**Supporting Statement Part A**

The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS)
(CMS-10774; OMB-0938-New)

## A. Background

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the U.S. Department of Health and Human Services (HHS) adopted specific code sets for diagnoses and procedures used in all transactions.

On January 16, 2009, HHS released the final rule mandating that all parties covered by HIPAA implement the International Classification of Diseases, 10th Revision (ICD–10) for medical coding.

The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) is the code set used for classifying procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals regarding prevention, diagnosis, treatment, and management. ICD–10–PCS is restricted to the reporting of inpatient procedures by hospitals. The Centers for Medicare and Medicaid Services (CMS) has lead responsibility for the maintenance and distribution of ICD–10–PCS procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) is the code set used for classifying diseases, injuries, impairments, other health problems and their manifestations, and causes of injury, disease, impairment, or other health problems in all healthcare settings. The Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) has lead responsibility for the ICD–10–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases.

The ICD–10 Coordination and Maintenance Committee (C&M) is a Federal interdepartmental committee comprised of representatives from CMS and NCHS, charged with routine maintenance, testing, enhancement, and the expansion of the ICD–10 code sets. The committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–10 coding systems to reflect newly developed procedures and technologies and newly identified diseases.

The Committee provides two meetings each year as a public forum to discuss proposed changes to ICD–10. Suggestions to CMS for ICD–10–PCS procedure code modifications come from both the public and private sectors. ICD–10–PCS modification requests can be proposals for new or revised procedure codes or requests for technical coding updates including but not limited to, enhancements to existing procedure code concepts, such as adding a new body part value or a new approach value. Requestors are asked to include a description of the procedure code or change being requested, and rationale for why the procedure code or change is needed. Supporting references and literature may also be submitted. Interested parties submit these ICD–10–PCS modification requests three months prior to a scheduled Spring or Fall C&M meeting via email to the following e-mail address: ICDProcedureCodeRequest@cms.hhs.gov.

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 ICD–10–PCS request(s). We are requesting approval because we believe the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) Application form designed for MEARIS™ collects the same data elements as collected in the current process for requesting new/revised ICD–10–PCS procedure codes as described on our webpage at: https://www.cms.gov/Medicare/Coding/ICD10/newrevisedcodes. We believe a change to an online applications has no impact on the data collection requirements or the burden associated with this collection. We also believe there is nothing new in the online application that a repeat applicant would not have seen in the current process and its associated instructions.

The ICD–10–PCS Application form designed for MEARIS™ is currently in development and is estimated to be launched in early 2022 to accept requests to be considered for discussion at the Fall 2022 C & M meeting.

## B. Justification

### 1. Need and Legal Basis

The HIPAA Act of 1996 required CMS to adopt standards for coding systems that are used for reporting health care transactions. The Transactions and Code Sets final rule (65 FR 50312) published in the **Federal Register** on August 17, 2000 adopted the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) Volumes 1 and 2 for diagnosis codes and ICD–9–CM Volume 3 for inpatient hospital services procedures as standard code sets for use by covered entities (health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard). ICD–9–CM Volumes 1 and 2, and ICD–9–CM Volume 3 were already widely used in administrative transactions when we promulgated the August 17, 2000 final rule, and we decided that adopting these existing code sets would be less disruptive for covered entities than modified or new code sets.

In the 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) §162.1002 was amended to adopt ICD–10–CM and ICD–10–PCS as medical data code sets under HIPAA, replacing ICD–9–CM, Volumes 1 and 2, and ICD–9–CM Volume 3, and mandated that all parties covered by HIPAA implement ICD-10 for transactions conducted on or after October 1, 2013 as described.

However, the Secretary of HHS 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, HHS released a final rule in the **Federal Register** on August 4, 2014 (79 FR

45128 through 45134) that included a new compliance date that required the use of ICD–10 to code services provided on or after October 1, 2015.

The ICD–10–PCS code set has been maintained, enhanced and expanded as a direct result of recommendations for updates (e.g. adding new codes, deleting codes, and editing descriptive material related to existing codes) received from interested stakeholders from both the public and private sectors. Thus, information collected in the application is significant to code set maintenance. The ICD–10–PCS code set maintenance is an ongoing process, as changes are implemented and updated; therefore, the process requires continual collection of information from applicants on a bi-annual basis. As new technology evolves and new complex medical procedures are developed, requests are submitted to CMS requesting modifications to the ICD–10–PCS code set. Requests have been received prior to HIPAA implementation and must continue to be collected to facilitate quality decision-making.

**2. Information Use**

When an application is submitted in MEARIS™, the DRG and Coding Team in the Division of Coding and DRGs (DCDRG) will have instant access to the application and accompanying materials to facilitate a more timely review of the application. Upon receipt of a procedure code request, CMS immediately acknowledges receipt of the request and communicates to the requestor that additional follow up will occur once an analyst has been assigned. In addition, CMS provides information via email communication in a letter to each requestor outlining the meeting process and, beginning in 2019, CMS initiated standard pre-meeting conference calls with requestors to discuss their procedure code topic request in more detail in advance of the ICD–10 C&M Committee Meetings. Also, prior to the committee meeting, we make the procedure code topic meeting materials publicly available, commonly referred to as the "Agenda packet" on our website at: https://www.cms.gov/Medicare/Coding/ ICD10/C-and-M-Meeting-Materials. Lastly, once the meeting has concluded, CMS sends a follow-up letter to the requestor informing them of next steps in the process so they can anticipate what to expect.

The ICD–10 C&M Committee's role is advisory. No decisions are made at public ICD–10 C&M Committee Meetings. Instead, representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, as well as the requestor, are provided an opportunity to contribute ideas on coding matters. Comments are encouraged both during the meetings and in writing. After carefully reviewing and considering the opinions expressed during the public meetings and in writing following the meeting, the Committee formulates recommendations, which then must be approved by the agencies. All final decisions are made by the Director of NCHS and the Administrator of CMS.

**3. Use of Information Technology**

There is no standard request form at this time. Requests are submitted via e-mail to the ICDProcedureCodeRequest@cms.hhs.gov mailbox. Applicants will be able to access the

International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) application, via the Medicare Electronic Application Request Information System™
(MEARIS™), on a designated website through CMS.gov. The electronic version of the ICD– 10–PCS application will collect the same information as solicited in the current process for requesting new/revised ICD–10–PCS procedure codes. 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 previously stated burden associated with this collection, and provides a more convenient way for our applicants to submit ICD–10–PCS code applications. Requests that are received by the established deadline will be considered for the upcoming cycle; and requests that are received after the deadline for any coding cycle, will be considered for inclusion in the next cycle.

**4. Duplication of Efforts**

This information collection does not duplicate other efforts.

**5. Small Businesses**

There will be minimal impact on small businesses as this process has been in place for years; and there is ample time allotted from the beginning of the cycle to the deadline to read, complete and submit a request. Timelines and upcoming key future dates are published in the meeting materials from each ICD–10 C&M meeting. Reminder messages are also sent to all subscribers to the ICD–10 Coordination and Maintenance Committee Meetings Govdelivery Subscriber List.

**6. Less Frequent Collection**

This information is collected one time and a coding action is rendered. However, the requestor can choose to submit another application in a subsequent coding cycle.

The information collected in the application is significant to ICD–10–PCS code set maintenance. If this information were not to be collected, CMS would not have a mechanism to receive recommendations from interested stakeholders from both the public and private sectors to alert us that a need exists to enhance, expand or otherwise maintain the only mechanism hospitals have to classify the procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients.

**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 published on 5/11/2021 (86 FR 25872)
No comments were received during the comment period.

The 30-day Federal Register notice published on 7/21/2021 (86 FR 38486)

*Outside Consultation*
Usability testing and feedback for the online application system is in process, effective April 2021. The usability testing will include 5-9 applicant users identified by CMS. The user emails and names will be 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. ICD–10–PCS codes are reported on a claim when hospitals have a claims processing need to identify inpatient hospital services. The existence of a code does not guarantee Medicare payment. CMS maintains the ICD–10–PCS code set, as designated by the Secretary, HHS; for use by all government and non-government insurers in identifying inpatient procedures on electronic medical claims forms, as designated under HIPAA. The ICD–10–PCS code set is in the public domain and may be freely downloaded, used and distributed.

**10. Confidentiality**

“CMS pledges privacy to the extent provided by law.”

**11. Sensitive Questions**

There are no sensitive questions.

## 12. Burden Estimates

We estimate the average response time to be 10 hours. The time estimate for preparation of the ICD–10–PCS Application is based upon the professional judgment of staff members at the Centers for Medicare and Medicaid Services and includes the time and effort involved with completing administrative requirements.

Based on our recent experience, in the next several years we estimate receiving approximately 80 requests annually for ICD–10–PCS classification modifications. We have chosen the average of 80 requests on a yearly basis for purposes of this PRA. It is estimated that there are 80 requests filed annually at an average response time of 10 hours per filing. Therefore, we have calculated the burden as follows: 80 requests x 10 hours per request = 800 burden hours (annual). We believe that we will continue to receive this average number of ICD–10–PCS code requests, our estimate of the number of requests is realistic, and using the average of 80 requests for the purposes of this PRA is reasonable.

The estimated maximum of requests for modification to the ICD–10–PCS classification is 80 per cycle year. The estimated time to read, execute, and submit this form is 10 hours.

**Time to fill out application (Electronic version):**
15 minutes – to read application instructions and questions
2 hrs. – to gather information in response to questions
2 hrs. – to gather performance data, study data and research current coding
1 hr. – to gather product information and FDA documentation
2 hrs. 45 min. – to copy/paste and/or type in responses
2 hrs. – to proof and edit
Total – 10 hrs.

The requestors will no longer be required to email CMS as the application process will be completely online.

We believe Medical and Health Service managers will be responding to the information collection requirements. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2020 http://www.bls.gov/oes/current/oes_md.htm) for Category 11-9111 (Medical and Health Services Managers), the mean hourly wage for a Medical and Health Services Manager is $56.98. We have added 100% of the mean hourly wage to account for fringe and Overhead benefits, which calculates to $113.96 ($56.98 + $56.98). We estimate the total annual cost to be $ 91,168 (800 hours x $113.96/hour).

## 13. 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. We do not anticipate any capital costs to the requestors.

## 14. Cost to Federal Government

The cost to evaluate ICD–10–PCS requests is estimated as follows based on review by analysts, contractors, medical officers, and supervisory staff. This review includes analyses of the submission, required coding research, database inputs, preparation of background papers for the agenda packet, review of draft coding options for appropriateness based on the request and the conventions of the ICD-10-PCS classification, pre-C&M meeting conferences with requestors and their representatives and the preparation of materials for internal clearance. This review also includes the drafting of both pre-C&M meeting and post-C&M meeting template letters to requestors, the review and feedback of presentation slides for content and 508 compliance, the preparation and posting of meeting materials related to the request for either the Spring or Fall ICD–10 C&M Committee Meeting and the receipt and summarization of public comments to finalize a decision. We estimate the total time to process, evaluate, present the request to the public and reach a decision is 40 to 80 hours per request. We use the midpoint of this range (60 hours) to derive the following estimated labor cost for government employees.

$38.37/hr (average salary GS 12, 13, 14)[1] X 60 hours per request X 80 requests (potential/projected number of requests) = $184,176.

## 15. Changes to Burden

There are no anticipated changes to the burden. The intent and substance of the electronic International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) Application form collects the same data elements as solicited in the current process for requesting new/revised ICD–10–PCS procedure codes as described on our webpage at: https://www.cms.gov/Medicare/Coding/ICD10/newrevisedcodes.

## 16. Publication / Tabulation Dates

The application will be available online on a designated website through CMS.gov. The dates and deadlines will be changed bi-annually to reflect the upcoming coding cycles. Content of the material will remain the same; however, questions may need to be revised periodically for clarity so that the requestor will know how to respond correctly.

The information collected in the application will not be made public for review. Upon receipt of a procedure code request, CMS immediately acknowledges receipt of the request and communicates to the requestor that additional follow up will occur once an analyst has been assigned. After initial analyst review, CMS informs the requestor if CMS will proceed with the topic and provides information via email communication in a letter to each requestor outlining the meeting. We make the procedure code topic meeting materials associated with the requests that have been accepted for discussion at a Spring or Fall ICD–10 C&M Committee Meetings publicly available in our “Agenda packet” which is published on our website at: https://www.cms.gov/Medicare/Coding/ ICD10/C-and-MMeeting-Materials.

Codes discussed at the Fall meeting are made available in Table 6B- New Procedure Codes of the following FY IPPS/LTCH PPS proposed rule if approved and generally are implemented October 1 of the following year. An implementation exception is for codes

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/

capturing new technology. If a clear and convincing case is made that the new code is needed to capture new technology, this new code may be implemented on April 1 of the following year. Codes discussed at the Spring meeting are not finalized in time to include in the proposed rule therefore, if approved they appear in the following fiscal year's (FY) Addenda posted to the CMS ICD–10 web page in June of each year.

**17. Expiration Date**

There is no collection data instrument used in the current 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 usage.

**18. Certification Statement**

There are no exceptions to the certification statement.

## C. Collections of Information Employing Statistical Methods

No statistical methods are employed.