AUC COI Comment/Response

We received 130 comments from a variety of commenters including medical specialty societies; health IT companies and standards organizations and EHR vendors; hospital systems and provider groups, individual practitioners; radiology benefit management companies; insurers; medical guideline developers and members of the public. We are largely adopting the proposed provisions with minimal changes that are intended to improve clarity. Based on public comments, we have made significant changes to three areas. First, we received significant comments with respect to requiring CDSMs to reasonably encompass the entire clinical scope of all priority clinical areas which commenters considered too strict and recommended that CMS modify to allow for flexibility to ensure AUC developed within and representing priority clinical areas be of as high a level of evidence as possible. We agreed with commenters and modified language to allow the requirement to be fulfilled if specified applicable AUC address less than the entire clinical scope of the priority clinical area and instead reasonably address the common and important clinical scenarios within each priority clinical area. Second, numerous commenters also encouraged CMS to include a requirement that qualified CDSMs notify ordering professionals in the event they are de-qualified. We agreed and added this requirement, but are not setting out such burden since we believe that the notification is a usual and customary business practice that is exempt from the PRA under 5 CFR 1320.3(b)(2). Third, many commenters cited insufficient time for CDSMs to incorporate requirements between the release of the final CDSM requirements on or around November 1, 2016, and the January 1, 2017 deadline for CDSM applications and suggested a delay of this deadline and/or provisional qualification based on their commitment to support required functionality. We recognize the challenges the timeline presents and have extended the deadline for this first round of applicants to March 1, 2017. All CDSMs qualified in this round only, will receive preliminary qualification to conclude at such time as we implement the consultation and reporting requirements of this program.

Comment: The majority of commenters addressed the proposal to require CDSMs to contain, at a minimum, AUC that encompass the entire clinical scope of priority clinical areas. Commenters were split regarding the proposed requirement. Some commenters suggested that CDSMs requiring minimum AUC content would add cost and be unnecessary for CDSMs that serve specialists. They favored CDSMs determining, along with the ordering practitioners they serve, what AUC content would be made available. Other commenters favored requiring every CDSM to contain comprehensive AUC. Those commenters said this was the intent of the PAMA since ordering professionals must consult for every advanced diagnostic imaging order and takes into account the lessons learned from the MID to avoid ordering practitioners from consulting for imaging services and not finding relevant AUC within their CDSM. Other commenters agreed with a minimum floor of AUC but expressed concerned about the way CMS proposed that the priority clinical areas must be addressed stating that encompassing the entire clinical scope of priority clinical areas is not preferred and would draw in AUC without a strong evidence base.

Response: We understand the significance of this aspect of the proposal, as well as the statements made by the commenters both for and against the requirement of an AUC floor related to priority clinical areas. We reiterate that, in alignment with statute, ordering professionals must consult for each advanced diagnostic imaging service ordered. Therefore, we believe many professionals will choose a qualified CDSM that best fits their ordering patterns and clinical practice. Those ordering a wide array of imaging services or perhaps infrequently ordering imaging services across a spectrum will align

themselves with a mechanism that fits their needs and contains comprehensive specified applicable AUC so when the qualified CDSM is consulted they will lessen their chances of the qualified CDSM identifying no applicable AUC as this was a major frustration of the MID.

Specialists may seek to align themselves with a qualified CDSM that contains AUC more exhaustive in one area of medicine to reflect the imaging services that they order most often.

We continue to believe that all tools should contain the specified applicable AUC needed by the ordering professionals they serve, as well as contain specified applicable AUC related to the priority clinical areas to ensure that if that professional needs to order an imaging service then they will not have to go outside their regular qualified CDSM for the consultation. We reiterate that we envision having a given qualified CDSM allow efficient access to ordering professionals of one or more specialty-focused specified applicable AUC sets along with more comprehensive specified applicable AUC sets. We believe the determination of which AUC sets are made accessible through a given CDSM should be demand-driven by ordering professionals, who would be choosing from a marketplace of options for both CDSMs and AUC, all of which meet basic CMS qualifications to ensure implementation of the PAMA statutory requirements.

To balance the requirement for the minimum floor, we believe it is important to reconsider the extent to which specified applicable AUC encompass the entire clinical scope of priority clinical areas. We agree that requiring the entire clinical scope may not yield consultation of the highest quality specified applicable AUC and that ordering professionals, particularly specialists, may not require specified applicable AUC addressing the entire clinical scope of a priority clinical area. Therefore, we agree with commenters who suggested we keep the AUC floor but allow the requirement to be fulfilled if specified applicable AUC address less than the entire scope of the priority clinical areas and instead reasonably address the common and important clinical scenarios within each priority clinical area.

Comment: Some commenters expressed concerns regarding CDSMs that either fail to requalify after the first 5-year qualification period or are found to no longer be adherent to CDSM requirements during the 5-year qualification period. One commenter recommended that CDSMs be temporarily suspended before being disqualified. Other commenters recommended that CMS ensure providers using these mechanisms not be penalized while they seek a new mechanism for consultation. Another commenter stated that the CDSM be required to notify ordering professionals of such a disqualification. Other commenters requested that qualification of CDSMs not be disrupted due to standard technical updates to CDSMs made during the 5-year qualification period.

Response: We agree and do not foresee penalties under these circumstances or disqualification of a CDSM due to a standard update assuming no changes are made to functionality that result in non-adherence to the CDSM requirements in §414.94(g)(1). We agree that qualified CDSMs be required to notify ordering professionals in the event of disqualification and have added this requirement under §414.94(g)(1).

Comment: Some commenters cited insufficient time for CDSMs to incorporate requirements between the release of the final CDSM requirements, on or around November 1, 2016, and the January 1, 2017 due date for qualified CDSM applications. These commenters requested that CMS delay the deadline and accept applications later into the year for this first round of applicants. Due to the limited time between finalization of CDSM requirements and the application deadline, another commenter

recommended that CDSMs be qualified based on their commitment to support required functionality, rather than an attestation that the existing functionality is fully implemented in a CDSM.

Response: We recognize the challenge CDSM developers may have submitting applications by January 1, 2017, and have extended the deadline only for the first round of applications to March 1, 2017. To this end, all CDSMs qualified in this round only, receive preliminary qualification to conclude at such time as we implement the consultation and reporting requirements of this AUC program.