

We received 103 public comments on our proposals for Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services. Commenters included mostly medical specialty societies and professional organizations, radiology benefit management companies, insurers, health systems and hospitals, medical technology organizations and experts, and medical professionals. Below are the comments related to the application process for provider-led entities (PLEs) to become qualified and the process for re-qualification. We have considered the comments and are adopting the proposed provisions specific to the PLE application and qualified PLE re-qualification processes with minimal changes.

Comment: Some commenters disagreed with our proposal to require qualified PLEs to reapply for qualification every 6 years, and were instead in favor of a shorter time frame for review.

Response: We carefully reviewed the timeline for reapplication and have determined that an application submitted by January of the fifth year of approval will receive a determination prior to the start of the qualified PLE's sixth year. Therefore, the cycle of approval for qualified PLEs is every 5 years. This is different than what was proposed as we had originally proposed a cycle that was every 6 years. As finalized, a PLE that becomes qualified for the first 5-year cycle beginning July 2016 would be required to submit an application for requalification by January 2021. A determination would be made by June 2021 and, if approved, the second 5-year cycle would begin in July 2021. For example:

Year 1 = July 2016 to June 2017

Year 2 = July 2017 to June 2018

Year 3 = July 2018 to June 2019

Year 4 = July 2019 to June 2020

Year 5 = July 2020 to June 2021 (reapplication is due by January 1, 2021).

We believe the reapplication timeline is appropriate and allows for PLEs, CDS mechanism developers and ordering practitioners to enter into longer term agreements without the constant concern that the PLE will lose its qualified status. We will assess whether a qualified PLE consistently has developed evidence-based AUC and met our other requirements at the time of requalification. We note, however, that if it appears that qualified PLEs are not maintaining compliance with our requirements for AUC development, we may terminate their qualified status.

Comment: One commenter recommended that CMS create a concise list of AUC development requirements or create a template for entities to use for their application and post the list or template to the CMS website.

Response: At least for the first round of applications for qualified PLEs, we will not be making available templates or applications. CMS might consider developing such templates or applications in the future if we find it would be useful, efficient or necessary.