

Supporting Statement – Part A
Appropriate Use Criteria (AUC) for Diagnostic Imaging Services
Consultation of Specified Applicable AUC through a Qualified Clinical
Decision Support Mechanism (CDSM)
CMS-10654, OMB 0938-1345

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) or CMS-10624 (OMB 0938-1315) package (Appropriate Use Criteria (AUC) for Diagnostic Imaging Services: Clinical Decision Support Mechanism (CDSM) Application Process) which pertains to the application process for qualification of CDSMs.

Background

The collection of information under the Appropriate Use Criteria (AUC) for Diagnostic Imaging Services program for AUC consultations is an essential component of this program required under sections 1834(q)(4)(A) and (B) of the Act (as amended by section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA)).

This iteration is associated with our CY 2019 Physician Fee Schedule final rule (November 23, 2018; 83 FR 59452) (CMS-1693-F, RIN 0938-AT31). The rule revises 42 CFR 414.94(j) to include AUC consultation by the ordering professional and clinical staff acting under the direction of the ordering professional. We believe this is strictly related to respondent types and wages, and would decrease our currently approved cost estimates associated with the CY 2018 Physician Fee Schedule final rule.

A. Justification

1. Need and Legal Basis

Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) amended Title XVIII of the Social Security Act to add section 1834(q) entitled, “Recognizing Appropriate Use Criteria for Certain Imaging Services,” which CMS to establish a program to promote the use of AUC for advanced diagnostic imaging services. This new program is available at 42 CFR 414.94.

Section 1834(q)(4)(A) of the Act as added by PAMA, specifies that ordering professionals not incurring a significant hardship exception consult with a qualified CDSM and consultation information be reported on claims to include (1) which qualified CDSM was consulted by the ordering professional for the service; (2) whether the service ordered would adhere to the applicable AUC specified, whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional).

Section 1834(q)(4)(B) of the Act as added by PAMA, specifies that in order for payment to be

made for applicable imaging services furnished in applicable settings and paid for under an applicable payment system AUC consultation information must be included on the Medicare claim.

2. Information Users

The information will be used by Medicare claims processing systems to determine payment for advanced diagnostic imaging services. Specifically, we will use the requirement of including the NPI of the ordering professional to identify who ordered the applicable imaging service. We will use the requirement of including which CDSM was consulted to identify that a qualified CDSM was consulted. Finally, we will use the requirement of reporting whether or not the service ordered would adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered in order to inform future calculations of outlier ordering professionals. This information will not be used to alter the payment amount of the advanced diagnostic imaging service furnished.

3. Use of Information Technology

The collection of information regarding AUC consultation is performed and maintained by the CDSM consistent with requirements of qualification in §414.94(g)(1)(x) and already involves the use of automated, electronic collection techniques. This collection does not require a signature from the submitter, and 100% of responses will be collected electronically. The basis of our decision for adopting this automated, electronic collection technique results from both the identification of the most administratively efficient manner to collect information and section 1834(q)(3)(B)(ii)(vii) of the Act to which the Secretary may specify that the mechanism perform other such functions for the ordering professional. Therefore, we believe that this means of collection is consistent with the Government Paperwork Elimination Act (GPEA).

The reporting of information regarding AUC consultation is performed on the relevant Medicare claim form and already involves the use of automated, electronic collection techniques.

Electronic data interchange is a technology alternative to the submission of paper claim forms. All of the data collected by a paper claim form can also be collected electronically, which further reduces costs and increases efficiency for providers and suppliers. Legislation has also been enacted which mandates claims be submitted electronically to Medicare. The Administrative Simplification Compliance Act amendment to section 1862(a) of the Social Security Act prescribes that “no payment may be made under Part A or Part B of the Medicare Program for any expenses incurred for items or services” for which a claim is received in a non-electronic form. Consequently, absent an applicable exception, paper claims received by Medicare will not be paid.

4. Duplication of Efforts

There are no duplicative efforts to collect this specific consultation information.

5. Small Businesses

There is no significant impact on small businesses to collect AUC consultation information as such information is performed and maintained by the CDSM consistent with requirements of qualification in §414.94(g)(1)(x), already involves the use of automated, electronic collection techniques, and Section 1834(q)(1)(C)(iii) of the Act requires that one or more of such mechanisms is available free of charge. There is also no significant impact on small businesses to report AUC consultation information as approximately 96.5% of small business submit electronic claims forms to Medicare, leaving only a small percentage that submit via paper.

6. Less Frequent Collection

In order for reimbursement to proceed in a timely and accurate manner, claims for reimbursement should be submitted soon after the provision of service. Consequently, there is no coherent or beneficial approach regarding the submitting of claims on a less frequent basis. Moreover, extended delays in the processing of Part B claims would increase the probability of errors while potentially imposing cash flow problems on physicians/suppliers as well as beneficiaries.

7. Special Circumstances

Ordering professionals not incurring a significant hardship exception or clinical staff acting under the direction of the ordering professional consult specified applicable AUC and AUC consultation information is reported with the submission of claim forms “on occasion.” In most circumstances, this is more often than quarterly. Submission of claim forms is necessary for reimbursement.

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

- 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

Serving as the 60-day notice, the CY 2019 PFS proposed rule (RIN 0938-AT31, CMS-1693-P) published in the Federal Register on July 27, 2018 (83 FR 35704). The rule was placed on display for public inspection on July 3, 2018. Comments were received. A summary of the comments and our response is attached to this PRA package.

The CY 2019 PFS final rule published on November 23, 2018 (83 FR 59452).

Outside Consultation

We have engaged governmental and nongovernmental stakeholders in discussions regarding the AUC program in general.

9. Payments/Gifts to Respondents

While furnishing professionals or imaging facilities will not be provided payment or gifts for this collection of information, such information would be necessary for payment of applicable imaging services furnished under these proposals.

10. Confidentiality

The AUC information provided on Medicare claim forms is protected and held confidential in accordance with 20 CFR 401.3. The information provided on these forms will become part of the Medicare contractors' computer history, microfilm, and hard copy records' retention system as published in the Federal Register, Part VI, "Privacy Act of 1974 System of Records," on September 20, 1976 (HI CAR 0175.04).

ROUTINE USE(S): Information from claims and related documents may be given to the Department of Veterans Affairs, the Department of Health and Human Services and/or the Department of Transportation consistent with their statutory administrative responsibilities under TRICARE/CHAMPVA; to the Department of Justice for representation of the Secretary of Defense in civil actions; to the Internal Revenue Service, private collection agencies, and consumer reporting agencies in connection with recoupment claims; and to Congressional Offices in response to inquiries made at the request of the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, local, foreign government agencies, private business entities, and individual providers of care, on matters relating to entitlement, claims adjudication, fraud, program abuse, utilization review, quality assurance, peer review, program integrity, third-party liability, coordination of benefits, and civil and criminal litigation related to the operation of TRICARE.

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)(4)(B) of the Act, AUC consultation information includes all of the following: (1) which qualified CDSM was consulted by the ordering professional; (2) whether the applicable imaging service ordered would adhere to specified applicable AUC, whether the applicable imaging service ordered would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the applicable imaging service ordered; (3) the NPI of the ordering professional who either consults specified applicable AUC or directs clinical staff acting under the direction of the ordering professional, the ordering professional’s service, if different from the furnishing professional.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2017 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 and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 1: National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Family and general practitioner	29-1062	100.27	100.27	200.54
Medical assistant	31-9092	16.15	16.15	32.30

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. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Information Collection Requirements and Burden Estimates

Recordkeeping is not a requirement of ordering professionals, and any inclusion of recordkeeping in the CY19 Physician Fee Schedule final rule was in error.

Consultations

The one-time burden associated with the requirements under §414.94(j) is the time and effort it will take each ordering professional or clinical staff to consult specified applicable AUC through a qualified CDSM. During the 18 month voluntary participation period, we estimate 10,230,000 responses in the form of consultations based on market research from current applicants for

qualification of their clinical decision support mechanisms for advanced diagnostic imaging services. This estimate is based on feedback from CDSMs with experience in AUC consultation as well as standards recommended by the Office of the National Coordinator (ONC) and the Healthcare Information Management Systems Society (HIMSS).

We estimate it would take 2 minutes at either \$200.54/hr for a family and general practitioner or \$32.30/hr for a medical assistant to use a qualified CDSM to consult specified applicable AUC. Ordering professionals with a significant hardship exception are not required to consult. The significant hardship exception process imposes no burden beyond the provision of identifying information and attesting to the applicable information. In this regard, the use of this process is not “information” as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA. To estimate the percentage of consultations available to be performed by these individuals, we analyzed 2014 Medicare Part B claims comparing evaluation and management visits for new (CPT codes 99201, 99202, 99203, 99204, and 99205) relative to established (CPT codes 99211, 99212, 99213, 99214, 99215) patients with place of service codes 11 (physician’s office). We found that approximately 10 percent of all claims incurred were for new patients. Therefore, we estimate that 90-percent of consultations will be performed by clinical staff, with the remaining 10 percent performed by the ordering professional. Per consultation, we estimate 2 minutes (0.033 hr) at either a cost of \$6.62 (0.033 hr x \$200.54/hr) or \$1.07 (0.033 hr x \$32.30/hr).

In aggregate, we estimate the voluntary period will incur a one-time burden of 337,590 hours (0.033 hr x 10,230,000 consultations) at a cost of \$16,583,771 ([337,590 hr x 0.10 x \$200.54/hr] + [337,590 hr x 0.90 x 32.30/hr]). Annually, we estimate 112,530 hours (337,590 hr/3 yr) at a cost of \$5,527,924 (\$16,583,771/3 yr). We are annualizing the one- time burden (by dividing our estimates by OMB’s 3-year approval period) since we do not anticipate any additional burden after the voluntary participation period ends.

We estimate that beginning January 1, 2020 when AUC consultation is required, the number of respondents would increase to 43,181,818 based on 2014 Medicare claims data for advanced diagnostic imaging services. As noted above, our revision would impact our burden estimate associated with this requirement. Therefore, we estimate an annual burden of 1,425,000 hours (0.033 hr x 43,181,818 consultations) at a cost of \$70,001,700 ([1,425,000 hr x 0.10 x \$200.54/hr] + [1,425,000 hr x 0.90 x \$32.30/hr]).

The voluntary and mandatory reporting requirements under §414.94(k) would not have any impact on any Medicare claim forms because the forms’ currently approved data fields, instructions, and burden are not expected to change as a result of these provisions. We also clarify our distinctions between reporting AUC consultation information and standardized communications on Medicare claims forms. The X12N insurance subcommittee develops and maintains standards for healthcare administrative transactions on professional (837p), institutional (837i), and dental (837d) transactions when submitting healthcare claims for a service or encounter. The current mandated version of 837 transactions is 5010™. While we have not finalized a process for implementing the reporting requirements at §414.94(k), we clarify that implementation of changes to the claim form transactions would not take place outside of the existing process described. Ordering professionals with a significant hardship exception are not required to consult. The significant hardship

exception process imposes no burden beyond the provision of identifying information and attesting to the applicable information.

Regulation Section(s)	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$/hr)	Total Cost (\$)
§414.94(j) (voluntary consultations)	586,386	3,410,000 (10,230,000/3)	0.033	11,253	200.54	2,256,677
			0.033	101,277	32.30	3,271,247
<i>Subtotal: Voluntary Consultations</i>	<i>586,386</i>	<i>3,410,000</i>	<i>0.033</i>	<i>112,530</i>	<i>Varies</i>	<i>5,527,924</i>
§414.94(j) (mandatory consultations)	586,386	4,318,181	0.033	142,500	200.54	28,576,950
		38,863,636	0.033	1,282,500	32.30	41,424,750
<i>Subtotal: Mandatory Consultations</i>	<i>586,386</i>	<i>43,181,818</i>	<i>0.033</i>	<i>1,425,000</i>	<i>Varies</i>	<i>70,001,700</i>
TOTAL	586,386	46,591,818	0.033	1,537,530	Varies	75,529,624

Significant Hardship Exception

Section 414.94(i)(3) provides for a significant hardship exception for ordering professionals who experience a significant hardship affecting their consultation of AUC when ordering an advanced diagnostic imaging service. The provision sets out a process whereby all ordering professionals can self-attest that they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. Although this is not a certification being used as a substitute for a collection of AUC consultation information because no consultation is required by statute to take place, the significant hardship exception process consists of appending to the order for an applicable imaging service the significant hardship information for inclusion on the Medicare claim in lieu of the AUC consultation information. This imposes no burden beyond providing identifying information and attesting to the applicable information. In this regard, the use of this process is not “information” as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.

Collection of Information Instruments and Instruction/Guidance Documents

Not applicable.

13. Capital Costs

We do not estimate there would be any capital costs associated with generating, maintaining, and disclosing or providing AUC consultation information by the ordering professional. Consistent with section 1834(q)(1)(C)(iii) of the Act and regulations at §414.94(b) one or more qualified CDSMs is available free of charge.

We do not estimate there would be any capital costs associated with the reporting of AUC

consultation information. Legislation, specifically The Administrative Simplification Compliance Act amendment to section 1862(a) of the Social Security Act, prescribes that “no payment may be made under Part A or Part B of the Medicare Program for any expenses incurred for items or services” for which a claim is received in a non- electronic form. Consequently, absent an applicable exception, paper claims received by Medicare will not be paid. Therefore, we estimate that capital costs associated with reporting AUC consultation information has already occurred to achieve regulatory compliance with requirements not associated with this information collection, for reasons other than to provide this information, and as part of customary and usual business practices.

14. Cost to Federal Government

Based on FY 2010 figures, the administrative cost to the Federal Government to administer Medicare Part B was \$3,514,000,000 or 1.3 percent of benefit payments.¹ On the average, the unit cost incurred to the Federal Government per claim was \$0.38² in FY 2008. This figure includes the direct costs and overhead cost for claims payment, reviews and hearings, and beneficiary/physician inquiry lines. While we have not finalized a mechanism by which to collect this information on a Medicare claim form, we have estimated the cost to the federal government to explore claims-based mechanisms to report AUC consultation information. To perform this estimate, we assumed that we would need to make a change request (CR) for our Medicare Administrative Contractors, Shared Systems Maintainers, and claims processing systems such as the Common Working File, to perform design thinking and analysis of implementing systems changes editing the existing Medicare claim forms. To this end, we estimate this work to cost about \$1 million dollars over the course of 1 year for an analysis and design CR. Once these systems features are discussed, we do not expect to need to repeat this work and therefore estimate this to be a one-time cost to the federal government.

15. Changes to Requirements and Burden

In the CMS-1693-F rule we revised §414.94(j) to allow the AUC consultation, when not performed personally by the ordering professional, to be performed by clinical staff acting under the direction of the ordering professional. Ordering professionals with a significant hardship exception are not required to consult. The significant hardship exception process imposes no burden beyond the provision of identifying information and attesting to the applicable information. In this regard, the use of this process is not “information” as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.

Since general practitioners make up a large group of practitioners who order applicable imaging services and would be required to consult AUC under this program use the “family and general practitioner” occupation title (see Table 1) to help calculate our cost estimates. The rule modifies the AUC consultation requirement by allowing clinical staff acting under the direction of the ordering professional to interact with the CDSM for AUC consultation. In this case we also use the

¹ Source: 2011 CMS Statistics, Table V.1.

² Source: 2009 CMS Statistics, Table V.5. (Data not available in 2011 CMS Statistics Table V.5)

“medical assistant” occupation to help calculate our revised cost estimates.

To derive the burden associated with the provision in §414.94(j) that would take effect January 1, 2020, we estimate it would take 2 minutes (0.033 hr) at \$32.30/hr for a medical assistant to consult with a qualified CDSM. To estimate the percentage of consultations available to be performed incident to, we analyzed 2014 Medicare Part B claims comparing evaluation and management visits for new (CPT codes 99201, 99202, 99203, 99204, and 99205) relative to established (CPT codes 99211, 99212, 99213, 99214, 99215) patients with place of service codes 11 (physician’s office). We found that approximately 10 percent of all claims incurred were for new patients. Therefore, we also estimate that 90-percent or 38,863,636 of the total consultations (43,181,818 total consultations x 0.90) could be performed by such auxiliary personnel, with the remaining 10 percent (43,181,818 x 0.10) performed by the ordering professional. In aggregate, we update our cost estimate to an annual burden of \$41,424,750 (1,282,500 hr x \$32.30/hr) or \$1.07 per consultation using the medical assistant occupation code 31-9092 with mean hourly wage of \$16.15 and 100 percent fringe benefits. We will continue to monitor our burden estimates and, if necessary, adjust those estimates for more precision once the program begins.

Additionally, the CY 2018 Physician Fee Schedule final rule (82 FR 52976) explicitly discussed and provided a voluntary period for ordering professionals to begin to familiarize themselves with qualified CDSMs. During the current 18-month voluntary participation period, we estimated there would be 10,230,000 consultations based on market research from current applicants for the qualification of their CDSMs for advanced diagnostic imaging services. Based on feedback from CDSMs with experience in AUC consultation, as well as standards recommended by the Office of the National Coordinator (ONC)³ and the Healthcare Information Management Systems Society (HIMSS)⁴, we estimated it would take 2 minutes (0.033 hr) at \$200.54/hr for a family and general practitioner or 2 minutes at \$32.30/hr for a medical assistant to use a qualified CDSM to consult specified applicable AUC. As mentioned above, we estimated that as many as 90-percent of practices would use such personnel to interact with the CDSM for AUC consultation. Consequently, we update our estimate of a cost to \$16,583,771.16 ([337,590 hr x 0.10 x \$200.54/hr] + [337,590 hr x 0.90 x \$32.30/hr]). Our currently approved time estimate of 337,590 hours (10,230,000 consultations x 0.033 hr) remain unchanged. Annually, we estimate **112,530 hours** (337,590 hr/3 yr) at a cost of **\$5,527,923.72** (\$16,583,771.16/3 yr). We are annualizing the one-time burden (by dividing our estimates by OMB's 3-year approval period) since we do not anticipate any additional burden after the 18-month voluntary participation period ends.

Beginning January 1, 2020, we anticipate **43,181,818 responses** in the form of consultations based on the aforementioned market research, as well as Medicare claims data for advanced diagnostic imaging services. As noted above, we estimate it would take 2 minutes (0.033 hr) at \$200.54/hr for a family and general practitioner or 2 minutes at \$32.30/hr for a medical assistant to use a qualified CDSM to consult specified applicable AUC. In aggregate, we update our estimate of an annual burden from 275,139,000 to **1,425,000 hours** (43,181,818 consultations x 0.033 hr/consultation) at a cost of **\$70,001,700** ([0.1 x 1,425,000 hr x \$200.54/hr] + [0.9 x 1,425,000 hr x \$32.30/hr]).

³ https://ecqi.healthit.gov/cds#quicktabs-tabs_cds3.

⁴ <http://www.himss.org/improving-outcomes-cds-practical-pearls-new-himss-guidebook>.

The change to our currently approved cost estimates is due to respondent occupation and hourly wage changes, resulting in a decrease of \$221,336,668 (\$205,137,300 + \$16,199,368). We are also correcting the number of respondents. Our per response and total time estimates remain unchanged.

Voluntary Consultations	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$/hr)	Total Cost (\$)
Currently Approved	10,230,000*	3,410,000	0.033	112,530	193.08	21,727,292
Revised §414.94(j)	586,386	3,410,000	0.033	112,530	\$32.30/hr and \$200.54/hr	5,527,924
Difference	(9,643,614)	No change	No change	No change	Varies	(16,199,368)

*10,230,000 respondents was entered in error, the correct figure should have been 586,386 respondents.

Mandatory Consultations	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$/hr)	Total Cost (\$)
Currently Approved	43,181,818*	43,181,818	0.033	1,425,000	193.08	275,139,000
Revised §414.94(j)	586,386	43,181,818	0.033	1,425,000	\$32.30/hr and \$200.54/hr	70,001,700
Difference	(42,595,432)	No change	No change	No change	Varies	(205,137,300)

*43,181,818 respondents was entered in error, the correct figure should have been 586,386 respondents.

16. Publication/Tabulation Dates

The reported consultation information will not be published by CMS.

17. Expiration Date

The expiration date will be displayed on the AUC website:

<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.

B. Collection of Information Employing Statistical Methods

There will be no statistical method employed in this collection of information.