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-New

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)).

For CMS to ensure that ordering professionals are consulting specified applicable AUC using a qualified clinical decision support mechanism (CDSM), reporting professionals are including this information on the Medicare claim form as required under section 1834(q)(4)(A) and (B) of the Act. Therefore, we are proposing in the CY 2018 Physician Fee Schedule proposed rule (CMS-1676-P) under §414.94(j) and §414.94(k) to require consultation and reporting to begin for specified applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on and after January 1, 2019.

We are also proposing, consistent with section 1834(q)(4)(B) of the Act, that the reporting professional include the following information on the Medicare claim: 1) which qualified CDSM was consulted by the ordering professional; 2) whether the service ordered would adhere to specified applicable AUC, whether the service ordered would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; 3) the national provider identifier (NPI) of the ordering professional who consults specified applicable AUC if different from the furnishing professional. The proposed reporting requirement would not have any impact on any Medicare claim forms because the forms' data fields, instructions, and burden are not expected to require any changes. Consequently, this collection of information request reflects the proposed consultation requirement and does not include the reporting requirement.

Section 414.94(b) of the Act defines applicable imaging service as an advanced diagnostic imaging service (as defined in section 1834(e)(1)(B) of the Act) for which the Secretary determines 1) one or more applicable AUC apply; 2) there are one or more qualified CDSMs listed; and 3) one or more of such mechanisms is available free of charge. This section defines applicable setting as a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. This section also defines applicable payment system as the physician fee schedule established under section 1848(b) of the Act, the prospective payment system for hospital outpatient department services under section 1833(t) of the Act, and the ambulatory surgical center payment system under section 1833(i) of the Act.

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.

As defined in §414.94(b), 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 Intermountain Healthcare.

On the other hand, as defined in §414.94(b), 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. To be qualified, a CDSM developer must submit an application documenting adherence to the requirements under §414.94(g)(1). The application process is described in §414.94(g)(2). The first list of qualified CDSMs will be available by June 30, 2017.

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 consult with a qualified decision support mechanism and provide to the furnishing professional 1) information about which qualified CDSM was consulted by the ordering professional for the service; 2) information regarding 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 furnishing professionals must include on the Medicare claim the above information in order for payment to be made for

applicable imaging services furnished in applicable settings and paid for under an applicable payment system.

2. Information Users

The information will be used by Medicare claims processing systems to determine payment for advanced diagnostic imaging services. In the future, we expect the consultation information to be used in the identification of outlier ordering professionals to apply prior authorization for applicable imaging services that are ordered by such professionals. We expect details on this component to be addressed in future rulemaking.

3. Use of Information Technology

The collection of information regarding AUC consultation by the ordering professional 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 by the furnishing professional 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 consult specified applicable AUC and furnishing professionals report AUC consultation information 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

The CY 2018 Physician Fee Schedule proposed rule (CMS-1676-P, RIN 0938-AT02) published in the Federal Register on July 21, 2017 (82 FR 33950) and is serving as the 60-day notice. The notice filed for public inspection on July 13, 2017. Comments are due September 11, 2017.

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 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)

In order for CMS to ensure ordering professionals are consulting specified applicable AUC using a qualified clinical decision support mechanism (CDSM), reporting professionals are including this information on the Medicare claim form as required under section 1834(q)(4)(A) and (B) of the Act. Therefore, we are proposing under §414.94(j) and §414.94(k) to require consultation and reporting to begin for specified applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on and after January 1, 2019.

We are also proposing, consistent with section 1834(q)(4)(B) of the Act, that 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 consults specified applicable AUC if different from the furnishing professional.

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 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)
Family and general practitioner	29-1062	96.54	96.54	193.08

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.

12.2 Information Collection Requirements and Burden Estimates

The one-time burden associated with the requirements under §414.94(j) is the time and effort it will take each ordering professional to consult specified applicable AUC through a qualified CDSM. During the proposed six month voluntary participation period, we estimate 3,410,000

respondents 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 $193.08/hr for a family and general practitioner to use a qualified CDSM to consult specified applicable AUC. Per consultation, we estimate 2 minutes (0.033 hr) at a cost of $6.37 (0.033 hr x $193.08/hr). In aggregate, we estimate a one-time burden of 112,530 hours (0.033 hr x 3,410,000 consultations) at a cost of $21,727,292.40 (112,530 hr x $193.08/hr). Annually, we estimate 37,510 hours (112,530 hr/3 yr) at a cost of $7,242,430.80 ($21,727,292.40/3 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 six month voluntary participation period ends.

We estimate that beginning January 1, 2019, the number of respondents would increase to 43,181,818 based on 2014 Medicare claims data for advanced diagnostic imaging services. As noted above, we estimate it would take 2 minutes (0.033 hr) at $193.08/hr for a family and general practitioner to use a qualified CDSM to consult specified applicable AUC. In this regard, we estimate 0.033 hours per consultation at a cost of $6.37 (0.033 hr x $193.08/hr). In aggregate, we estimate an annual burden of 1,425,000 hours (0.033 hr x 43,181,818 consultations) at a cost of $275,139,000 (1,425,000 hr x $193.08/hr).

The proposed 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 the proposed provisions.

12.3 Summary of Annual Burden Estimates

Regulation Section(s)	OMB Control Number	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*
§414.94(j) (voluntary consultations)	0938-New	3,410,000	1,136,666.67 (3,410,000/3)	0.033	37,510	193.08	7,242,431
§414.94(j) (mandatory consultations)		43,181,818	43,181,818	0.033	1,425,000	193.08	275,139,000
Total	--	46,591,818	44,318,485	0.033	1,462,510	193.08	282,381,431

12.4 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 information regarding AUC consultation by the furnishing professional. 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 by the furnishing professional 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 $0.38[2] in FY 2008. This figure includes the direct costs and overhead cost for claims payment, reviews and hearings, and beneficiary/physician inquiry lines.

15. Changes to Burden

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

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:

18. Certification Statement

There are no exceptions to the certification statement.

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)