

Supporting Statement-A

Ambulatory Surgical Center Covered Procedures List (ASC CPL)

(CMS-10809, OMB 0938-New)

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Supporting Statement – Part A

Background

The Ambulatory Surgical Center Covered Procedures List (ASC CPL) was authorized in accordance with section 1833(i)(1) of the Social Security Act, which requires the Secretary to specify surgical procedures which are appropriately performed on an inpatient basis in a hospital, but which also can be performed safely on an ambulatory basis in an ASC, critical access hospital, or hospital outpatient department. The statute also requires the Secretary to regularly review and update the ASC CPL.

An ASC is defined in regulations as a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission (42 CFR 416.2). Under current regulations, in order for a service to be added to the ASC CPL, it must meet the following general standards: (1) The procedure must be separately paid under the OPPS; (2) the procedure must not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC; and (3) standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure (42 CFR 416.166(b)). Current ASC CPL regulations require the agency to make individual, nationwide decisions for each service on the list.

Procedures are not placed on the CPL under current regulations if they meet any of the following general exclusions: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care; (7) can only be reported using CPT unlisted surgical procedure code; or (8) are otherwise excluded under Medicare (42 CFR 416.166(c)).

During rulemaking, CMS receives surgical procedure code nominations from a variety of external interested parties and evaluates them for inclusion to the CPL in the OPPS/ASC proposed rule. After reviewing the nominations and evaluating them against the criteria, CMS proposes the list of procedures that they will add to the CPL for the following calendar year. The public has 60 days to comment on the proposals, CMS takes these perspectives into account, and the final list of procedures on the CPL is finalized in the OPPS/ASC final rule.

For CY 2022, CMS proposed to formalize the interested party nomination process. CMS proposed that external parties, for example, medical specialty societies or other members of the public, could nominate procedures to be added to the ASC CPL. CMS anticipated

that interested parties, such as specialty societies that specialize in and have a deep understanding of the complexities involved in providing certain procedures, would be able to provide valuable suggestions as to which additional procedures may reasonably and safely be performed in an ASC. While members of the public may already suggest procedures to be added to the ASC CPL through meetings with CMS or through public comments on the proposed rule, CMS believed it would be beneficial to enable the public, particularly specialty societies who are very familiar with procedures in their specialty, to formally nominate procedures based on the latest evidence available as well as input from their memberships. The majority of commenters, which included device manufacturers, hospital associations, and ambulatory surgery associations, supported the proposal to establish a formal process for the public to nominate procedures for addition to the ASC CPL. Interested parties believed this process would provide more transparency and engagement on procedures earlier in the process, formalize the review process, and allow for more gradual expansion of the ASC CPL.

In the CY 2022 OPPTS/ASC final rule (86 FR 63458), CMS finalized that implementing a formalized process whereby the public notifies CMS of procedures to be added to the ASC CPL that would provide more transparency and increase opportunities for CMS to engage with providers and external interested parties in adding procedures to the ASC CPL. This information collection request describes the formal nomination process for OPPTS/ASC rulemaking that was developed.

In the CY 2023 OPPTS/ASC final rule (87 FR 72076), CMS finalized the name of the process as the “Pre-Proposed Rule CPL Recommendation Process” and revised the start date of the recommendation process to January 1, 2024 in the regulatory text.

We are requesting new collection approval from OMB.

A. Justification

1 . Need and Legal Basis

As described in the background section, CMS annually reviews and updates the ASC CPL, as authorized in accordance with section 1833(i)(1) of the Social Security Act. Surgical procedures codes nominated and sent in by external interested parties for CMS review are a key part of CMS review.

2. Information Users

The information collected in this request will be used by CMS annually to determine what covered surgical procedures should be added to the ASC CPL. Specifically, the policy

analysts and medical officers in the Division of Outpatient Care will individually review each procedure nomination, as well as any supporting evidence (clinical studies, literature, data or letters of support) submitted. The agency will use this information to propose a list of covered surgical procedures for the OPPTS/ASC Proposed Rule starting with the CY 2024 Proposed Rule.

3. Use of Information Technology

Historically, interested party procedure nominations were sent informally through email. CMS has streamlined and formalized this process by creating a website where interested parties can submit their procedure nominations, any relevant evidence they have to share, and answer a few key questions. This more structured process makes it easier for the public to submit nominations and for CMS to process them.

This information collection involves the electronic submission of interested party procedure nominations through a module on the MEARIS™ website.¹ The OPPTS payment system already uses several information modules through the MEARIS™ system to collect applications for other OPPTS and ASC policy areas and the nomination process was added as a new module to the existing MEARIS™ website.² The module requires the respondent to:

- a. Provide basic contact information about the person(s) requesting the nomination:
 - i. Name (first/last/(optional) middle);
 - ii. Organization;
 - iii. Occupation/Job Title;
 - iv. Phone number (extension optional);
 - v. Email;
 - vi. Relationship (Consultant/Other).
- b. Provide basic information about each procedure they are nominating for addition or removal:
 - i. Check a box (add/remove) indicating whether or not they are nominating a procedure to be added or removed from the ASC CPL;
 - ii. Enter the HCPCS or CPT code currently used for the nominated procedure; iii. Enter the current code descriptor for the procedure (optional); iv. Check a box (yes/no/unsure) indicating if the nominated code meets all the current ASC CPL criteria at 42 CFR § 416.166; and
 - v. Check a box (yes/no/unsure) indicating if the nominated code has previously been on the ASC CPL.
- c. In addition to the mandatory entries under a. and b. above, respondents are invited at the end of the module to add any brief additional details/comments on the nominated procedure that they might have and to attach any additional evidence or supporting documents.

Since the infrastructure of this website was already in place for other similar OPPS/ASC applications, adding an additional module was the most logical, and least burdensome, method of collecting nominations. An additional advantage of this method is that many external interested parties and members of the public are already familiar with this system, as they have used it for submitting information for other OPPS and ASC policy areas.

1 <https://mearis.cms.gov/public/home>

2 <https://mearis.cms.gov/public/resources?app=asc-cpl>

This collection does not require a signature from the respondent.

If this information collection request is approved, the electronic module would be available for use by the public starting on January 1, 2024.

Respondents will solely use this module to complete their nominations (100% electronic use).

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This information collection minimizes the burden of small businesses or entities that submit procedure nominations. Historically, the informal process provided no guidance or structure for submission. Consequently, submissions varied with respect to the information provided and the format in which it was presented.

This information collection provides a designated place where procedure nominations can be submitted and clear guidance on the process for doing so. The standardized module format additionally ensures that all required information is captured, and irrelevant/unnecessary information omitted.

This reduces the burden on small businesses/entities by:

- a. Clarifying the procedure nomination submission requirements, including where and how to make nominations and what specific information needs to be included;
- b. Reducing or eliminating time-consuming and costly follow-up with CMS to correct/resubmit nominations that were submitted with incomplete information;

- c. Reducing or eliminating time-consuming and costly research to include information/supporting evidence with the submission that is irrelevant or unnecessary.

6. Less Frequent Collection

Section 1833(i)(1) of the Social Security Act (i)(1) requires that the Secretary shall, in consultation with appropriate medical organizations, specify those surgical procedures which can be performed safely on an ambulatory basis in an ambulatory surgical center. The statute states that the lists of procedures should be reviewed and updated not less often than every 2 years.

However, recent OPPS/ASC regulations have established an annual review and collection process for procedure nominations. 42 CFR § 416.166(d) states that, as of January 1, 2024, the public may nominate a surgical procedure for inclusion on the list of ASC covered surgical procedures and that nominations submitted by March 1 of a calendar year will be considered by CMS for inclusion on the ASC list “for the following calendar year.” If CMS determines that a nominated procedure should be included on the list, CMS must propose its addition “in the next available annual rulemaking.” Consequently, as expected by the public, the collection of this information should occur at least annually.

If the collection is not conducted or conducted less frequently than annually, the consequences to the Medicare program could negatively impact health care for Medicare beneficiaries. Given innovations in medical technology and surgical technique, surgical procedures are rapidly advancing and becoming safer to perform in different sites of services, such as ASCs. Annual review of procedures ensures that the Medicare program is continuously evaluating and adding new procedures that could increase Medicare beneficiary choice and access to improvements in surgical care.

7. Special Circumstances

No special circumstances exist that would cause the information collection to be conducted in a manner described at 5 CFR § 1320.5(d)(2)(i)-(viii).

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published in the Federal Register on 06/15/2023 (88 FR 39255).

No comments were received.

The 30-day Federal Register notice published in the Federal Register on INSERT, 2023 (88 FR INSERT).

9. Payments/Gifts to Respondents

No payment or gift will be made to respondents through this information collection process.

10. Confidentiality

Since the procedure nomination(s) submitted by the respondent will be written into the public rulemaking process, this information will not be confidential. However, all personal identifying information, such as the contact information of the respondent, will only be used for internal use. There is no statutory, regulatory, or agency policy that would require an assurance of confidentiality for this process.

11. Sensitive Questions

No sensitive questions are included in the information collection.

12. Burden Estimates (Hours & Wages)

The table below illustrates the estimated annual respondent burden hours and costs.

A	B	C	D	E	F
Expected Number of Respondents (Based on average of previous years)	Frequency of Response	Expected Number of Nominations (Based on average of previous years)	Expected Amount of time for respondent to enter the information for each nomination	Total Annual Hour Burden (Based on expected number of nominations x .50 hours)	Total Annual Cost Burden (Based on Federal Minimum Wage x Total Annual Hour Burden)
15	Once a Year	100	.50 hours	50	\$1620.00

Explanation of how the Respondent Burden Hours were Estimated:

Total annual burden hours (column E) were calculated by multiplying the expected number of nominations (based on previous years' averages) (column C) by the estimated amount of time

it will take a respondent to nominate a procedure via the module (Column D). The assumption is that a nomination will take an average of 30 minutes (.50 hours) to add to the module. This estimate is based on the amount of information requested and the nature/complexity of that information, as described in detail under Item 3. The only significant variable in the amount of time it will take a respondent to enter information into the module would appear to be whether or not a respondent elects to complete the “additional information” field for the nomination and, if so, the length of that additional information. 30 minutes would appear to be a reasonable average taking this variable into account (presumably it will take a respondent less than 30 minutes to complete a submission that contains no additional information, and it could potentially take more than 30 minutes for a respondent to complete a submission which includes additional information).

Explanation of how the Respondent Costs for Burden Hours were Estimated:

Total annual cost burden (column F) was calculated by multiplying the total annual burden hours (column E) by the hourly wage rate of \$32.40.

The hourly wage rate was calculated by taking the U.S. minimum wage for 2023 (\$16.20 see <https://www.dol.gov/agencies/whd/government-contracts/eo14026/>) and multiplying it by two to account for fringe benefits (services provided beyond the employee's normal rate of pay).

13. Capital Costs

All costs associated with this effort are reported in Items 12 and 14. There are no capital costs associated with this collection.

14. Cost to Federal Government

The estimated annual cost to the government for collecting these data includes the following:

- a. Modifying the contract*;
 - b. Working with an IT contractor*; and
 - c. Direct CMS expenses for labor.
- * One-time cost to create new module.

CMS personnel involved in this data collection include approximately .35 FTEs broken out by pay grade in the table below:

CMS Personnel

Grade	FTE	2023 Annual Salary	Cost to Government
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GS 13 Step 5	.25	\$121,065.	\$66,585.
GS 15 Step 1	.10	\$148,484.	\$59,393.
TOTAL	.35	\$269,549.	\$125,978

CMS staff costs are approximately \$125,978. There are no costs for materials, supplies, reproduction, postage, telephone or travel. Thus, in-house CMS cost will be \$125,978.

15. Changes to Burden

This is a new collection.

16. Publication/Tabulation Dates

The results of the information collection (i.e., any interested party nominated procedures received prior to March 1 of each year which CMS decides to propose for inclusion on the ASC list) will be published in the annual proposed OPPS rule (typically published on July 1). Any of the procedures proposed for inclusion by CMS that are finalized for inclusion following publication of the proposed rule will be published in the annual final OPPS rule (typically published on November 1).

17. Expiration Date

CMS will display the expiration date on the first page or cover page of the newly created module.

18. Certification Statement

There are no exceptions to this certification statement.