clinical data registry during a reporting period specified in paragraph (k)(1) of this section, using the reporting mechanism specified in paragraph (k)(2) of this section.

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(2) Reporting mechanism. An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use the qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.

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(5) Satisfactory participation criteria for individual eligible professionals and group practices for the 2018 PQRS payment adjustment. An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a QCDR for the 2018 PQRS payment adjustment must report information on quality measures identified by the QCDR in the following manner:

(i) For the 12-month 2018 PQRS payment adjustment reporting period, report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the eligible professional's patients. Of these measures, report on at least 3 outcome measures, or, if 3 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures – resource use, patient experience of care, or efficiency/appropriate use.

(ii) [Reserved]

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35. Section 414.94 is added to Subpart B to read as follows:

§414.94 Appropriate use criteria for advanced diagnostic imaging services.

(a) Basis and scope. This section implements the following provisions of the Act:

(1) Section 1834(q)--Recognizing Appropriate Use Criteria for Certain Imaging Services.

(2) Section 1834(q)(1)--Program Established.

(3) Section 1834(q)(2)--Establishment of Applicable Appropriate Use Criteria.

(b) Definitions. As used in this section unless otherwise indicated—

Advanced diagnostic imaging service means an imaging service as defined in section 1834(e)(1)(B) of the Act.

Applicable imaging service means an advanced diagnostic imaging service (as defined in section 1834(e)(1)(B) of the Act) for which the Secretary determines –

(i) One or more applicable appropriate use criteria apply;

(ii) There are one or more qualified clinical decision support mechanisms listed; and

(iii) One or more of such mechanisms is available free of charge.

Applicable setting means 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.

Appropriate use criteria (AUC) means criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria must be evidence-based. An AUC set is a collection of individual appropriate use criteria. An individual criterion is information presented in a manner that links: a specific clinical condition or presentation; one or more services; and, an assessment of the appropriateness of the service(s).

Furnishing professional means a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who furnishes an applicable imaging service.

Ordering professional means a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who orders an applicable imaging service.

Priority clinical areas means clinical conditions, diseases or symptom complexes and associated advanced diagnostic imaging services identified by CMS through annual rulemaking and in consultation with stakeholders which may be used in the determination of outlier ordering professionals.

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.

Specified applicable appropriate use criteria means any individual appropriate use criterion or AUC set developed, modified or endorsed by a qualified PLE.

(c) Qualified provider-led entity. To be qualified by CMS, a PLE must adhere to the evidence-based processes described in paragraph (c)(1) of this section when developing or modifying AUC. A qualified PLE may develop AUC, modify AUC developed by another qualified PLE, or endorse AUC developed by other qualified PLEs.

(1) Requirements for qualified PLEs developing or modifying AUC. A PLE must perform all of the following when developing or modifying AUC:

(i) Utilize an evidentiary review process when developing or modifying AUC that includes:

(A) A systematic literature review of the clinical topic and relevant imaging studies; and

(B) An assessment of the evidence using a formal, published and widely recognized methodology for grading evidence. Consideration of relevant published consensus statements by professional medical specialty societies must be part of the evidence assessment.

(ii) Utilize at least one multidisciplinary team with autonomous governance, decision-making and accountability for developing or modifying AUC. At a minimum the team must be comprised of seven members including at least one practicing physician with expertise in the clinical topic related to the appropriate use criterion being developed or modified, at least one practicing physician with expertise in the imaging studies related to the appropriate use criterion, at least one primary care physician or practitioner as described in sections 1833(u)(6), 1833(x)(2)(A)(i)(I), and 1833(x)(2)(A)(i)(II) of the Act, at least one expert in statistical analysis and at least one expert in clinical trial design. A given team member may be the team's expert in more than one domain.

(iii) Utilize a publicly transparent process for identifying potential conflicts of interest and for resolving conflicts of interest of members on the multidisciplinary team, the PLE and any other party participating in AUC development or modification, to include recusal or exclusion of individuals as appropriate. The PLE must document the following information and make it available in timely fashion to a public request, for a period of not less than 5 years after the most recent published update of the relevant AUC:

(A) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations including the PLE and any other party participating in AUC development or modification that may financially benefit from the AUC. These financial

relationships may include, for example, compensation arrangements such as salary, grant, speaking or consulting fees, contract, or collaboration agreements.

(B) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations including the PLE or any other party participating in AUC development or modification that may financially benefit from the AUC.

(iv) Publish each individual criterion on the PLE's website and include an identifying title, authors (at a minimum, all members of the multidisciplinary AUC development team must be listed as authors), and key references used to establish the evidence.

(v) Identify each appropriate use criterion or AUC subset that are relevant to a priority clinical area with a statement on the PLE's website. To be identified as being relevant to a priority clinical area, the criterion or AUC subset must reasonably address the entire clinical scope of the corresponding priority clinical area.

(vi) Identify key points in an individual criterion as evidence-based or consensus-based, and grade such key points in terms of strength of evidence using a formal, published and widely recognized methodology.

(vii) Utilize a transparent process for the timely and continual updating of each criterion. Each criterion must be reviewed and, when appropriate, updated at least annually.

(viii) Publicly post the process for developing or modifying the AUC on the PLE's website.

(ix) Disclose parties external to the PLE when such parties have involvement in the AUC development process.

(2) Process to identify qualifying PLEs. PLEs must meet all of the following criteria:

(i) PLEs must submit an application to CMS for review that documents adherence to each of the AUC development requirements outlined in paragraph (c)(1) of this section;

(ii) Applications will be accepted by CMS only from PLEs that meet the definition of PLE in paragraph (b) of this section;

(iii) Applications must be received by CMS annually by January 1;

(iv) All approved qualified PLEs in each year will be included on the list of qualified PLEs posted to the CMS website by June 30 of that year; and

(v) Approved PLEs are qualified for a period of 5 years.

(vi) Qualified PLEs are required to re-apply. The application must be received by CMS by January 1 of the 5th year after the PLE's most recent approval date.

(d) Endorsement. Qualified PLEs may endorse the AUC set or individual criteria of other qualified PLEs, under agreement by the respective parties, in order to enhance an AUC set.

(e) Identifying priority clinical areas. (1) CMS identifies priority clinical areas through annual rulemaking and in consultation with stakeholders.

(2) CMS will consider incidence and prevalence of disease, the volume and variability of use of particular imaging services, and strength of evidence supporting particular imaging services. We will also consider applicability of the clinical area to a variety of care settings and to the Medicare population.

(3) The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) may make recommendations to CMS.

(4) Priority clinical areas will be used by CMS to identify outlier ordering professionals (section 1834(q)(5) of the Act).

(f) Identification of non-evidence-based AUC or other non-adherence to requirements for qualified PLEs. (1) CMS will accept public comment to facilitate identification of AUC sets, subsets or individual criterion that are not evidence-based, giving priority to AUC associated with priority clinical areas and to AUC that conflict with one another. CMS may also independently identify AUC of concern.

(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC.

(3) If a qualified PLE is found non-adherent to the requirements in paragraph (c) of this section, CMS may terminate its qualified status or may consider this information during re-qualification.

36. Section 414.605 is amended by revising the definition of "Basic life support (BLS)" to read as follows:

§ 414.605 Definitions.

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Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished. Also, at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the State or local authority where the services are furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. These laws may vary from State to State.

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§ 414.610 [Amended]