

Supporting Statement – Part A
Appropriate Use Criteria for Advanced Diagnostic Imaging Services
CMS-10570 (OMB 0938-1288)

This package was first approved on June 24, 2016 and was associated with a November 16, 2015, final rule (80 FR 70886) (CMS-1631-FC; RIN 0938-AS40).

This package seeks to reinstate the collection of information. This package includes revisions to the burden estimates to take into account the actual number of applications received in the first few years of the program as well as updating the wage estimates using the most current 2019 BLS wage index.

Background

The collection of information under the Appropriate Use Criteria (AUC) for Diagnostic Imaging Services program is an essential component of this program. In general, AUC are a set of individual criteria that present information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context. A provider-led entity (PLE) as defined in 42 CFR § 414.94(b) is a national professional medical specialty society or other organization that is comprised primarily of providers or practitioners who, either within the organization or outside the organization, predominantly provide direct patient care.

Per the definition of AUC in § 414.94(b), AUC are criteria developed or endorsed by national professional medical specialty societies or other PLEs. This program requires professionals ordering applicable imaging services as defined in § 414.94(b) to consult with specified applicable AUC, which are criteria developed, endorsed or modified by a qualified PLE. In order for CMS to identify PLEs that are qualified to develop AUC, we developed requirements that entities must meet in their AUC development processes. To ensure that these requirements are met, we require PLEs to submit information demonstrating their adherence to these requirements. CMS qualifies those PLEs that demonstrate adherence to the requirements for a period of five years. Qualified PLEs are also required, during the 5th years after their most recent approval date, to ensure adherence has been maintained and to account for any changes in the entities' processes. Qualified PLEs must reapply every five years and must submit the applications by January 1 of the 5th year after the PLE's most recent approval date. The first PLEs were qualified in June 2016 through June 2021 and are expected to reapply by January 1, 2021.

A. Justification

1. Need and Legal Basis

Section 218(b) of the Protecting Access to Medicare Act (PAMA) of 2014 amended the Medicare Part B statute by adding a new section 1834(q) of the Act entitled, “Recognizing Appropriate Use Criteria for Certain Imaging Services,” which directs the Secretary to establish a program to promote the use of AUC. This program is codified at 42 CFR § 414.94.

To implement this program, we first established a process by which PLEs become qualified by Medicare to develop or endorse AUC. The cornerstone of this process is for PLEs to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. It is through this demonstration that we meet the requirements of section 1834(q)(2)(B) of the Act to take into account certain considerations for the AUC. Section 1834(q)(2)(B) specifies that the Secretary must consider whether AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on studies that are published and reviewable by stakeholders. It is not feasible for us to review every individual criterion. Rather, we have established a qualification process and requirements for qualified PLEs in order to ensure that the AUC development or endorsement processes used by a PLE result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B).

In order to become and remain a qualified PLE, we require PLEs to demonstrate adherence to specific requirements when developing, modifying or endorsing AUC. The requirements include: a systematic literature review of the clinical topic and relevant imaging studies; AUC development led by at least one multidisciplinary team with autonomous governance; a process for identifying team members’ conflicts of interest; publication of individual appropriate use criterion on each organization’s website; identification of AUC that are relevant to priority clinical areas; identification of key decision points for individual criterion as evidence-based or consensus-based and strength of evidence grading per a formal, published, and widely recognized methodology; a transparent process for the timely and continual updating of each criterion; a process for developing, modifying or endorsing AUC publicly posted on the entity’s website; and disclosure of external parties involved in the AUC development process.

2. Information Users

The information is used by CMS to determine if PLEs demonstrate adherence to the AUC development requirements set forth for this program. CMS reviews the submitted information and determines whether to qualify the entity based upon their submission. CMS reviews re-application information in a similar manner to ensure adherence to the AUC development requirements. CMS posts the names of all qualified PLEs to the CMS website.

3. Use of Information Technology

Submissions are only accepted electronically. Because submissions include a large amount of information and are reviewed by numerous CMS staff, it was important to establish a single streamlined means for submission and have the ability to readily distribute internally. As such, hard copy submissions are not feasible for this program. A signature is not required for the submission. We created the following email address to which 100% of submissions must be sent: ImagingAUC@cms.hhs.gov.

4. Duplication of Efforts

Similar information is not currently collected by CMS that could be used or modified to demonstrate adherence by PLEs to the AUC development requirements. This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

There may be small entities or small businesses that are PLEs. To the extent they choose to apply to become qualified PLEs under this AUC program then they would be impacted. The burden associated with this application to become qualified is already at a minimum and because of the nature of the application, we do not believe small entities would be adversely impacted compared to larger entities.

6. Less Frequent Collection

This collection of information is essential to ensure that PLEs are developing AUC as required by this program. Demonstrating adherence to the AUC development requirements is important to ensure that AUC are developed consistent with the comprehensive requirements in statute and regulation. Failure to collect this information could result in the use of lower quality AUC that may not be developed by appropriate experts and may not be evidence based which would compromise the value of this program and the intended outcomes of reducing overutilization and ensuring appropriate use of advanced diagnostic imaging services. Less frequent collection of information than every five years for purposes of re-application would have the same effect as it is important to ensure that qualified PLEs maintain adherence to the AUC development requirements.

7. Special Circumstances

This information collection does not involve any special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on XXXXXXXX.

We have continued to engage governmental and nongovernmental stakeholders in discussions regarding the AUC program in general.

9. Payments/Gifts to Respondents

No payment or gifts will be provided to respondents.

10. Confidentiality

There is no assurance of confidentiality regarding applications. CMS posts the names of the qualified PLEs to the CMS website. In addition, applications may be subject to FOIA.

11. Sensitive Questions

Questions of a sensitive nature are not part of this collection of information.

12. Burden Estimates (Hours & Wages)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

Estimated Hourly Wages				
Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialists	13-1000	36.61	36.61	73.22
Medical and Health Services Managers	11-9111	55.37	55.37	110.74
Physicians, all Other; and Ophthalmologists, Except Pediatric	29-1228	97.81	97.81	195.62

Except where noted, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements/Burden

Consistent with section 1834(q) of Title XVIII of the Act (as amended by section 218(b) of the PAMA), we have adopted specific requirements for the development of appropriate use criteria (AUC) that can be specified under § 414.94 as part of the Medicare program. PLEs that use processes that meet certain requirements and want to be recognized as qualified PLEs for the purpose of this section may apply to CMS.

Applications must be submitted electronically and demonstrate how the organization's processes for developing AUC meet the requirements specified in § 414.94(c)(1) which include: a systematic literature review of the clinical topic and relevant imaging studies; led by at least one multidisciplinary team with autonomous governance; a process for identifying and resolving conflicts of interest of team members, the PLE and any other party participating in AUC development or modification; publication of individual appropriate use criterion on the qualified PLE's website; identification of AUC that are relevant to priority clinical areas; identification of key decision points for individual criterion as evidence-based or consensus-based and strength of evidence grading per a formal, published, and widely recognized methodology; a transparent process for the timely and continual updating of each criterion (at least annually); a process for developing, modifying or endorsing AUC publicly posted on the entity's website; and the disclosure of external parties involved in the AUC development process.

To be identified as a qualified PLE by CMS, organizations must meet the definition of PLE, and demonstrate adherence to the requirements in their application for CMS review and use the application process identified in § 414.94(c)(2) of the regulations. Applicant PLEs must submit applications documenting adherence to each AUC development requirement; applications are accepted annually by January 1; all qualified PLEs approved in each year are posted to the CMS website by June 30; all qualified PLEs must re-apply every 5 years; and re-applications must be submitted by January 1 during the 5th year after the qualified PLE's most recent approval date. If a qualified PLE is found to be non-adherent to the requirements identified above, CMS may terminate its qualified status or may consider this information during re-qualification.

At the time of establishment of the program in 2015, we estimated the one-time burden associated with the requirements under § 414.94(c)(2) to be the time and effort it would take each of the 30 organizations that had expressed interest in developing AUC to compile, review and submit documentation demonstrating adherence to the AUC development requirements. At that time, we anticipated 30 respondents based on the number of national professional medical specialty societies and other organizations that had expressed interest in participating in this program as well as other entities we expected to participate.

We estimated it would take 20 hours at \$67.38/hr for a business operations specialist to compile, prepare and submit the required information, 5 hours at \$99.68/hr for a medical and

health services manager to review and approve the submission, and 5 hours at \$187.48/hr for a physician to review and approve the submission materials. In this regard, we estimate 30 hours per submission at a cost of \$2,783.40 per organization. In aggregate, we estimate 900 hours (30 hr x 30 submissions) at \$83,502 (\$2,783.40 x 30 submissions).

There are currently 22 qualified PLEs over the five-year period. In 2016, the first year we accepted and reviewed PLE applications, we received 19 applications. Of the 19 entities requesting qualification, we determined that 11 met the regulatory requirements so 11 PLEs were qualified from the first group of applicants. One of these entities later withdrew its participation, so 10 PLEs remain qualified from the first group of applicants. In 2017, we received nine applications and qualified seven new PLEs. In 2018, we received six applications and qualified three new PLEs. In 2019, we received four applications and qualified two new PLEs. In 2020, we did not receive any applications.

We previously estimated that after the first year of applications, we annually expected less than 10 new applicants to apply to become qualified PLEs in years 2-5. This estimation was correct. Since we have received fewer than ten respondents in each year after 2016, the information collection requirements for new applicants are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

Qualified PLEs must re-apply every 5 years. Therefore, by January 1, 2021, we expect that the 10 entities approved in 2016 and still participating, will re-apply. We continue to expect the burden for re-applying to be half the burden of the initial application process. The PLEs will be able to make modifications to their original application which should result in a burden of 10 hours at \$73.22/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hours at \$110.74/hr for a medical and health services manager to review and approve the submission, and 2.5 hours at \$195.62/hr for a physician to review and approve the submission materials. Annually, we estimate 15 hours per submission at a cost of \$1,498.00 per organization. In aggregate, we estimate 150 hours (15 hr x 10 submissions) at \$14,980 (\$1,498 x 10 submissions).

We previously estimated that after the first year of applications, we annually expected less than 10 applicants to apply to become qualified PLEs in years 2-5. After five years of experience, we have confirmed that there will be less than 10 re-applicants in each of the years 2022-2025. We expect the seven PLEs approved in 2017 will reapply in 2022. In 2023, we expect the three entities approved in 2018 will reapply. We expect two re-applications in 2024 and no re-applications in 2025. Since we will receive fewer than ten re-applications in each year after 2021, the information collection requirements for renewing applicants in years 2022 through 2025 are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

Section 414.94(f)(3) provides that CMS may terminate the qualified status of a PLE if it finds that the PLE is not adherent to the requirements in § 414.94(c). In this instance the PLE

would need to re-qualify to reinstate their status. The requalification requirements are associated with an administrative action. In accordance with the implementing regulations of the PRA at 5 CFR § 1320.4(a)(2) and (c), the associated burden is exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). We also estimate that the requalification process would apply to fewer than ten respondents per year. Consequently, the information collection requirements are also exempt under 5 CFR § 1320.3(c) of the Paperwork Reduction Act's implementing regulations.

Summary of Annual Burden Estimates

Regulation Section(s)	Respondents	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$)	Total Cost (\$)
414.94(c)(2) (reapplication)	10	10	15	150	Varies (see above)	14,980
Total	10	10	--	150	Varies (see above)	14, 980

13. Capital Costs

Not applicable.

14. Cost to Federal Government

We estimate the cost to the federal government based on the percentage of time required by each of the staff with Baltimore/Washington DC locality pay involved in reviewing the applications submitted. We estimate the following percentages of time and cost for each FTE and the total cost below using the 2020 OPM pay scale (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB.pdf>):

Position	% time	Salary	Cost
1 GS-15, step 5 Supervisory Health Insurance Specialist	5	161,730	8,086.50
1 GS-15, step 5 Medical Officer	10	161,730	16,173.0
1 GS-15, step 5 Health Insurance Specialist	15	161,730	24,259.50
1 GS-13, step 5 Health Insurance Specialist	20	116,353	23,270.60
1 GS-9, step 5 Health Insurance Specialist	10	67,473	6,747.30
			Total Cost: \$78,536.90

15. Changes to Burden

The changes to burden consist of the following:

- 1) Reduction of the number of respondents based on the number of actual responses received in year 1 (2016), which decreases the total annual hours and total cost. Removal of the one-time burden calculation for new applications, since we have received less than ten applications each year since 2017.
- 2) Updated the wage estimates using the most currently available U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates. The broad category 29-1060 which included all physicians and surgeons was deleted from the BLS wage estimates for 2019, replaced with several more detailed categories. We chose 29-1228 (Physicians, All Other; and Ophthalmologists, Except Pediatric) as the most appropriate category that would include radiologists.
- 3) Reflecting the burden associated with re-applications as a one-time cost, instead of an annualized cost spread over 5 years, due to the number of applications received and approved each year.

The changes result in a net decrease in respondents, total annual burden hours and total cost. In summary, the total burden hours decreased from 1,350 hours to 150 hours and the total cost decreased from \$84,984 to \$14,980.

16. Publication/Tabulation Dates

Information collected under this program will not be published by CMS.

17. Expiration Date

We will display the expiration date on the Appropriate Use Criteria Program website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html>.

18. Certification Statement

There are no exceptions to the certification statement.