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

This package is associated with a November 16, 2015, final rule (80 FR 70886) (CMS-1631-FC; RIN 0938-AS40).

Background

The collection of information under the new 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 §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 will require 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 have developed requirements that entities must meet in their AUC development processes. To ensure that these requirements are met, we are requiring PLEs to submit information demonstrating their adherence to these requirements. Those PLEs that demonstrate adherence to the requirements are then qualified by CMS to develop AUC. Qualified PLEs are also required, during the 5th year after their most recent approval date, to ensure adherence has been maintained and to account for any changes in the entities' processes.

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 us to establish a new program to promote the use of AUC. This new program is located at 42 CFR 414.94.

To implement this program we are first establishing 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 will be used by CMS to determine if PLEs demonstrate adherence to the AUC development requirements set forth for this program. We will review the submitted information and determine whether to qualify the entity based upon their submission. Information submitted when qualified PLEs re-apply during the 5th year of approval after the most recent approval date will be reviewed in a similar manner to ensure adherence to the AUC development requirements. All qualified PLEs will be posted to the CMS website.

3. Use of Information Technology

Submissions will only be accepted electronically. Because submissions will include a large amount of information and will be reviewed by numerous CMS staff, it is important that we 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 have created the following email address to which 100% of submissions must be sent: ImagingAUC@cms.hhs.gov.

4. Duplication of Efforts

Because this is a brand new Medicare program, 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 NPRM served as the 60-day Federal Register notice which published on July 15, 2015 (80 FR 41685). The NPRM was placed on public inspection on July 8 whereby comments were due on Sept 8. We received public comments regarding our proposed requirements and burden, we have considered the comments and are adopting the proposed provisions with minimal change. The changes do not affect the burden estimates calculated for this information collection.

The final rule is serving as the 30-day Federal Register notice (November 16, 2015; 80 FR 70886). The final rule was placed on public inspection on October 30 whereby comments are due on/by December 29, 2015.

We have engaged 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. Applicants that are considered to be qualified PLEs will have their entity's name posted 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 2014 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	33.69	33.69	67.38
Medical and Health Services Managers	11-9111	49.84	49.84	99.68
Physicians and Surgeons	29-1060	93.71	93.71	187.48

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 will be accepted annually by January 1 starting January 1, 2016~~7~~; all qualified PLEs approved in each year will be posted to the CMS website by June 30; and all qualified PLEs must re-apply every 5 years and 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.

The one-time burden associated with the requirements under §414.94(c)(2) is the time and effort it will take each of the 30 organizations that have expressed interest in developing AUC to compile, review and submit documentation demonstrating adherence to the AUC development requirements. We anticipate 30 respondents based on the number of national professional medical specialty societies and other organizations that have expressed interest in participating in this program as well as other entities we have not heard from but would expect to participate.

We estimate it will 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).

After the anticipated initial 30 respondents, we expect less than 10 applicants to apply to become qualified PLEs annually. Since we estimate fewer than ten respondents, the information collection requirements 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 in years 5-10, we expect that the initial 30 entities will re-apply. The ongoing burden for re-applying is expected 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 $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hours at $99.68/hr for a medical and health services manager to review and approve the submission, and 2.5 hours at $187.48/hr for a physician to review and approve the submission materials. Annually, we estimate 15 hours per submission at a cost of $1,391.70 per organization. In aggregate, we estimate 450 hours (15 hr x 30 submissions) at $41,751 ($1,391.70 x 30 submissions).

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) (initial)	30	30	30	900	Varies (see above)	83,502
414.94(c)(2) (reapplication)			15	450		6,959
Total	30	60	--	1,350	Varies (see above)	90,461

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 2015 OPM pay scale (http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/DCB.pdf):

Position	% time	Salary	Cost
1 GS-15, step 5 Supervisory Health Insurance Specialist	5	143,079	7,153.95
1 GS-15, step 5 Medical Officer	10	143,079	14,307.90
1 GS-15, step 5 Health Insurance Specialist	15	143,079	21,461.85
1 GS-13, step 5 Health Insurance Specialist	20	102,932	20,586.40
1 GS-9, step 5 Health Insurance Specialist	10	59,689	5,968.90
			Total Cost: $69,479

15. Changes to Burden

There are no changes to burden, this is a new collection.

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.