Supporting Statement
Medicare and Medicaid Programs: Conditions for Coverage for Ambulatory Surgical Centers
(CMS-10279)
(OMB No. 0938-1071)

A. Background

The purpose of this package is to request from the Office of Management and Budget (OMB) the approval to reinstate, with changes, the collection of information, associated with OMB No. 0938-1071, titled "Medicare and Medicaid Programs: Conditions for Coverage (Cfc) for Ambulatory Surgical Centers." The collection of information expired on 12/31/2022.

The Cfc for ASCs are regulation based on criteria described and codified at § 42 CFR 416[1]. The Cfc establish standards designed to ensure that each ASC has properly trained staff to provide the appropriate type and level of care for the environment of ASC patients.

To determine ASC compliance with CMS standards, CMS, via the Secretary, authorizes States, through contracts, to survey ASC facilities. For Medicare purposes, certification is based on the State survey agency's recording of an ASC provider's compliance or non-compliance with the health and safety Cfc as published and codified in 42 CFR 416.40 to 485.54. The information collections aid surveyors as they assess ASC compliance or non-compliance. This information collection does not contain any collection instruments.

The burden to ASCs from the collection of information that corresponds to this package (OMB No. 0938-1071) stem from the requirements as codified in 42 CFR 416.40 to 485.54, specifically: Quality Assessment and Performance Improvement (QAPI) at §416.43; Notice of rights and responsibilities at §416.50; and Patient assessment and admission at §416.52. We refer to these as IC-1, IC-2 and IC-3, respectively.

Note there are also other collections of information that impact ASC. These collections of information stem from the requirements as codified at 42 CFR §416.54 "Emergency preparedness." These information collections are not included in this OMB No. 0938-1071 as they are accounted for in OMB No. 0938-1325.

The previous iteration of this OMB No. 0938-1071 had a burden of 262,946 annual hours at an annual cost of $28,144,370. For this requested reinstatement, with changes, the adjusted annual hourly burden is 97,527 hours at a cost of $11,089,427. The reasons for this change, is the previous iteration of this IC assumed the development associated with IC-1 and IC-2 occurred frequently. We have revised this as development of drafts only occur on a one-time basis. More information on the ICs can be found in section 12.

[1] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-416

B. Justification

1. Need and Legal Basis

Section 934 of the Omnibus Budget Reconciliation Act of 1980, implemented under 42 CFR 416, allows ASCs meeting health, safety, and other standards specified by the Secretary to participate in Medicare. Section 934 amended various sections of the Social Security Act, including sections 1832 and 1863 which instruct the Secretary to consult with appropriate State Agencies and recognize national listing or accreditation bodies in developing the conditions (health and safety requirements), and section 1864, which authorizes the Secretary to use States in determining compliance with the requirements, referred to in regulations as CfCs.

The CfCs are designed to ensure that each ASC has properly trained staff to provide the appropriate type and level of care for that ASC and provide a safe physical environment for patients.

2. Information Users

The CfCs are used by Federal (CMS) or State surveyors (employed by State survey agencies) as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare**.** Surveyors make an in-person visit to ASCs to perform the complete survey.

3. Use of Information Technology

ASCs may use various information technologies to draft, collect, maintain and store information. Information technologies related to patient medical records is also allowed as long as the information collected is consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. These information collection regulation do not prescribe how the ASC should prepare, maintain, update or revise the required information but allows for the flexibility for facilities to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Efforts

These requirements are specified in ways that do not require an ASC to duplicate efforts. If an ASC already maintains these general records, regardless of format, they are in compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records from one ASC to another acceptable.

5. Small Businesses

These requirements will not have a significant impact on ASCs and other suppliers that are small entities. Further, most of the requirements in this rule are part of ASCs' standard

practices. We understand that there are different sizes of ASCs and that the burden for ASCs of different sizes will vary.

6. Less Frequent Collection

CMS does not collect information directly from ASCs, rather CMS relies on State surveyors (employed by State survey agencies) to review the collection of information at the time of their certification and at the time of their facility visit. The information collection serves as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare**.** Surveyors make an in-person visit to ASCs to perform the complete their survey.

The collection of information does not prescribe the manner, timing, or frequency of the records or information that must be available. ASC records are reviewed at the time of a survey for initial or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare CfCs, which in turn, would jeopardize the health and safety of ASC patients and provision of quality healthcare.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published XXXXXXX (88 FR XXXXX)

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

Confidentiality will be maintained to the extent provided by law. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates

To estimate the burden for IC-1 to IC-3 we first provide the global assumptions and estimates used to estimate the associated burden per IC. Table 1 provides the hourly wages for the labor

categories who would be responsible within the ASC to complete the IC-1 to IC-3 for years 2023, 2024, 2025 or years 1, 2 and 3, respectively.

To estimate labor wages, we use concordant salary labor category as defined in the Bureau of Labor Statistics (BLS) using May 2019, 2020, 2021, 2022, National Occupational Employment and Wages data. We specifically use the hourly wages as related to the Ambulatory Health Care Services industry - NAICS 621000.

Starting in 2022, we apply a 100% increase to the estimated BLS hourly wage rate to factor in the costs ASCs pay for employee total benefits such as Paid leave, Supplemental Pay, Insurance, Retirement and Savings, and Legally Required Benefits. This results in a more accurate hourly wage rate estimate. See Table 1, column e.

Once we find the appropriate hourly wage rates from the past four years, we are then able to project the hourly wages for year 1 (2023), year 2 (2024), and year 3 (2025). To project hourly wages, we apply the annual growth rate which occurred between 2019 to 2022. See Table 1, column f. We apply the average growth to predict the estimated loaded hourly, see Table 2.

After we determine the wages estimates, we determine the number of ASCs impacted for Year 1, 2, and 3. We do this by reviewing CMS records on the number of ASCs for the last five calendar years: 2018 to 2022. See Table 3. Using these records, we then determine the average rate of growth. Taking the average number of ASCs between 2018 to 2022 and using an average annual growth rate of 1.2% we estimate the number of ASCs to be 6,183 for 2023 or Year 1, 6,257 for 2024 or Year 2, and 6,332 for 2025 or Year 3. Averaging Year 1 to Year 3 we fine the average annual number of ASCs impacted between Year 1 to Year 3 to be an estimated 6,257 ASCs, see Table 3 and Table 4.

Table 1. Labor Hourly Wages

Occupation Title	Occupation Code	Mean Hourly Wage 2019 *(a)*	Mean Hourly Wage 2020 *(b)*	Mean Hourly Wage 2021 *(c)*	Mean Hourly Wage 2022 *(d)*	Loaded Mean Hourly Wage[2] 2022 *(e = d × 100%)*	Growth Rates Average Growth Rate 2019 to 2022 *(f = (b - a/ b) + (c-b/c) + (d-c/d)/3)*100*
Registered Nurse	29-1141	$36.14	$37.58	$38.65	$46.73	$93	8%
General and Operations Managers	11-1021	$56.17	$56.92	$54.23	$62.02	$124	3%
Physician	29-1210	$127.30	$129.06	$135.51	$131.79	$264	1%

[2] Rounded to the nearest dollar.

Medical Secretaries and Administrative Assistants	43-6013	$18.29	$18.78	$19.04	$18.85	$38	1%

Table 2 Projected Labor Hourly Wages

CMS labor category title	BLS Occupation Title	BLS Occupation Code	Projected Loaded Hourly Wage 2023 *(a = Table 1 col. e × (1 + Table 1 column f)*	Projected Loaded Hourly Wage 2024 *(b = a × (1 + Table 1 column f)*	Projected Loaded Hourly Wage 2025 *(c = b × 1+ Table 1 column f)*	Projected Annual Average *(d = a + b + c/ 3)*
Quality Assurance Registered Nurse	Registered Nurse	29-1141	$100	$108	$117	$108
Adminstrator	General and Operations Managers	11-1021	$128	$132	$136	$132
Physician	Physician	29-1210	$267	$270	$273	$270
Office Clerk	Medical Secretaries and Administrative Assistants	43-6013	$38	$38	$38	$38

Table 3. Number of ASCs

Description	2022 *(a)*	2021 *(b)*	2020 *(c)*	2019 *(d)*	2018 *(e)*	Average *(f = a + b + c + d + e / 5)*
Number of ASCs	6,109	6,170	5,961	5,902	5,817	5,992
Percent Change in Number of ASCs	-1%	3%	1%	1%	-	1.20%
Number of ASCs removed/added	-61	209	59	85	-	73

Table 4. Projected Number of ASCs

Description	Year 1 *(a = Table 3, column a × (1 + 1.02)*	Year 2 *(b = a × (1 + 1.02)*	Year 3 *(c= b ×(1 + 1.02)*	Projected Annual Average *(d = a + b + c / 3)*
Number of ASCs	6,183	6,257	6,332	6,257
Percent Change in Number of ASCs	-	1.2%	1.2%	1.19%
Number of ASCs removed/added	-	74	75	75

IC-1 Quality Assessment and Performance Improvement at §416.43

IC-1 is the associated burden for ASC to comply with §416.43 Quality Assessment and Performance Improvement, specifically as it relates to the Standard 416.43(d) "Performance improvement projects."

As stated in final rule[3], "Medicare Program: … Changes to the Ambulatory Surgical Center Conditions for Coverage," published in 2008, ASCs are required to develop, implement, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program as stated at §416.43(d). In addition, ASC must maintain documentary evidence of its quality assessment and performance improvement program. The QAPI program must be able to demonstrate measurable improvement in indicators related to improved health outcomes and by the identification and reduction of medical errors. This regulation requires ASC to use all relevant quality indicator data to design its QAPI program, monitor the effectiveness and safety of services and quality of care, identify, and prioritize improvement opportunities. For ASCs this means facilities must track adverse patient events, analyze their causes, and implement preventative actions and mechanisms that include feedback and learning throughout the ASC. This also means ASC must measure its success and track performance in its performance improvement initiatives to ensure that the improvements are continuous. The documentation associated with §416.43(d) is the time and effort necessary to develop, draft, and implement a QAPI program as well as record quality data and the necessary annual reports of their performance improvement initiative.

As stated in information collection stemming from the 2008 final rule, we continue to estimate that it will take 18 hours for each ASC to develop, implement and monitor its own quality assessment performance improvement program.

Since the information collection started in 2008, we can assume existing ASCs have already

[3] 73 FR 68812

developed and implemented their QAPI and thus only retain the burden of continuing to maintain their data collection efforts to maintain their QAPI program, including the reporting requirements. As show in Table 4 we anticipate 75 new ASCs per year will be impacted by requirement IC-1a.

As stated in the previous iteration of this information collection we continue to estimate maintenance of an ASC's QAPI program or the data collection and reporting requirements take 12 hours per year. We refer to this as IC-1b. As show in Table 5 we anticipate 6,257 ASCs will be impacted by requirement IC-1b.

As for the estimated labor, we continue to estimate the program will be developed and implemented by the ASC's administrator. We continue to estimate the data collection and the reporting will be completed by a Quality Assurance Registered Nurse.

As shown in Table 2 we estimate the average loaded hourly rate of a Registered Nurse to be $108 and $132 for an Administrator. As shown in Table 5, the total annual burden associated with the developing and implementing (IC-1a) the QAPI program for years 1 to 3 is 1,349 annual hours at a cost of $146,114. The total annual burden for data collection and reporting requirement or maintaining the program is (IC-1b) 75,084 hours at an annual cost of $9,911,088. The resulting total annual burden for IC-1 for years 1 to 3 is 76,433 hours at a cost of $10,057,202.

Table 5 - Annual Burden for IC-1

IC	Number of Impacted ASCs (a)	Labor Cost (b)	Total Burden Hours Per ASC (c)	Total Burden Cost per ASC (e = b × c)	Total Burden Hours to Industry (d = a × c)	Total Cost to Industry (f = a × b × c)
Developing QAPI (1C-1a)	75	$108	18	$1,950	1,349	$146,114
Maintenance of QAPI (1C-1b)	6,257	$132	12	$1,584	75,084	$9,911,088
Total	-	-	-	$3,534	76,433	$10,057,202

IC-2 Standard: Notice of rights and responsibilities at §416.50

IC-2 is the associated burden for ASC to comply with requirement at §416.50, "Notice of rights and responsibilities."

As stated in final rule[4], "Medicare Program: … Changes to the Ambulatory Surgical Center Conditions for Coverage," published in 2008, section 416.50 sets out the requirements ASCs must meet when informing a patient of his or her rights and responsibilities.

Section 416.50(a)(1) requires that ASCs provide their patients or, as appropriate, patient's

[4] 73 FR 68812

representative with a verbal and written notice of the patient's rights in advance of the procedure to be performed at the ASC and in a language and manner that the patient or patient's representative understands. Further, section 416.50(a)(2)(i) requires ASCs to provide the patient or representative with information concerning its policies on advance directives, including a description of applicable State law. Section 416.50(a)(2)(iii) requires ASCs document in the patient's medical record that indicates whether or not the patient has executed an advance directive. We refer to the collection of information associated with requirement at 416.50(a)(1), 416.50(a)(2)(ii) and 416.50(a)(2)(iii) collectively as IC-2a.

The burden associated IC-2a is the time and effort to draft and disseminate this information to the ASC patients. As stated in the 2008 rule, the most effective and efficient manner to furnish this information is to develop general notices which can be subsequently discussed and/or distributed as needed. We continue to expect that ASCs will use this simple and inexpensive approach in order to meet these requirements.

We continue to anticipate these notices will continue to be written by a registered nurse or labor equivalent and the development of these notices will take one hour and will continue to be developed on a one-time basis per ASC.

Similar to the estimation mythology in IC-1a, we continue to estimate only new ASCs will need to develop these notices.

Given this information, we estimate the total annual burden for IC-2a, is 75 hours at an annual cost of $6,968. See Table 6.

As stated in the 2008 final rule we do not estimate a burden to maintain drafts, as maintaining drafts requires minimal time and effort.

In addition to the notifications, section 416.50(a)(3) imposes recordkeeping and reporting requirements. Specifically, §416.50(a)(3)(ii) states ASCs must fully document all alleged violations relating, but not limited to, mistreatment, neglect, verbal, mental, sexual or physical abuse. Section 416.50(a)(3)(iii) requires ASC to immediately report the allegations to a person in authority in the ASC. Further, under §416.50(a)(3)(iv), the ASC must immediately report substantiated allegations to the State and local bodies having jurisdiction, and the State survey agency if warranted. In addition, §416.50(a)(3)(v) requires ASCs to document how the grievance was addressed and the ASC must also provide the patient with a written notice of its decision.

We refer to the collection of information associated these requirements collectively as IC-2b.

The burden associated with this requirement is the time and effort necessary to fully document the alleged violation or complaint, disclose the written notice to each patient who filed a grievance, and report the alleged violations to the aforementioned entities.

We continue to estimate that on average, it will take each ASC 15 minutes to develop and disseminate about 12 notices on an annual basis or about 3 hours per ASC, for a total burden of 18,771 hours. We continue to estimate an ASC office clerk at a loaded hourly rate of $38 will be responsible for this requirement. This results in annual cost of $713,298, see Table 6

The resulting total annual burden for IC-2 for years 1 to 3 is 18,846 hours at a cost of $720,266, see Table 6.

Table 6 - Annual Burden for IC-2

IC	Number of Impacted ASCs *(a)*	Labor Cost *(b)*	Total Burden Hours Per ASC *(c)*	Total Burden Cost per ASC *(d = b × c)*	Total Burden Hours to Industry *(e = a × c)*	Total Cost to Industry *(f = a × b × c)*
Notice of rights and responsibilities (IC-2a)	75	$93	1	$93	75	$6,968
Recordkeeping and reporting (IC-2b)	6,257	$38	3	$114	18,771	$713,298
Total	-	-	-	-	18,846	$720,266

IC-3 Standard: Standard: Patient assessment and admission §416.52

IC-3 is the associated burden with Cfc standard "Patient assessment and admission" at §416.52(a). This regulation requires the operating physician and ASC to determine which patients would require more extensive testing and assessment prior to surgery. The burden associated with this requirement would be the time and effort necessary to create new policies for when, and whether, the ASC would require pre-operative examination and testing, and on what time schedule. We continue to assume that creating these policies (which could leave such decisions to the surgeon's discretion in most or all cases) would require 10 hours of physician time, 10 hours of RN time, and 10 hours of clerical time, at the rates established in Table 2 for a total of 30 hours per facility. As stated in the 2008 final rule, this is a one-time cost and thus only applies to new facilities. Therefore, the total one-time burden for all 75 is 2,248 hours at a cost of $311,959.

Table 7- Annual Burden for IC-3

Labor	Labor Cost (a)	Number of Impacted ASCs (b)	Total Burden Hours Per ASC (c)	Total Burden Cost per ASC (e = b × c)	Total Burden Hours to the Industry (d = b × c)	Total Cost to the Industry (f = a × b × c)
Physician	$270	75	10	$2,700	749	$202,311
Registered Nurse	$108	75	10	$1,083	749	$81,174
Office Clerk	$38	75	10	$380	749	$28,473
Total	-	150	-	$4,163	2,248	$311,959

The total annual burden for IC-1 to IC-3 is an annual burden of 97,527 hours at an annual cost of $11,089,427.

Table 8. Total Burden for IC-1 to IC-3

IC	Annual Burden Hours	Annual Burden Cost
IC-1a	1,349	$146,114
IC-1b	75,084	$9,911,088
Sub-total	76,433	$10,057,202
IC-2a	75	$6,968
IC-2b	18,771	$713,298
Sub-total	18,846	$720,266
IC-3	2,248	$311,959
Total	**97,527**	**$11,089,427**

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Due to the *1864 Agreement*[5] State Survey Agencies facilitate the review of ASCs for compliance with CfCs. While state surveyors facilitate the review, CMS funds the states through contracts to facilitate these reviews. Thus, the cost to the federal government is the cost for the state to facilitate the reviews of ASCs for compliance as well as the cost to submit this PRA package for OMB approval of these associated information collections.

The burden for state surveyors to facilitate the review was calculated using an average salary of $64 per hour for a State Survey Agency reviewer which includes benefits and overhead.

IC-1 Quality Assessment and Performance Improvement at §416.43

§416.43(d): State Survey Agency reviewers are required to review ASCs' QAPI programs, and we estimate the cost to the Federal government to review each program to be approximately 4 hours, with a net cost of $256 per ASC (4 hours × $64). The total burden to the Federal

[5] Center for Medicaid and Medicare (CMS). (2022). "State Obligations to Survey to the Entirety of Medicare and Medicaid Health and Safety Requirements under the 1864 Agreement". https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/state-obligations-survey-entirety-medicare-and-medicaid-health-and-safety-requirements-under-1864

government is estimated to be $1,594,112 ($256 × 6,227 ASCs) and 24,908 hours (4 hours ×6,227 facilities). Expressed in terms of federal employee full time equivalents (FTE)[6] we estimate 12 FTEs (6,227 x 4 ÷2,080 = 12)

IC-2 Standard: Notice of rights and responsibilities at §416.50

§416.50(a)(1): State Survey Agency reviewers are responsible for ensuring ASCs' compliance with the requirement to provide patients with notice of their rights prior to the start of the surgical procedure. We estimate the cost to the Federal government to ensure each ASC's compliance to be approximately 1 hour, with a net cost of $64 per ASC (1 hour × $64). This would be a one-time cost only for new facilities, therefore the total burden for the Federal government for all 75 new ASCs, is $4,800 ($64 ×75 facilities) and 75 hours (75 hour × 1 facilities) or 0.04 FTE.

§416.50(d): State Survey Agency reviewers are responsible for reviewing ASCs' grievance procedures and policies. We estimate the cost to the Federal government to ensure each ASC's compliance to be approximately 1 hour, with a net cost of $64 per ASC (1 hour x $64). The total burden to the Federal government is estimated to be $ 398,528 ($64 x 6,227 ASCs) and 6,227 hours (1 hour x 6,227 facilities) or 3 FTE.

IC-3 Standard: Standard: Patient assessment and admission §416.52

§416.52(a): State Survey Agency reviewers are responsible for reviewing ASCs' policies for when to require some form of history and physical as part of the pre-operative examination and testing. We estimate that the cost to the Federal government to review each ASC's policies to be approximately 2 hours, with a net cost of $128 per ASC (2 hours x $64). This would be a one-time cost only for new facilities, therefore the total burden for the Federal government for all 75 new ASCs, is $9,600 ($128 x 75 facilities) and 150 hours (2 hours x 75 facilities) or 0.07 FTE.

Refer to Table 9 for the total burden to the Federal government for reviewing and ensuring ASCs' compliance with these requirements.

Table 9. Total Burden and Cost Estimates for Government

IC	Hourly Burden per ASC	Loaded Hourly Labor Rate	Total per ASC	Number of ASCs	Total to Industry Hours	Total Industry Cost	FTE
IC-1	4	$64	$256	6,227	24,908	$1,594,112	12.00
IC-2a	1	$64	$64	75	75	$4,800	0.04
IC-2b	1	$64	$64	6,227	6,227	$398,528	3.00
IC-3	2	$64	$128	75	150	$9,600	0.07
Total	8		$512	-	31,360	$2,007,040	15.11

[6] We assume one FTE is 2,080 hours per year.

Total the state surveyors who are collecting the information collections is 15.11 FTEs.

In addition to the cost of facilitating ASC reviews for compliance, the cost to federal government also includes the cost to develop and submit this PRA package for OMB compliance. To develop this cost, we use pull from the anticipated time it takes to develop a PRA package for ASCs. Using this information, we know it takes about 90 hours per three-year period or about 30 hours per year or 0.01 FTEs to develop and complete a PRA package. Typically, a GS-13, step 1 federal government employee completes this PRA packages which makes the cost to the federal government about $38.92 per hour or $1,168 per year. The federal employee responsible for updating the PRA packages is located at CMS headquarters office.

Total cost to federal government is $2,008,208 per year ($2,007,040 + $1,168 =$2,008,208) expressed as 31,390 hours per year (31,360 +30 =31,390) or 15.12 FTEs (15.11 + 0.01= 15.12).

15. Changes to Burden

Changes to the burden are a reflection of three changes: 1) A correction in the assumption in the previous iteration that development (IC-1) of notifications and draft policy (IC-3) occur more than a one-time basis and 2) an increase in the number of affected ASCs from 5,557 to 6,227. These changes and updates result in a 170 percent net decrease in annual burden hours, from 262,946 to 97,527 and a 154 percent net decrease in annual cost, from $28,144,370 to $11,089,427..

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.

18. Certification Statement

There is no exception to this statement.