eligible professionals (or in the case of reporting under paragraph (e) of this section, group practices) who are successful electronic prescribers.

[75 FR 73620, Nov. 29, 2010, as amended at 76 FR 54968, Sept. 6, 2011; 76 FR 73472, Nov. 28, 2011; 77 FR 69368, Nov. 16, 2012; 80 FR 71379, Nov. 16, 2015]

§ 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 payment system means the following:

(i) The physician fee schedule established under section 1848(b) of the Act;

(ii) The prospective payment system for hospital outpatient department services under section 1833(t) of the Act; and

(iii) The ambulatory surgical center payment systems under section 1833(i) of the Act.

Applicable setting means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, an independent diagnostic testing facility, 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).

Clinical decision support mechanism (CDSM) means the following: an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4)) of the Act or private sector mechanisms independent from certified EHR technology or established by the Secretary.

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 Web site 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 Web site. 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 Web site.

(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 Web site 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).

(5) Priority clinical areas include the following:

(i) Coronary artery disease (suspected or diagnosed).

(ii) Suspected pulmonary embolism.

(iii) Headache (traumatic and nontraumatic).

(iv) Hip pain.

(v) Low back pain.

(vi) Shoulder pain (to include suspected rotator cuff injury).

(vii) Cancer of the lung (primary or metastatic, suspected or diagnosed).

(viii) Cervical or neck pain.

(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.

(g) *Qualified clinical decision support mechanisms (CDSMs).* Qualified CDSMs are those specified as such by CMS. Qualified CDSMs must adhere to the requirements described in paragraph (g)(1) of this section.

(1) *Requirements for qualification of CDSMs.* A CDSM must meet all of the following requirements:

(i) Make available specified applicable AUC and its related supporting documentation.

(ii) Identify the appropriate use criterion consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.

(iii) Make available, at a minimum, specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas identified in paragraph (e)(5) of this section.

(iv) Be able to incorporate specified applicable AUC from more than one qualified PLE.

(v) Determines, for each consultation, the extent to which the applicable imaging service is consistent with specified applicable AUC.

(vi) Generate and provide a certification or documentation at the time of order that documents which qualified CDSM was consulted; the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM; whether the service ordered would adhere to specified applicable AUC; whether the service ordered would not adhere to specified applicable AUC; or whether the specified applicable AUC consulted was not applicable to the service ordered. Certification or documentation must:

(A) Be generated each time an ordering professional consults a qualified CDSM.

(B) Include a unique consultation identifier generated by the CDSM.

(vii) Modifications to AUC within the CDSM must comply with the following timeline requirements:

(A) Make available updated AUC content within 12 months from the date the qualified PLE updates AUC.

(B) A protocol must be in place to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.

(C) Specified applicable AUC that reasonably address common and important clinical scenarios within any new priority clinical area must be made available for consultation through the qualified CDSM within 12 months of the priority clinical area being finalized by CMS.

(viii) Meet privacy and security standards under applicable provisions of law.

(ix) Provide to the ordering professional aggregate feedback regarding their consultations with specified applicable AUC in the form of an electronic report on at least an annual basis.

(x) Maintain electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years.

(xi) Comply with modification(s) to any requirements under paragraph (g)(1) of this section made through rulemaking within 12 months of the effective date of the modification.

(xii) Notify ordering professionals upon de-qualification.

(2) *Process to specify qualified CDSMs.* (i) The CDSM developer must submit an application to CMS for review that documents adherence to each of the CDSM requirements outlined in paragraph (g)(1) of this section;

(ii) *Receipt of applications.* (A) Applications must be received by CMS annually by January 1 (except as stated in paragraph (g)(2)(ii)(B) of this section).

(B) For CDSM applicants seeking qualification in CY 2017, applications must be submitted by March 1, 2017; and

(*1*) Applications that document current adherence to qualified CDSM requirements will receive full qualification.

(*2*) Applications that do not document current adherence to each qualified CDSM requirement, but that document how and when each requirement is reasonably expected to be met, will receive preliminary qualification.

(*3*) A preliminary qualification period begins under paragraph (2) on June 30, 2017 and ends on the effective date of the requirements under sections 1834(q)(4)(A) and 1834(q)(4)(B) of the Act.

(*4*) A CDSM with preliminary qualification will become fully qualified by the end of the preliminary qualification period, or earlier if CMS determines that the CDSM has demonstrated adherence to each qualified CDSM requirement, unless we determine that the CDSM fails to meet all requirements (including those requirements they expected to meet in paragraph (g)(2)(ii)(B)(*2*) of this section) by the end of the preliminary qualification period.

(iii) All qualified CDSMs specified by CMS in each year will be included on the list of specified qualified CDSMs posted to the CMS Web site by June 30 of that year; and

(iv) Qualified CDSMs are specified by CMS as such for a period of 5 years.

(v) Qualified CDSMs are required to re-apply during the fifth year after they are specified by CMS in order to maintain their status as qualified

CDSMs. This application must be received by CMS by January 1 of the 5th year after the most recent approval date.

(h) *Identification of non-adherence to requirements for qualified CDSMs.* (1) If a qualified CDSM is found non-adherent to the requirements in paragraph (g)(1) of this section, CMS may terminate its qualified status or may consider this information during requalification.

(i) *Exceptions.* Consulting and reporting requirements are not required for orders for applicable imaging services made by ordering professionals under the following circumstances:

(1) Emergency services when provided to individuals with emergency medical conditions as defined in section 1867(e)(1) of the Act.

(2) For an inpatient and for which payment is made under Medicare Part A.

(3) Significant hardships for ordering professionals who experience any of the following:

(i) Insufficient internet access.

(ii) EHR or CDSM vendor issues.

(iii) Extreme and uncontrollable circumstances.

(j) *Consulting.* (1) Except as specified in paragraphs (i) and (j)(2) of this section, ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2020.

(2) Ordering professionals may delegate the consultation with specified applicable AUC required under paragraph (j)(1) of this section to clinical staff acting under the direction of the ordering professional.

(k) *Reporting.* The following information must be reported on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting, paid for under an applicable payment system defined in paragraph (b) of this section, and ordered on or after January 1, 2020:

(1) The qualified CDSM consulted by the ordering professional.

(2) Information indicating:

(i) Whether the service ordered would adhere to specified applicable AUC;

(ii) Whether the service ordered would not adhere to specified applicable AUC; or

(iii) Whether the specified applicable AUC consulted was not applicable to the service ordered.

(3) The NPI of the ordering professional who consulted specified applicable AUC as required in paragraph (j) of this section, if different from the furnishing professional.

[80 FR 71380, Nov. 16, 2015, as amended at 80 FR 80554, Nov. 15, 2016; 82 FR 53363, Nov. 15, 2017; 83 FR 60074, Nov. 23, 2018]

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies, Splints, Casts, and Certain Intraocular Lenses (IOLs)

SOURCE: 66 FR 45176, Aug. 28, 2001, unless otherwise noted.

§ 414.100 Purpose.

This subpart implements fee schedules for PEN items and services, splints and casts, and IOLs inserted in a physician's office as authorized by section 1842(s) of the Act.

[78 FR 72252, Dec. 2, 2013]

§ 414.102 General payment rules.

(a) *General rule.* For PEN items and services furnished on or after January 1, 2002, and for splints and casts and IOLs inserted in a physician's office on or after April 1, 2014, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—-

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with §§ 414.104 thru 414.108.

(b) *Payment classification.* (1) CMS or the carrier determines fee schedules for parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, splints and casts, and IOLs inserted in a physician's office, as specified in §§ 414.104 thru 414.108.

(2) CMS designates the specific items and services in each category through program instructions.