

Supporting Statement Part A

Medicare Severity Diagnosis Related Groups Reclassification Request (MS-DRGs) (CMS-10775; OMB-0938-New)

A. Background

Generally, under the Inpatient Prospective Payment System (IPPS), Medicare payment to the hospital varies based on hospital-specific and patient-specific characteristics. Each Medicare claim for inpatient services is classified into the applicable Medicare Severity Diagnosis-Related Group (MS-DRG) for payment based on certain patient-specific elements, including the principal diagnosis, additional or secondary diagnoses, and procedures reported on the claim. The MS-DRG classification system currently has 337 base DRGs, most of which are split into 2 or 3 MS-DRGs based on the presence of either a complication or comorbidity (CC) or major complication or comorbidity (MCC), resulting in a total of 767 MS-DRGs for FY 2021.

Effective October 1, 2015, providers use the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis code set in all healthcare settings and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) is the code set used for inpatient hospital procedure coding. These diagnosis and procedure codes are mapped or “grouped” to specific MS-DRGs for payment under the IPPS using the ICD-10 MS-DRG Grouper software.

The ICD-10 coding system was initially adopted for transactions conducted on or after October 1, 2013, as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS Final Rule published in the **Federal Register** on January 16, 2009 (74 FR 3328 through 3362) (hereinafter referred to as the “ICD-10-CM and ICD-10-PCS final rule”). However, the Secretary of Health and Human Services issued a final rule (77 FR 54664) that delayed the compliance date for ICD-10 from October 1, 2013, to October 1, 2014. On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) was enacted, which specified that the Secretary may not adopt ICD-10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD-10 beginning October 1, 2015.

The public may submit requests to create a new MS-DRG(s), modify an existing MS-DRG(s), change the severity level designation for a diagnosis code(s), change the operating room (O.R.) designation of a procedure code(s), reassign diagnosis and/or procedure codes among Major Diagnostic Categories (MDCs), modify the Medicare Code Editor (MCE), or modify the surgical hierarchy. We examine these requests using statistical analysis and the judgment of our clinical advisors to evaluate the requested changes and consider any proposed updates to the MS-DRGs. Interested parties can include any information they choose to support a MS-DRG change request.

We have found that with the implementation of ICD-10, some requested changes require extensive research of appropriate materials in evaluating the potential change. With the continued increase in the number and complexity of the requested changes to the MS-DRG classification since adoption of the ICD-10 MS-DRGs, and in order to consider as many requests as possible, more time is needed to carefully evaluate the requested changes, analyze claims data, and consider any proposed updates. We estimate receiving approximately 50 requests annually. This estimated number of requests is based on the fact the number of requests we receive each year has been gradually increasing. We believe we will continue to receive an increased number of MS-DRG classification change requests.

For purposes of this PRA submission, we are requesting that a new online application system, Medicare Electronic Application Request Information System™ (MEARIS™), be approved for public use to submit materials to CMS in support of their MS-DRG request(s). The MS-DRG Reclassification Request form designed for MEARIS™ is currently in development and is estimated to be launched in April 2022 to accept requests to be considered for the FY 2024 IPPS/LTCH PPS rulemaking cycle.

B. Justification

1. Need and Legal Basis

Section 1886(d)(4) of the Act establishes a classification system, referred to as DRGs, for inpatient discharges and adjusts payments under the IPPS based on appropriate weighting factors assigned to each MS-DRG. Section 1886(d)(4)(C)(i) of the Act specifies adjustments to the classification and weighting factors shall occur “at least annually to reflect changes in treatment patterns, technology, and other factors which may change the relative use of hospital resources.”

For consideration of a classification change to the ICD-10 MS-DRGs, interested parties currently must submit requests by the specified date via e-mail to the CMS MS-DRG Classification Change Mailbox located at MSDRGClassificationChange@cms.hhs.gov. Requests for FY 2023 consideration are due by November 1, 2021.

2. Information Use

The requests are evaluated in the Division of Coding and DRGs (DCDRG) by the DRG and Coding Team and the clinical advisors (medical officers) in both the Technology, Coding and Pricing Group (TCPG) and the Hospital and Ambulatory Policy Group (HAPG), along with the CMS contractor(s). This team participates via conference calls in the review of MedPAR claims data to analyze and perform clinical review of the requested changes. Based on the examination of claims data and clinical judgment, the team provides recommendations to CMS and HHS leadership for proposed changes. Per the statute, proposed MS-DRG changes and payment adjustments must go through notice and comment rulemaking giving the opportunity for the public to comment. Finalized MS-DRG changes are effective with discharges on and after October 1, consistent with the beginning of the fiscal year. CMS makes the updated MS-DRG

Grouper software and related materials that reflects the changes available to the public for free via download at: <https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software>

When an application is submitted in MEARIS™, the DRG and Coding Team in DCDRG will have instant access to the application request and accompanying materials to facilitate a more timely review of the request, including the ability to efficiently inform other team members involved in the process that information is available for their review and input.

3. Use of Information Technology

There is no standard request form at this time. Requests are submitted via e-mail to the MSDRGClassificationChange@cms.hhs.gov mailbox and generally include an opening statement about the organization or individual submitting the request, their area of expertise and the purpose of their request. The requests typically include the specific list of diagnosis and/or procedure codes with their descriptions, the MS-DRG, and/or the Major Diagnostic Category (MDC) of interest if applicable. The request will also identify any data analysis that may have been performed in support of their request. Occasionally, depending on the nature of the requests, supporting literature may also be submitted in association with the request. Requestors will be able to access the Medicare Severity Diagnosis Related Groups Reclassification Request application via the Medicare Electronic Application Request Information System™ (MEARIS™), on a designated website through CMS.gov. The electronic version of the MSDRG application will collect the same information as solicited in the current process for requesting MS-DRG classification changes. This secure online application maintained by CMS enables applicants to submit their responses to our application questions directly to CMS as opposed to sending the requested information via email. We believe these changes have no impact on the current standard request form and provides a more convenient way for our applicants to submit MS-DRG classification change request applications. Requests that are received by the established deadline will be considered for the upcoming rulemaking cycle; and requests that are received after the deadline, will be considered for inclusion in the next rulemaking cycle.

4. Duplication of Efforts

This information collection does not duplicate other efforts.

5. Small Businesses

This does not have a significant economic impact on small businesses. The current process has been in place for several years and there is sufficient notice provided in rulemaking for the deadline to submit MS-DRG classification requests for consideration in the next fiscal year.

6. Less Frequent Collection

This information is collected upon submission by the requestor in order to comply with current regulatory requirements. Reducing or eliminating this collection would contradict the current regulation.

Each request is submitted as a single application for consideration, however, multiple requests may be submitted by one requestor.

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

Federal Register

The 60-day Federal Register Notice (86 FR 29265) published to the Federal Register 06/01/2021. No comments were received.

We expect the 30-day Federal Register notice that is anticipated to be published TBD to contain the information pertaining to this information collection.

Outside Consultation

Usability testing and feedback for the online application system is in process, effective May 2021. The usability testing will include 5-9 applicant users identified by CMS. The user emails and names have been provided to the Softrams User Experience team who will conduct remote

moderated one-on-one testing with each user via Zoom. This user testing/feedback collection has not been approved by OMB.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents. A single MS-DRG is assigned to an inpatient hospital claim to reflect the clinical condition chiefly responsible for the patient's admission and/or the services that were provided to treat the conditions reported. While all inpatient claims will "group" to a single MS-DRG, not all services that are billed are covered and paid under Medicare coverage policies. Coding, coverage and payment policy under the IPPS is separate and distinct from one another.

10. Confidentiality

"CMS pledges privacy to the extent provided by law."

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates

For MS-DRG classification change requests, the burden associated with the submission of the request includes the time and effort involved with completing administrative requirements (e.g. data specifications), obtaining the data, analysis of the data, retaining clinicians to provide clinical input and preparing the documents to submit in connection with the request. These administrative requirements exist with the current process and will continue with the online application system.

Based on our recent experience, in the next several years we estimate receiving approximately 50 requests annually for MS-DRG classification change requests. We have chosen the average of 50 requests on a fiscal year basis for purposes of this PRA. This estimated number of requests is based on the fact the number of requests we receive each year has gradually been increasing from 19 to 50. One requestor may submit multiple requests for various topics, therefore, those requests are counted individually as separate and distinct from one another versus being counted as one request. We believe that we will continue to receive this average number of MS-DRG classification change requests, our estimate of the number of requests is realistic, and using the average of 50 requests for the purposes of this PRA is reasonable.

We estimate the time associated with collecting the information for a MS-DRG classification change request and submitting the request electronically to CMS will continue to vary based on the type of request. For example, the collection of information relating to requests that involve

the creation of a new or revised MS-DRG may require analysis of any number of the 72,621 diagnosis codes and/or the 78,136 procedure codes associated with one or more of the current 767 MS-DRGs, in one or more of the 25 Major Diagnostic Categories (MDCs).

We estimate the time associated with gathering information for what we will refer to as a simple, straightforward request and separately, a complex, multi-part request will continue to be anywhere from 1-120 working days and from one hour to 960 hours (using the extreme example of 120 days x 8 hours per day = 960 hours). We believe this is reasonable and consistent with the current process of gathering information for the various types of requests. We estimate the total burden for the collection of information to be 48,000 hours (960 hours x 50 requests).

When computed, assuming a mean hourly wage of \$46.46 per hour (based on data from the 2020 Bureau of Labor and Statistics website at <https://www.bls.gov/oes/current/oes132098.htm> for the position of Financial Analysts or Specialists) plus 100 percent for fringe benefits (\$46.46 per hour x 2), the estimated cost per request is \$92.92 per hour. Continuing with the extreme example, the total cost burden to respondents or record-keepers resulting from the collection of this information is \$ 4,460,150 (960 hours x \$92.92/hour = \$89,203 x 50 requests).

Some requestors choose the option to purchase Medicare Provider Analysis and Review (MedPAR) data to provide a detailed cost analysis demonstrating the need for a MS-DRG classification change. The MedPAR data is available for purchase from the CMS contractor Research Data Assistance Center (ResDAC) for a fee dependent on the beneficiary count (https://resdac.org/sites/datadocumentation.resdac.org/files/2021-01/CMS%20Fee%20List%20for%20Research%20Files_25.pdf) For purposes of this PRA package we have used the amount of \$3,000. In the event that all requestors purchase the MedPAR data, we assume an additional burden of \$3,000 per requestor for a total additional burden of \$150,000 (\$3,000 x 50 requests).

This results in a total annual cost burden to respondents or record-keepers of \$4,610,150 (\$4,460,150 + \$150,000).

13. Capital Costs

There are no capital costs. The application will be available online on a designated website through CMS.gov. Requestors will need a computer with internet access, which is publicly available.

14. Cost to Federal Government

The cost to process the information submitted is estimated as follows based on review by analysts, medical officers, and supervisory staff. This review includes analyses of the submission, entering each request into a Tracker log by MDC and topic ID number, summarization of each issue and request into a Topics document for communication with our contractor and to inform the proposed Grouper specifications, review of the coding and MS-DRG logic, review of proposals for new codes that were discussed at recent ICD-10

Coordination and Maintenance Committee meetings, required data calculations, database inputs, and conferences with contractors, requestors and their representatives. We estimate the total time to process, evaluate and reach a proposed decision is 80 to 120 hours per request. We use the midpoint of this range (100 hours) to derive the following estimated labor cost for government employees. (This estimate does not include the time to draft language for briefing papers that will inform the discussion to be drafted for public comment in the IPPS/LTCH PPS proposed rule nor any additional rulemaking related procedures performed (e.g. additional analyses during clearance) involving the request.)

\$38.37/hr (average salary GS 12, 13, 14)¹ X 100 hours per request x 50 requests (potential/projected number of requests) = \$191,850.

15. Changes to Burden

There are no anticipated changes to burden. The content of the electronic MS-DRG Reclassification Request application form collects the same data variables as currently solicited for consideration of a MS-DRG classification change as described in our annual IPPS rulemaking.

16. Publication/Tabulation Dates

Requests are currently submitted to CMS on a rolling basis and will continue to be submitted in this manner using the electronic application form when it becomes available. Requests received by November 1, 2021 will be considered for FY 2023 or a future date depending on the nature and complexity of the request.

Upon receipt of the MS-DRG request by the established deadline, the DRG and Coding Team, with input from the HAPG and TCPG Medical Officers and recommendations from our contractor's clinical advisors (i.e. the MS-DRG workgroup), draft proposals that include CMS's claims analysis for each of the MS-DRG requests. Each of these MS-DRG requests that are summarized as proposals are made publicly available when put on display via the Federal Register website at <https://www.federalregister.gov/agencies/centers-for-medicare-medicaid-services> and subsequently published in the Notice of Proposed Rule Making (NPRM).

In the NPRM we ask the public to submit comments in response to our proposed recommendations for each of the MS-DRG requests during the allotted 60-day comment period. As public comments are received during and through the close of the comment period, they are grouped according to their topic area. Subsequently, in the fiscal year's Final Rule, we publish a summarized account of comments for each MS-DRG request along with our response that includes the finalized policy that has been approved through HHS during the clearance process.

¹ Office of Personnel Management. 2021 General Schedule (Base). Retrieved on April 7, 2021 from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2021/general-schedule/>

17. Expiration Date

There is no collection data instrument used in the collection of this information. However, upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the expiration date. The OMB approval expiration date will also be made available in the MEARIS™ application once available for use.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There are no statistical methods.