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

This package is associated with a July 15, 2015, NPRM (CMS-1631-P; 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 order for CMS to identify provider-led entities 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 provider-led entities to submit information demonstrating their adherence to these requirements. Those provider-led entities that demonstrate adherence to the requirements are then qualified by CMS to develop AUC. Qualified provider-led entities are also required to re-apply every six years 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 PAMA 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 provider-led entities become qualified by Medicare to develop or endorse AUC. The cornerstone of this process is for provider-led entities to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. It is through this demonstration that we propose to 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 criteria. Rather, we are establishing a qualification process and requirements for qualified provider-led entities in order to ensure that the AUC development or endorsement processes used by a provider-led entity result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B).

In order to become and remain a qualified provider-led entity, we are requiring a provider-led entity 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 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; and a process for developing, modifying or endorsing AUC publicly posted on the entity's website.

2. Information Users

The information will be used by CMS to determine if provider-led entities 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 every six years when qualified provider-led entities must re-apply will be reviewed in a similar manner to ensure adherence to the AUC development requirements. All qualified provider-led entities 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. Before the start of this program we will identify an email address to which 100% of submissions must be sent.

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 provider-led entities 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 provider-led entities. To the extent they choose to apply to become qualified provider-led entities 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 provider-led entities 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 six years for purposes of re-application would have the same effect as it is important to ensure that qualified provider-led entities 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 is serving 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 are due Sept 8.

We have engaged governmental and nongovernmental stakeholders in discussions regarding the AUC program in general. Some discussions addressed various aspects of this collection of information, however we did not request feedback on these specific requirements as the proposed rule was pending during stakeholder interactions. We expect to receive informative and constructive comments regarding this collection of information during the public comment period following the release of the proposed rule which we will use in finalizing programmatic requirements.

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 provider-led entities 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.

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

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.

Burden Estimates

The ongoing burden associated with the requirements under §414.94(c)(2) is specific to the time and effort it would take each of the 30 organizations with interests in AUC to compile, review and submit documentation of adherence to the proposed 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 expect to participate.

We estimate it will take 20 hr at $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 5 hr at $99.68/hr for a medical and health services manager to review and approve the submission, and 5 hr at $187.48/hr for a physician to review and approve the submission materials. Annually, we estimate 30 hr per submission at a cost of $2,783.40 per organization. In aggregate, we estimate 900 hr (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 provider-led entities 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 provider-led entities must re-apply every 6 years. Therefore in years 7-10, we expect those initial 30 entities will re-apply. The burden of re-applying is expected to be half the burden of the initial application process. The provider-led entity will be able to make modifications to their original application which should result in a burden of 10 hr at $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hr at $99.68/hr for a medical and health services manager to review and approve the submission, and 2.5 hr at $187.48/hr for a physician to review and approve the submission materials. For each re-application, we estimate 15 hr per submission at a cost of $1,391.70 per organization. In aggregate, we estimate 450 hr (15 hr x 30 submissions) at $41,751 ($1,391.70 x 30 submissions). As this collection is only every six years, we estimate an annual burden of 75 hr (450 hr/6) and $6,958.50 ($41,751/6).

Summary

Section(s) in title 42 of the CFR	Respondents	Responses (total)	Burden per Response	Total Annual Burden (hr)	Labor Rate for Reporting ($/hr)	Total Cost ($)
414.94(c)(1) and (2)	30	30	5 hr	150	187.48	28,113
			5 hr	150	99.68	14,952
			20 hr	600	67.38	40,332
Total (Apply)	30	30	30	900	n/a	83,502

Section(s) in title 42 of the CFR	Respondents	Responses (total)	Burden per Response	Total Annual Burden (hr)	Annualized Burden (hr)	Labor Rate for Reporting ($/hr)	Total Cost ($)
414.94(c)(1) and (2)	30	30	2.5 hr	75	**12.5**	187.48	2,343.50
			2.5 hr	75	**12.5**	99.68	1,246.00
			10 hr	300	**50**	67.38	3,369.00
Total (Reapply)	30	30	15	450	**75**	n/a	6,958.50

13. Capital Costs

Operation, maintenance and purchase would not be beyond the scope of the normal duties of affected organizations. These organizations are already doing this type of work or have already taken it upon themselves to establish similar processes to what we are requiring. Annually, we estimate 30 hr per submission at a cost of $2,783.40 per organization. In aggregate, we estimate 900 hr (30 hr x 30 submissions) at $83,502 ($2,783.40 x 30 submissions). Starting six years into the program the anticipated 30 qualified provider-led entities are required to re-apply and we expect the burden of re-applying to be half the burden of the initial application process. Annually, we estimate 15 hr per submission at a cost of $1,391.70 per organization. In aggregate, we estimate 450 hr (15 hr x 30 submissions) at

$41,751 ($1,391.70 x 30 submissions). As this collection is only every six years, we estimate an annual burden of 75 hr (540 hr/6) and $6,958.50 ($41,751/6).

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 payscale (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

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

These information collection requirements do not employ statistical methods.