

**Justification for a Non-substantive Change**  
Appropriate Use Criteria for Advanced Diagnostic Imaging Services  
CMS-10570 (OMB 0938-1288)

**Background**

Consistent with section 1834(q) of Title XVIII of the Social Security Act (as amended by section 218(b) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), we have adopted requirements for the development of appropriate use criteria (AUC) under 42 CFR 414.94. The provisions were finalized on November 16, 2015 (80 FR 70886) (RIN 0938-AS40; CMS-1631-FC).

Among the provisions, a provider-led entity (PLE) that meets certain requirements and wants to be recognized as a qualified PLE (for the purpose of this section) may apply to CMS. As discussed in the final rule and in the rule’s information collection request, applications must be submitted electronically and demonstrate how the organization’s processes for developing AUC meet the requirements specified in §414.94(c)(1). To be identified as a qualified PLE by CMS, the organization 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.

PLE applications documenting adherence to each AUC development requirement will be accepted annually by January 1 starting January 1, 2016; 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.

**Change and Justification Statement**

While the aforementioned final rule sets out an application starting date of January 1, 2016 (see 80 FR 71111), our information collection request inadvertently set out an application starting date of January 1, 2017. The January 1, 2017, application date was approved by OMB on June 24, 2016.

This proposed revision corrects the “January 1, 2017,” application date to read, “January 1, 2016.” We are submitting this revision as a nonsubstantive change request since the correct date is set out in the implementing final rule. In this regard the change does not have any impact on our program requirements and it does not have any burden implications.

The corrected Supporting Statement is attached to this nonsubstantive change request. The only change in that document is correcting the “January 1, 2017,” application starting date to read, “January 1, 2016.”

None of the ICS are affected by this correction. They remain attached to this package without change.