Dates

There are no publication and tabulation dates.

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 by employing statistical methods.

[2] 2019 Council for Affordable Quality Healthcare (CAQH) Index Report:
(https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf?token=SP6YxT4u)