Supporting Statement – Part A
Appropriate Use Criteria (AUC) for Diagnostic Imaging Services: Clinical Decision Support Mechanism (CDSM) Application Process
CMS-10624, OMB 0938-TBD

Background

The collection of information under the Appropriate Use Criteria (AUC) for Diagnostic Imaging Services program is an essential component of this program. In order for CMS to identify clinical decision support mechanisms (CDSMs) that are qualified to be used by ordering professionals for consultation with specified applicable AUC, we have developed proposed requirements for CDSMs under §414.94(g)(1) in the CY 2017 Physician Fee Schedule Notice of Proposed Rulemaking. To ensure that these requirements are met, we are proposing that CDSMs apply for qualification by CMS by submitting information demonstrating their adherence to these requirements under §414.94(g)(2). Those CDSMs that demonstrate adherence to the requirements will then be qualified by CMS. We are proposing that qualified CDSMs are also required, during the 5th year after their most recent approval date, to reapply to ensure adherence has been maintained and account for any changes in the mechanisms.

This information collection request should not be confused with our CMS-10570 (OMB 0938-1288) package (Appropriate Use Criteria for Advanced Diagnostic Imaging Services) which pertains to the application process for provider-led entities (PLEs).

As defined in in 42 CFR 414.94, a provider-led entity (PLE) means a national professional medical specialty society or other organization that is comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care. To be qualified, PLEs must submit an application documenting adherence to the requirements for developing or modifying AUC under §414.94(c)(1). The application process is described in §414.94(c)(2). Some examples of qualified PLEs include the American College of Cardiology Foundation, the American College of Radiology, and Brigham and Women's Physicians Organization.

On the other hand, as our CY 2017 NPRM proposes, a CDSM is an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology or private sector mechanisms independent from certified EHR technology or established by the Secretary. Our CY 2017 NPRM proposes that to be qualified, a CDSM developer must submit an application documenting adherence to the requirements for tools under §414.94(g)(1). The proposed application process is described in §414.94(g)(2) and is the focus of this information collection request.

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.

Section 1834(q)(3)(B) specifies that qualified CDSMs must meet specific requirements including: make available to the ordering professional applicable AUC and the documentation supporting the appropriateness of the applicable imaging service that is ordered; where there is more than one applicable appropriate use criterion specified for an applicable imaging service, indicate the criteria it uses for the service; determine the extent to which an applicable imaging service that is ordered is consistent with the applicable AUC; generate and provide to the ordering professional documentation to demonstrate that the qualified CDSM was consulted by the ordering professional; be updated on a timely basis to reflect revisions to the specification of applicable AUC; meet applicable privacy and security standards; and perform such other functions as specified by the Secretary (which may include a requirement to provide aggregate feedback to the ordering professional). Based upon these statutory requirements, we have proposed a qualification process and requirements for qualified CDSMs.

2. Information Users

The information will be used by CMS to determine if CDSMs demonstrate adherence to the CDSM requirements set forth for this program. We will review the submitted information and determine whether to qualify the CDSM based upon their submission. Information submitted when qualified CDSMs 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 requirements. All qualified CDSMs 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 of CDSMs to the 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 develop CDSMs. To the extent they choose to apply to become qualified CDSMs 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 CDSMs meet the requirements of this program. Demonstrating adherence to the CDSM 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 ordering professionals consulting specified applicable AUC through CDSMs that to not meet the statutory requirements under Section 1834(q)(3)(B) which include not only program specific requirements and functionality, but privacy and security standards. Failure of qualified CDSMs to meet these requirements 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 CDSMs maintain adherence to the requirements.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other

agencies for compatible confidential use; or

- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

Federal Register

The July 15, 2016 (81 FR 46162), proposed rule (CMS-1654-P, RIN 0938-AS81) is serving as the 60-day Federal Register notice.

Outside Consultation

We have engaged governmental and nongovernmental stakeholders in discussions regarding the AUC program in general. We expect to receive public comments regarding our proposed requirements and burden, and will consider the comments when finalizing these 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 CDSMs will have their entity's name posted to the CMS website. In addition, applications may be subject to FOIA.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

Consistent with section 1834(q) of the Act (as amended by section 218(b) of the PAMA), we have proposed specific requirements for clinical decision support mechanisms (CDSMs) that can be qualified CDSMs under §414.94 of our regulations as part of the Medicare appropriate use criteria (AUC) program. CDSMs that believe they meet the requirements to be qualified CDSMs (for the purpose of this section) may apply to CMS to be specified as a qualified CDSM.

Applications must be submitted electronically and demonstrate how the CDSM meets the

requirements under §414.94(g)(1). Specifically, applications must demonstrate how the CDSM: (1) makes available specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered; (2) identifies the appropriate use criterion consulted in the event the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario; (3) makes available, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas identified in §414.94(e)(5); (4) has the technical capability to incorporate specified applicable AUC from more than one qualified PLE; (5) determines the extent to which an applicable imaging service is consistent with a specified applicable appropriate use criterion consulted for a patient's specific clinical scenario, or a determination of "not applicable" when the mechanism does not contain a criterion applicable to that patient's specific clinical scenario; (6) generates and provides a certification or documentation each time an ordering professional consults a qualified CDSM that includes a unique consultation identifier to the ordering professional that documents which qualified CDSM was consulted, the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM, and whether the service ordered would adhere to specified applicable AUC or whether specified applicable AUC was not applicable to the service ordered; (7) updates AUC content at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or an individual appropriate use criterion; (8) has a protocol to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed; (9) makes available for consultation specified applicable AUC that reasonably encompass the entire clinical scope of any new priority clinical area within 12 months of the priority clinical area being finalized by CMS; (10) meets privacy and security standards under applicable provisions of law; (11) provides the ordering professional aggregate feedback regarding their consultation with specified applicable AUC in the form of an electronic report on an annual basis; (12) maintains electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years; and (13) complies with modification(s) to any requirements under §414.94(g)(1) made through rulemaking within 12 months of the effective date of the modification.

To be specified as a qualified CDSM by CMS, mechanism developers must document adherence to the requirements in their application for CMS review and use the application process identified in §414.94(g)(2). If a qualified CDSM 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.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialists	13-1000	34.09	34.09	68.18
Computer Systems Analysts	15-1121	43.36	43.36	86.72
Computer and Information Systems Managers	11-3021	67.69	67.69	135.58
Lawyers	23-1011	65.51	65.51	131.02

As indicated, 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.

Proposed Information Collection Requirements and Burden Estimates

The one-time burden associated with the requirements under §414.94(g)(2) is the time and effort it would take each of the 30 CDSM developers, as estimated by CMS, the Office of the National Coordinator (ONC), and the Agency for Healthcare Research and Quality (AHRQ), that have interests in incorporating AUC consultation into their mechanisms' functionality to compile, review and submit documentation demonstrating adherence to the proposed CDSM requirements. We anticipate 30 respondents based on the number of existing CDSMs that have expressed an interest in incorporating AUC for advanced diagnostic imaging as well as our estimation of the number of CDSM developers that may be interested in incorporating AUC for advanced diagnostic imaging in the future as their mechanisms develop and evolve. Each respondent will voluntarily compile, review and submit documentation that demonstrates their adherence to the proposed CDSM requirements listed above.

We estimate that it will take 10 hours at $68.18/hr for a business operations specialist to compile, prepare and submit the required information; 2.5 hours at $86.72/hr for a computer system analyst to review and approve the submission; 2.5 hours at $135.58/hr for a computer and information systems manager to review and approve the submission; and 5 hours at $131.02/hr for a lawyer to review and approve the submission. In this regard, we estimate 20 hours per submission at a cost of $1,892.65. In aggregate, we estimate 600 hours (20 hr x 30 submissions) at $56,779.50 ($1,892.65 x 30 submissions).

After the anticipated initial 30 respondents, we expect less than 10 applicants to apply to become qualified CDSMs annually. Since we estimate fewer than 10 respondents, the information collection requirements are exempt (5 CFR 1320.2(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

Qualified CDSMs must re-apply every 5 years. Therefore in years 6-10, we expect 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 CDSM developers will be able to make modifications to their original application which should result in a burden of 5 hours at $68.18/hr for a business operations specialist to compile, prepare and submit the required information; 1.25 hours at $86.72/hr for a computer system analyst to review and approve the submission; 1.25 hours at $135.58/hr for a computer and information systems manager to review and approve the submission; and 2.5 hours at $131.02/hr for a lawyer to review and approve the submission. For each CDSM developer we estimate 10 hr per submission at a cost of $946.33. In aggregate, we estimate 300 hr (10 hr x 30 submissions) at $28,389.90 ($946.33 x 30 submissions). However, since the renewal is every 5 years we are adjusting the total annual burden to 60 hours (300 hr/5 years) at a cost of $5,677.98 ($28,389.90/5 years).

Summary of Annual Burden Estimates

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)*
414.94(g)(2)	0938-New (CMS-10624)	30	30	20	600	varies	56,780
	0938-New (CMS-10624)		6 (30 responses/ 5 yr)	10	60	varies	5,678
TOTAL		**30**	**36**	**30**	**660**	**varies**	**62,458**

Collection of Information Instruments

None. We have proposed that to be qualified, a CDSM developer must submit an application documenting adherence to the requirements for tools under §414.94(g)(1). The proposed application process is described in §414.94(g)(2).

13. Capital Costs

This collection would not impose any capital costs.

14. Cost to Federal Government ADJUST FOR 2016

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 2016 OPM payscale (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB.pdf):

Position	% time	Annual Salary	Cost
1 GS-15, step 5 Supervisory Health Insurance Specialist	5	145,162	7,258.10
1 GS-15, step 5 Medical Officer	5	145,162	7,258.10
1 GS-15, step 5 Health Insurance Specialist	10	145,162	14,516.20
1 GS-13, step 5 Health Insurance Specialist	20	104,433	20,886.60
1 GS-9, step 5 Health Insurance Specialist	10	60,557	6,055.70
			Total Cost: $55,974.70

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

The expiration date will be displayed.

18. Certification Statement

There are no exceptions to the certification statement.