



Guidance for AAHRPP Organizations that Comply with the Common Rule

After a long process, final revisions have been published to the Common Rule. The federal government announced a delay in implementation until July 2018, and left open the possibility of an additional delay in implementation. The purpose of this message is to explain what to expect from AAHRPP, given there is some uncertainty about the current implementation date. This guidance is intended to be proactive and help organizations plan for policy revisions, even as we recognize any ongoing uncertainty about the implementation date may require additional revision of this Guidance. Please rest assured that, as with all our activities, we will endeavor to work closely with our accredited and not-yet-accredited organizations to facilitate smooth and reasonable processes related to AAHRPP accreditation. We will provide additional information as we learn more, and we will be updating materials in light of regulatory agency guidance and emerging best practices. We look forward to hearing from you with questions, suggestions, and innovative practices you may be developing as you plan for implementation.

AAHRPP Standards are broad, and the vast majority of Standards and Elements are not affected by the revised regulations. We recognize that in the areas that may need to be updated, it will take time to revise policies, forms, and electronic systems, conduct education, and transition to the revised Common Rule. We will track federal regulatory and guidance activities closely and develop further AAHRPP guidance in a transparent, timely process designed to give our organizations ample time to understand and integrate the new requirements.

For organizations that comply with the Common Rule:

Organizations whose entire accreditation/reaccreditation process is completed prior to July 19, 2018:

- **Organizations whose entire accreditation process will be completed prior to July 19, 2018 will be evaluated using the current Evaluation Instrument (version October 2016).** AAHRPP will provide additional information in our newsletter and on our website.

Organizations whose Step 1 application is submitted prior to July 19, 2018 but whose site visit occurs on or after July 19, 2018:

- **Although the Step 1 application will be evaluated based on the February 2018 version of the Evaluation Instrument, Organizations need not have written materials in their application that address the new requirements of the Common Rule, which become effective on July 19, 2018.** Rather, policies, forms, and other materials designed to comply with the revised Common Rule may *optionally* be submitted as part of your application. AAHRPP will provide comments, but organizations will not be asked to make revisions to written materials to address the revised Common Rule.
- **The site visit agenda will be developed to ascertain from the organization how it is planning to address new regulatory requirements.**

Organizations whose entire accreditation/reaccreditation process occurs after July 19, 2018:

- **The entire process will be conducted in accordance with the new regulations and AAHRPP’s revised Evaluation Instrument (version February 2018 or after).** Applications will be reviewed to ensure policies and procedures meet requirements in the revised regulations. The Step 1 Review report provided by AAHRPP will specify any additions or changes that need to be made to policies to comply with the revised regulations. The revised regulations will be in force at the time of the site visit, and site visitors will evaluate compliance with the revised regulations.

Applicant	Evaluation Instrument version	Site Visit
Process completed before July 19, 2018	October 2016	Will not evaluate compliance with revised Common Rule.
Applicants whose applications are submitted before July 19, 2018, and whose site visit will occur on or after July 19, 2018	February 2018	Will not evaluate compliance with revised Common Rule in Step 1, unless requested. Will discuss the organization’s plans to comply with the new rule during 2018 site visit.
Applicants whose entire accreditation process occurs after July 19, 2018.	February 2018	Will evaluate compliance with revised Common Rule

Please feel free to contact AAHRPP’s Director of Accreditation, Dr. Robert Hood (at 202-783-1112 or rhood@aahrpp.org) with any questions you may have regarding implementation of this AAHRPP guidance.