

**§ 414.4 Fee schedule areas.**

(a) *General.* CMS establishes physician fee schedule areas that generally conform to the geographic localities in existence before January 1, 1992.

(b) *Changes.* CMS announces proposed changes to fee schedule areas in the FEDERAL REGISTER and provides an opportunity for public comment. After considering public comments, CMS publishes the final changes in the FEDERAL REGISTER.

[59 FR 63463, Dec. 8, 1994]

**§ 414.5 Hospital services paid under Medicare Part B when a Part A hospital inpatient claim is denied because the inpatient admission was not reasonable and necessary, but hospital outpatient services would have been reasonable and necessary in treating the beneficiary.**

(a) If a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under § 482.30(d) of this chapter or § 485.641 of this chapter after a beneficiary is discharged that the beneficiary's inpatient admission was not reasonable and necessary, the hospital may be paid for any of the following Part B inpatient services that would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted as an inpatient, provided the beneficiary is enrolled in Medicare Part B:

(1) Services described in § 419.21(a) of this chapter that do not require an outpatient status.

(2) Physical therapy services, speech-language pathology services, and occupational therapy services.

(3) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l) of Act.

(4) Except as provided in § 419.2(b)(11) of this chapter, prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(5) Except as provided in § 419.2(b)(10) of this chapter, durable medical equipment supplied by the hospital for the patient to take home.

(6) Clinical diagnostic laboratory services.

(7)(i) Effective December 8, 2003, screening mammography services; and

(ii) Effective January 1, 2005, diagnostic mammography services.

(8) Effective January 1, 2011, annual wellness visit providing personalized prevention plan services as defined in § 410.15 of this chapter.

(b) If a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under § 482.30(d) of this chapter or § 485.641 of this chapter after a beneficiary is discharged that the beneficiary's inpatient admission was not reasonable and necessary, the hospital may be paid for hospital outpatient services described in § 412.2(c)(5), § 412.405, § 412.540, or § 412.604(f) of this chapter or § 413.40(c)(2) of this chapter that are furnished to the beneficiary prior to the point of inpatient admission (that is, the inpatient admission order).

(c) The claims for the Part B services filed under the circumstances described in this section must be filed in accordance with the time limits for filing claims specified in § 424.44(a) of this chapter.

[78 FR 50968, Aug. 19, 2013]

**Subpart B—Physicians and Other Practitioners**

SOURCE: 56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, unless otherwise noted.

**§ 414.20 Formula for computing fee schedule amounts.**

(a) *Participating supplier.* The fee schedule amount for a participating supplier for a physician service as defined in § 414.2 is computed as the product of the following amounts:

(1) The RVUs for the service.

(2) The GAF for the fee schedule area.

(3) The CF.

(b) *Nonparticipating supplier.* The fee schedule amount for a nonparticipating supplier for a physician service as defined in § 414.2 is 95 percent of the fee schedule amount as calculated in paragraph (a) of this section.

[62 FR 59101, Oct. 31, 1997]

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### § 414.21 Medicare payment basis.

Medicare payment is based on the lesser of the actual charge or the applicable fee schedule amount.

[62 FR 59101, Oct. 31, 1997]

### § 414.22 Relative value units (RVUs).

CMS establishes RVUs for physicians' work, practice expense, and malpractice insurance.

(a) *Physician work RVUs*—(1) *General rule.* Physician work RVUs are established using a relative value scale in which the value of physician work for a particular service is rated relative to the value of work for other physician services.

(2) *Special RVUs for anesthesia and radiology services*—(i) *Anesthesia services.* The rules for determining RVUs for anesthesia services are set forth in § 414.46.

(ii) *Radiology services.* CMS bases the RVUs for all radiology services on the relative value scale developed under section 1834(b)(1)(A) of the Act, with appropriate modifications to ensure that the RVUs established for radiology services that are similar or related to other physician services are consistent with the RVUs established for those similar or related services.

(b) *Practice expense RVUs.* (1) Practice expense RVUs are computed for each service or class of service by applying average historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average practice expense percentage for a service or class of services is computed as follows:

(i) Multiply the average practice expense percentage for each specialty by the proportion of a particular service or class of service performed by that specialty.

(ii) Add the products for all specialties.

(3) For services furnished beginning calendar year (CY) 1994, for which 1994 practice expense RVUs exceed 1994 work RVUs and that are performed in office settings less than 75 percent of the time, the 1994, 1995, and 1996 practice expense RVUs are reduced by 25 percent of the amount by which they exceed the number of 1994 work RVUs.

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Practice expense RVUs are not reduced to less than 128 percent of 1994 work RVUs.

(4) For services furnished beginning January 1, 1998, practice expense RVUs for certain services are reduced to 110 percent of the work RVUs for those services. The following two categories of services are excluded from this limitation:

(i) The service is provided more than 75 percent of the time in an office setting; or

(ii) The service is one described in section 1848(c)(2)(G)(v) of the Act, codified at 42 U.S.C. 1395w–4(c)(2)(G). Section 1848(c)(2)(G)(v) of the Act refers to the 1998 proposed resource-based practice expense RVUs (as specified in the June 18, 1997 physician fee schedule proposed rule (62 FR 33158)) for the specific site, either in-office or out-of-office, increased from its 1997 practice expense RVUs.)

(5) For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) Usually there are two levels of practice expense RVUs that correspond to each code.

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in a hospital, a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5) of this chapter, or via telehealth under § 410.78 of this chapter.

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in all locations other than those listed in paragraph (b)(5)(i)(A) of this section, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

(C) *Outpatient therapy and CORF services.* Outpatient therapy services (including physical therapy, occupational therapy, and speech-language pathology services) and CORF services billed under the physician fee schedule are paid using the nonfacility practice expense RVUs.

(ii) [Reserved]

(6)(i) CMS establishes criteria for supplemental surveys regarding specialty practice expenses submitted to CMS that may be used in determining practice expense RVUs.

(ii) Any CMS-designated specialty group may submit a supplemental survey.

(iii) CMS will consider for use in determining practice expense RVUs for the physician fee schedule survey data and related materials submitted to CMS by March 1, 2004 to determine CY 2005 practice expense RVUs and by March 1, 2005 to determine CY 2006 practice expense RVUs.

(c) *Malpractice insurance RVUs.* (1) Malpractice insurance RVUs are computed for each service or class of services by applying average malpractice insurance historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average historical malpractice insurance percentage for a service or class of services is computed as follows:

(i) Multiply the average malpractice insurance percentage for each specialty by the proportion of a particular service or class of services performed by that specialty.

(ii) Add all the products for all the specialties.

(3) For services furnished in the year 2000 and subsequent years, the malpractice RVUs are based on the relative malpractice insurance resources.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42493, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 62 FR 59102, Oct. 31, 1997; 63 FR 58910, Nov. 2, 1998; 64 FR 59441, Nov. 2, 1999; 65 FR 25668, May 3, 2000; 65 FR 65440, Nov. 1, 2000; 67 FR 43558, June 28, 2002; 68 FR 63261, Nov. 7, 2003; 72 FR 66932, Nov. 27, 2007; 73 FR 69935, Nov. 19, 2008; 76 FR 73471, Nov. 28, 2011; 81 FR 79879, Nov. 14, 2016; 81 FR 80553, Nov. 15, 2016]

#### § 414.24 Publication of RVUs and direct PE inputs.

(a) *Definitions.* For purposes of this section, the following definitions apply:

*Existing code* means a code that is not a new code under paragraph (c)(2) of this section, and includes codes for which the descriptor is revised and

codes that are combinations or subdivisions of previously existing codes.

*New code* means a code that describes a service that was not previously described or valued under the PFS using any other code or combination of codes.

(b) *Revisions of RVUs and Direct PE Inputs.* For valuations for calendar year 2017 and beyond, CMS publishes, through notice and comment rule-making in the FEDERAL REGISTER (including proposals in a proposed rule), changes in RVUs or direct PE inputs for existing codes.

(c) *Establishing RVUs and Direct PE inputs for new codes—(1) General rule.* CMS establishes RVUs and direct PE inputs for new codes in the manner described in paragraph (b) of this section.

(2) *Exception for new codes for which CMS does not have sufficient information.* When CMS determines for a new code that it does not have sufficient information to include proposed RVUs or direct PE inputs in the proposed rule, but that it is in the public interest for Medicare to use a new code during a payment year, CMS will publish in the FEDERAL REGISTER RVUs and direct PE inputs that are applicable on an interim basis subject to public comment. After considering public comments and other information on interim RVUs and PE inputs for the new code, CMS publishes in the FEDERAL REGISTER the final RVUs and PE inputs for the code.

(d) *Values for local codes (HCPCS Level 3).* (1) Carriers establish relative values for local codes for services not included in HCPCS levels 1 or 2.

(2) Carriers must obtain prior approval from CMS to establish local codes for services that meet the definition of “physician services” in § 414.2.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 79 FR 68003, Nov. 13, 2014]

#### § 414.26 Determining the GAF.

CMS establishes a GAF for each service in each fee schedule area.

(a) *Geographic indices.* CMS uses the following indices to establish the GAF:

(1) An index that reflects one-fourth of the difference between the relative value of physicians’ work effort in each of the different fee schedule areas as

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determined under § 414.22(a) and the national average of that work effort.

(2) An index that reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in each of the different fee schedule areas as determined under § 414.22(b) compared to the national average of those costs.

(3) An index that reflects the relative costs of malpractice expenses in each of the different fee schedule areas as determined under § 414.22(c) compared to the national average of those costs.

(b) *Class-specific practice cost indices.* If the application of a single index to different classes of services would be substantially inequitable because of differences in the mix of goods and services comprising practice expenses for the different classes of services, more than one index may be established under paragraph (a)(2) of this section.

(c) *Adjusting the practice expense index to account for the Frontier State floor—*

(1) *General criteria.* Effective on or after January 1, 2011, CMS will adjust the practice expense index for physicians' services furnished in qualifying States to recognize the practice expense index floor established for Frontier States. A qualifying State must meet the following criteria:

(i) At least 50 percent of counties located within the State have a population density less than 6 persons per square mile.

(ii) The State does not receive a non-labor related share adjustment determined by the Secretary to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(2) *Amount of adjustment.* The practice expense value applied for physicians' services furnished in a qualifying State will be not less than 1.00.

(3) *Process for determining adjustment.*

(i) CMS will use the most recent population estimate data published by the U.S. Census Bureau to determine county definitions and population density. This analysis will be periodically revised, such as for updates to the decennial census data.

(ii) CMS will publish annually a listing of qualifying Frontier States receiving a practice expense index floor attributable to this provision.

(d) *Computation of GAF.* The GAF for each fee schedule area is the sum of the physicians' work adjustment factor, the practice expense adjustment factor, and the malpractice cost adjustment factor, as defined in this section:

(1) The geographic physicians' work adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the work component and the geographic physicians' work index value established under paragraph (a)(1) of this section.

(2) The geographic practice expense adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the practice expense component, multiplied by the geographic practice cost index (GPCI) value established under paragraph (a)(2) of this section.

(3) The geographic malpractice adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the malpractice component, multiplied by the GPCI value established under paragraph (a)(3) of this section.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 75 FR 73616, Nov. 29, 2010]

### § 414.28 Conversion factors.

CMS establishes CFs in accordance with section 1848(d) of the Act.

(a) *Base-year CFs.* CMS established the CF for 1992 so that had section 1848 of the Act applied during 1991, it would have resulted in the same aggregate amount of payments for physician services as the estimated aggregate amount of these payments in 1991, adjusted by the update for 1992 computed as specified in § 414.30.

(b) *Subsequent CFs.* For calendar years 1993 through 1995, the CF for each year is equal to the CF for the previous year, adjusted in accordance with § 414.30. Beginning January 1, 1996, the CF for each calendar year may be further adjusted so that adjustments to the fee schedule in accordance with section 1848(c)(2)(B)(ii) of the Act do not cause total expenditures under the fee schedule to differ by more than \$20 million from the amount that would

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have been spent if these adjustments had not been made.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 53877, Oct. 18, 1995; 60 FR 63177, Dec. 8, 1995]

### § 414.30 Conversion factor update.

Unless Congress acts in accordance with section 1848(d)(3) of the Act—

(a) *General rule.* The CF update for a CY equals the Medicare Economic Index increased or decreased by the number of percentage points by which the percentage increase in expenditures for physician services (or for a particular category of physician services, such as surgical services) in the second preceding FY over the third preceding FY exceeds the performance standard rate of increase established for the second preceding FY.

(b) *Downward adjustment.* The downward adjustment may not exceed the following:

(1) For CYs 1992 and 1993, 2 percentage points.

(2) For CY 1994, 2.5 percentage points.

(3) For CYs 1995 and thereafter, 5 percentage points.

[55 FR 23441, June 8, 1990, as amended at 60 FR 63177, Dec. 8, 1995; 61 FR 42385, Aug. 15, 1996]

### § 414.34 Payment for services and supplies incident to a physician's service.

(a) *Medical supplies.* (1) Except as otherwise specified in this paragraph, office medical supplies are considered to be part of a physician's practice expense, and payment for them is included in the practice expense portion of the payment to the physician for the medical or surgical service to which they are incidental.

(2) If physician services of the type routinely furnished in provider settings are furnished in a physician's office, separate payment may be made for certain supplies furnished incident to that physician service if the following requirements are met:

(i) It is a procedure that can safely be furnished in the office setting in appropriate circumstances.

(ii) It requires specialized supplies that are not routinely available in physicians' offices and that are generally disposable.

(iii) It is furnished before January 1, 1999.

(3) For the purpose of paragraph (a)(2) of this section, provider settings include only the following settings:

(i) Hospital inpatient and outpatient departments.

(ii) Ambulatory surgical centers.

(4) For the purpose of paragraph (a)(2) of this section, "routinely furnished in provider settings" means furnished in inpatient or outpatient hospital settings or ambulatory surgical centers more than 50 percent of the time.

(5) CMS establishes a list of services for which a separate supply payment may be made under this section.

(6) The fee schedule amount for supplies billed separately is not subject to a GPCI adjustment.

(b) *Services of nonphysicians that are incident to a physician's service.* Services of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

### § 414.36 Payment for drugs incident to a physician's service.

Payment for drugs incident to a physician's service is made in accordance with § 405.517 of this chapter.

### § 414.39 Special rules for payment of care plan oversight.

(a) *General.* Except as specified in paragraphs (b) and (c) of this section, payment for care plan oversight is included in the payment for visits and other services under the physician fee schedule. For purposes of this section a nonphysician practitioner (NPP) is a nurse practitioner, clinical nurse specialist or physician assistant.

(b) *Exception.* Separate payment is made under the following conditions for physician care plan oversight services furnished to beneficiaries who receive HHA and hospice services that are covered by Medicare:

(1) The care plan oversight services require recurrent physician supervision of therapy involving 30 or more minutes of the physician's time per month.

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(2) Payment is made to only one physician per patient for services furnished during a calendar month period. The physician must have furnished a service requiring a face-to-face encounter with the patient at least once during the 6-month period before the month for which care plan oversight payment is first billed. The physician may not have a significant ownership interest in, or financial or contractual relationship with, the HHA in accordance with § 424.22(d) of this chapter. The physician may not be the medical director or employee of the hospice and may not furnish services under an arrangement with the hospice.

(3) If a physician furnishes care plan oversight services during a post-operative period, payment for care plan oversight services is made if the services are documented in the patient's medical record as unrelated to the surgery.

(c) *Special rules for payment of care plan oversight provided by nonphysician practitioners for beneficiaries who receive HHA services covered by Medicare.* (1) An NPP can furnish physician care plan oversight (but may not certify a patient as needing home health services) only if the physician who signs the plan of care provides regular ongoing care under the same plan of care as does the NPP billing for care plan oversight and either—

(i) The physician and NPP are part of the same group practice; or

(ii) If the NPP is a nurse practitioner or clinical nurse specialist, the physician signing the plan of care also has a collaborative agreement with the NPP; or

(iii) If the NPP is a physician assistant, the physician signing the plan of care is also the physician who provides general supervision of physician assistant services for the practice.

(2) Payment may be made for care plan oversight services furnished by an NPP when:

(i) The NPP providing the care plan oversight has seen and examined the patient;

(ii) The NPP providing care plan oversight is not functioning as a consultant whose participation is limited to a single medical condition rather

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than multi-disciplinary coordination of care; and

(iii) The NPP providing care plan oversight integrates his or her care with that of the physician who signed the plan of care.

[59 FR 63463, Dec. 8, 1994; 60 FR 49, Jan. 3, 1995; 60 FR 36733, July 18, 1995, as amended at 69 FR 66423, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005]

### § 414.40 Coding and ancillary policies.

(a) *General rule.* CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes.

(b) *Specific types of policies.* CMS establishes uniform national ancillary policies necessary to implement the fee schedule for physician services. These include, but are not limited to, the following policies:

(1) Global surgery policy (for example, post- and pre-operative periods and services, and intra-operative services).

(2) Professional and technical components (for example, payment for services, such as an EEG, which typically comprise a technical component (the taking of the test) and a professional component (the interpretation)).

(3) Payment modifiers (for example, assistant-at-surgery, multiple surgery, bilateral surgery, split surgical global services, team surgery, and unusual services).

### § 414.42 Adjustment for first 4 years of practice.

(a) *General rule.* For services furnished during CYs 1992 and 1993, except as specified in paragraph (b) of this section, the fee schedule payment amount or prevailing charge must be phased in as specified in paragraph (d) of this section for physicians, physical therapists (PTs), occupational therapists (OTs), and all other health care practitioners who are in their first through fourth years of practice.

(b) *Exception.* The reduction required in paragraph (d) of this section does not apply to primary care services or to services furnished in a rural area as defined in section 1886(d)(2)(D) of the Act that is designated under section 332(a)(1)(A) of the Public Health Service Act as a Health Professional Shortage Area.

(c) *Definition of years of practice.* (1) The “first year of practice” is the first full CY during the first 6 months of which the physician, PT, OT, or other health care practitioner furnishes professional services for which payment may be made under Medicare Part B, plus any portion of the prior CY if that prior year does not meet the first 6 months test.

(2) The “second, third, and fourth years of practice” are the first, second, and third CYs following the first year of practice, respectively.

(d) *Amounts of adjustment.* The fee schedule payment for the service of a new physician, PT, OT, or other health care practitioner is limited to the following percentages for each of the indicated years:

- (1) First year—80 percent
- (2) Second year—85 percent
- (3) Third year—90 percent
- (4) Fourth year—95 percent

[57 FR 42493, Sept. 15, 1992, as amended at 58 FR 63687, Dec. 2, 1993]

#### § 414.44 Transition rules.

(a) *Adjusted historical payment basis—*

(1) *All services other than radiology and nuclear medicine services.* For all physician services other than radiology services, furnished in a fee schedule area, the adjusted historical payment basis (AHPB) is the estimated weighted average prevailing charge applied in the fee schedule area for the service in CY 1991, as determined by CMS without regard to physician specialty and as adjusted to reflect payments for services below the prevailing charge, adjusted by the update established for CY 1992.

(2) *Radiology services.* For radiology services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 1834(b), adjusted by the update established for CY 1992.

(3) *Nuclear medicine services.* For nuclear medicine services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 6105(b) of Public Law 101-239 and section 4102(g) of Public Law 101-508, adjusted by the update established for CY 1992.

(4) *Transition adjustment.* CMS adjusts the AHPB for all services by 5.5 percent

to produce budget-neutral payments for 1992.

(b) *Adjustment of 1992 payments for physician services other than radiology services.* For physician services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 115 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 115 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(c) *Adjustment of 1992 payments for radiology services.* For radiology services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 109 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 109 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 9 percent of the fee schedule amount is substituted for the fee schedule amount.

(d) *Computation of payments for CY 1993.* For physician services subject to the transition rules in CY 1992 and furnished during CY 1993, the fee schedule

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is equal to 75 percent of the amount that would have been paid in the fee schedule area under the 1992 transition rules, adjusted by the amount of the 1993 update, plus 25 percent of the 1993 fee schedule amount.

(e) *Computation of payments for CY 1994.* For physician services subject to the transition rules in CY 1993, and furnished during CY 1994, the fee schedule is equal to 67 percent of the amount that would have been paid in the fee schedule area under the 1993 transition rules, adjusted by the amount of the 1994 update, plus 33 percent of the 1994 fee schedule amount.

(f) *Computation of payments for CY 1995.* For physician services subject to the transition rules in CY 1994 and furnished during CY 1995, the fee schedule is equal to 50 percent of the amount that would have been paid in the fee schedule area under the 1994 transition rules, adjusted by the amount of the 1995 update, plus 50 percent of the 1995 fee schedule amount.

### § 414.46 Additional rules for payment of anesthesia services.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Base unit* means the value for each anesthesia code that reflects all activities other than anesthesia time. These activities include usual preoperative and postoperative visits, the administration of fluids and blood incident to anesthesia care, and monitoring services.

(2) *Anesthesia practitioner*, for the purpose of anesthesia time, means a physician who performs the anesthesia service alone, a CRNA who is not medically directed who performs the anesthesia service alone, or a medically directed CRNA.

(3) *Anesthesia time* means the time during which an anesthesia practitioner is present with the patient. It starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the beneficiary, that is, when the beneficiary may be placed safely under postoperative care. Anesthesia time is a continuous time period from the start

of anesthesia to the end of an anesthesia service. In counting anesthesia time, the anesthesia practitioner can add blocks of anesthesia time around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption.

(b) *Determinations of payment amount—Basic rule.* For anesthesia services performed, medically directed, or medically supervised by a physician, CMS pays the lesser of the actual charge or the anesthesia fee schedule amount.

(1) The carrier bases the fee schedule amount for an anesthesia service on the product of the sum of allowable base and time units and an anesthesia-specific CF. The carrier calculates the time units from the anesthesia time reported by the anesthesia practitioner for the anesthesia procedure. The physician who fulfills the conditions for medical direction in § 415.110 (Conditions for payment: Anesthesiology services) reports the same anesthesia time as the medically-directed CRNA.

(2) CMS furnishes the carrier with the base units for each anesthesia procedure code. The base units are derived from the 1988 American Society of Anesthesiologists' Relative Value Guide except that the number of base units recognized for anesthesia services furnished during cataract or iridectomy surgery is four units.

(3) Modifier units are not allowed. Modifier units include additional units charged by a physician or a CRNA for patient health status, risk, age, or unusual circumstances.

(c) *Physician personally performs the anesthesia procedure.* (1) CMS considers an anesthesia service to be personally performed under any of the following circumstances:

(i) The physician performs the entire anesthesia service alone.

(ii) The physician establishes an attending physician relationship in one or two concurrent cases involving an intern or resident and the service was furnished before January 1, 1994.

(iii) The physician establishes an attending physician relationship in one case involving an intern or resident and the service was furnished on or



after January 1, 1994 but prior to January 1, 1996. For services on or after January 1, 1996, the physician must be the teaching physician as defined in §§415.170 through 415.184 of this chapter.

(iv) The physician and the CRNA or AA are involved in a single case and the services of each are found to be medically necessary.

(v) The physician is continuously involved in a single case involving a student nurse anesthetist.

(vi) The physician is continuously involved in a single case involving a CRNA or AA and the service was furnished prior to January 1, 1998.

(2) CMS determines the fee schedule amount for an anesthesia service personally performed by a physician on the basis of an anesthesia-specific fee schedule CF and unreduced base units and anesthesia time units. One anesthesia time unit is equivalent to 15 minutes of anesthesia time, and fractions of a 15-minute period are recognized as fractions of an anesthesia time unit.

(d) *Anesthesia services medically directed by a physician.* (1) CMS considers an anesthesia service to be medically directed by a physician if:

(i) The physician performs the activities described in §415.110 of this chapter.

(ii) The physician directs qualified individuals involved in two, three, or four concurrent cases.

(iii) Medical direction can occur for a single case furnished on or after January 1, 1998 if the physician performs the activities described in §415.110 of this chapter and medically directs a single CRNA or AA.

(2) The rules for medical direction differ for certain time periods depending on the nature of the qualified individual who is directed by the physician.

(i) If more than two procedures are directed on or after January 1, 1994, the qualified individuals could be AAs, CRNAs, interns, or residents. The medical direction rules apply to student nurse anesthetists only if the physician directs two concurrent cases, each of which involves a student nurse anesthetist or the physician directs one case involving a student nurse anes-

thetist and the other involving a CRNA, AA, intern, or resident.

(ii) For services furnished on or after January 1, 2010, the medical direction rules do not apply to a single anesthesia resident case that is concurrent to another case which is paid under the medical direction payment rules as specified in paragraph (e) of this section.

(3) Payment for medical direction is based on a specific percentage of the payment allowance recognized for the anesthesia service personally performed by a physician alone. The following percentages apply for the years specified:

(i) CY 1994–60 percent of the payment allowance for personally performed procedures.

(ii) CY 1995–57.5 percent of the payment allowance for personally performed services.

(iii) CY 1996–55 percent of the payment allowance for personally performed services.

(iv) CY 1997–52.5 percent of the payment allowance for personally performed services.

(v) CY 1998 and thereafter–50 percent of the payment allowance for personally performed services.

(e) *Special payment rule for teaching anesthesiologist involved in a single resident case or two concurrent cases.* For physicians' services furnished on or after January 1, 2010, if the teaching anesthesiologist is involved in the training of physician residents in a single anesthesia case or two concurrent anesthesia cases, the fee schedule amount must be 100 percent of the fee schedule amount otherwise applicable if the anesthesia services were personally performed by the teaching anesthesiologist and the teaching anesthesiologist fulfilled the criteria in §415.178 of this chapter. This special payment rule also applies if the teaching anesthesiologist is involved in one resident case that is concurrent to another case paid under the medical direction payment rules.

(f) *Physician medically supervises anesthesia services.* If the physician medically supervises more than four concurrent anesthesia services, CMS bases the fee schedule amount on an anesthesia-specific CF and three base units. This

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represents payment for the physician's involvement in the pre-surgical anesthesia services.

(g) *Payment for medical or surgical services furnished by a physician while furnishing anesthesia services.* (1) CMS allows separate payment under the fee schedule for certain reasonable and medically necessary medical or surgical services furnished by a physician while furnishing anesthesia services to the patient. CMS makes payment for these services in accordance with the general physician fee schedule rules in § 414.20. These services are described in program operating instructions.

(2) CMS makes no separate payment for other medical or surgical services, such as the pre-anesthetic examination of the patient, pre- or post-operative visits, or usual monitoring functions, that are ordinarily included in the anesthesia service.

(h) *Physician involved in multiple anesthesia services.* If the physician is involved in multiple anesthesia services for the same patient during the same operative session, the carrier makes payment according to the base unit associated with the anesthesia service having the highest base unit value and anesthesia time that encompasses the multiple services. The carrier makes payment for add-on anesthesia codes according to program operating instructions.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 60 FR 63177, Dec. 8, 1995; 64 FR 59441, Nov. 2, 1999; 67 FR 80041, Dec. 31, 2002; 68 FR 63261, Nov. 7, 2003; 74 FR 62006, Nov. 25, 2009]

## § 414.48 Limits on actual charges of nonparticipating suppliers.

(a) *General rule.* A supplier, as defined in § 400.202 of this chapter, who is nonparticipating and does not accept assignment may charge a beneficiary an amount up to the limiting charge described in paragraph (b) of this section.

(b) *Specific limits.* For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the fee schedule amount for nonparticipating suppliers. For items or services CMS excludes from payment under the physician fee schedule (in accordance with section 1848 (j)(3) of the Act), the limiting charge is 115 percent

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of 95 percent of the payment basis applicable to participating suppliers as calculated in § 414.20(b).

[58 FR 63687, Dec. 2, 1993, as amended at 62 FR 59102, Oct. 31, 1997]

## § 414.50 Physician or other supplier billing for diagnostic tests performed or interpreted by a physician who does not share a practice with the billing physician or other supplier.

(a) *General rules.* (1) For services covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special billing rules set forth in section 1833(h)(5)(A) of the Act), if a physician or other supplier bills for the technical component (TC) or professional component (PC) of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such physician or other supplier through common ownership or control as described in § 413.17 of this chapter) and the diagnostic test is performed by a physician who does not share a practice with the billing physician or other supplier, the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the TC or PC of the diagnostic test may not exceed the lowest of the following amounts:

(i) The performing supplier's net charge to the billing physician or other supplier. For purposes of this paragraph (a)(1) only, with respect to the TC, the performing supplier is the physician who supervised the TC, and with respect to the PC, the performing supplier is the physician who performed the PC.

(ii) The billing physician or other supplier's actual charge.

(iii) The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

(2) The following requirements are applicable for purposes of paragraph (a)(1) of this section:

(i) The net charge must be determined without regard to any charge that is intended to reflect the cost of

equipment or space leased to the performing supplier by or through the billing physician or other supplier.

(ii) A performing physician shares a practice with the billing physician or other supplier if he or she furnishes substantially all (which, for purposes of this section, means “at least 75 percent”) of his or her professional services through such billing physician or other supplier. The “substantially all” requirement will be satisfied if, at the time the billing physician or other supplier submits a claim for a service furnished by the performing physician, the billing physician or other supplier has a reasonable belief that:

(A) For the 12 months prior to and including the month in which the service was performed, the performing physician furnished substantially all of his or her professional services through the billing physician or other supplier; or

(B) The performing physician will furnish substantially all of his or her professional services through the billing physician or other supplier for the next 12 months (including the month in which the service is performed).

(iii) A physician will be deemed to share a practice with the billing physician or other supplier with respect to the performance of the TC or PC of a diagnostic test if the physician is an owner, employee or independent contractor of the billing physician or other supplier and the TC or PC is performed in the office of the billing physician or other supplier. The “office of the billing physician or other supplier” is any medical office space, regardless of number of locations, in which the ordering physician or other ordering supplier regularly furnishes patient care, and includes space where the billing physician or other supplier furnishes diagnostic testing, if the space is located in the same building (as defined in § 411.351) in which the ordering physician or other ordering supplier regularly furnishes patient care. With respect to a billing physician or other supplier that is a physician organization (as defined in § 411.351 of this chapter), the “office of the billing physician or other supplier” is space in which the ordering physician provides substantially the full range of patient care

services that the ordering physician provides generally. The performance of the TC includes both the conducting of the TC as well as the supervision of the TC.

(b) *Restriction on payment.* (1) The billing physician or other supplier must identify the performing supplier and indicate the performing supplier’s net charge for the test. If the billing physician or other supplier fails to provide this information, CMS makes no payment to the billing physician or other supplier and the billing physician or other supplier may not bill the beneficiary.

(2) Physicians and other suppliers that accept Medicare assignment may bill beneficiaries for only the applicable deductibles and coinsurance.

(3) Physicians and other suppliers that do not accept Medicare assignment may not bill the beneficiary more than the payment amount described in paragraph (a) of this section.

[72 FR 66400, Nov. 27, 2007, as amended at 73 FR 2432, Jan. 15, 2008; 73 FR 69935, Nov. 19, 2008]

#### **§ 414.52 Payment for physician assistants’ services.**

Allowed amounts for the services of a physician assistant furnished beginning January 1, 1992 and ending December 31, 1997, may not exceed the limits specified in paragraphs (a) through (c) of this section. Allowed amounts for the services of a physician assistant furnished beginning January 1, 1998, may not exceed the limits specified in paragraph (d) of this section.

(a) For assistant-at-surgery services, 65 percent of the amount that would be allowed under the physician fee schedule if the assistant-at-surgery service was furnished by a physician.

(b) For services (other than assistant-at-surgery services) furnished in a hospital, 75 percent of the physician fee schedule amount for the service.

(c) For all other services, 85 percent of the physician fee schedule amount for the service.

(d) For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, 85 percent of the physician fee

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schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

#### § 414.54 Payment for certified nurse-midwives' services.

(a) For services furnished after December 31, 1991, allowed amounts under the fee schedule established under section 1833(a)(1)(K) of the Act for the payment of certified nurse-midwife services may not exceed 65 percent of the physician fee schedule amount for the service.

(b) For certified nurse-midwife services furnished on or after January 1, 2011, allowed amounts may not exceed 100 percent of the physician fee schedule amount that would be paid to a physician for the services.

[75 FR 73616, Nov. 29, 2010]

#### § 414.56 Payment for nurse practitioners' and clinical nurse specialists' services.

(a) *Rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a rural area (as described in section 1861(s)(2)(K)(iii) of the Act) may not exceed the following limits:

(1) For services furnished in a hospital (including assistant-at-surgery services), 75 percent of the physician fee schedule amount for the service.

(2) For all other services, 85 percent of the physician fee schedule amount for the service.

(b) *Non-rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a nursing facility may not exceed 85 percent of the physician fee schedule amount for the service.

(c) *Beginning January 1, 1998.* For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule

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amount for the service. For assistant-at-surgery services, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[63 FR 58911, Nov. 2, 1998]

#### § 414.58 Payment of charges for physician services to patients in providers.

(a) *Payment under the physician fee schedule.* In addition to the special conditions for payment in §§ 415.100 through 415.130, and § 415.190 of this chapter, CMS establishes payment for physician services to patients in providers under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) *Teaching hospitals.* Services furnished by physicians in teaching hospitals may be made on a reasonable cost basis set forth in § 415.162 of this chapter if the hospital exercises the election described in § 415.160 of this chapter.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 63189, Dec. 8, 1995]

#### § 414.60 Payment for the services of CRNAs.

(a) *Basis for payment.* The allowance for the anesthesia service furnished by a CRNA, medically directed or not medically directed, is based on allowable base and time units as defined in § 414.46(a). Beginning with CY 1994—

(1) The allowance for an anesthesia service furnished by a medically directed CRNA is based on a fixed percentage of the allowance recognized for the anesthesia service personally performed by the physician alone, as specified in § 414.46(d)(3); and

(2) The CF for an anesthesia service furnished by a CRNA not directed by a physician may not exceed the CF for a service personally performed by a physician.

(b) *To whom payment may be made.* Payment for an anesthesia service furnished by a CRNA may be made to the CRNA or to any individual or entity

(such as a hospital, critical access hospital, physician, group practice, or ambulatory surgical center) with which the CRNA has an employment or contract relationship that provides for payment to be made to the individual or entity.

(c) *Condition for payment.* Payment for the services of a CRNA may be made only on an assignment related basis, and any assignment accepted by a CRNA is binding on any other person presenting a claim or request for payment for the service.

[60 FR 63178, Dec. 8, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 59441, Nov. 2, 1999; 77 FR 69363, Nov. 16, 2012]

**§ 414.61 Payment for anesthesia services furnished by a teaching CRNA.**

(a) *Basis for payment.* Beginning January 1, 2010, anesthesia services furnished by a teaching CRNA may be paid under one of the following conditions:

(1) The teaching CRNA, who is not under medical direction of a physician, is present with the student nurse anesthetist for the pre and post anesthesia services included in the anesthesia base units payment and is continuously present during anesthesia time in a single case with a student nurse anesthetist.

(2) The teaching CRNA, who is not under the medical direction of a physician, is involved with two concurrent anesthesia cases with student nurse anesthetists. The teaching CRNA must be present with the student nurse anesthetist for the pre and post anesthesia services included in the anesthesia base unit. For the anesthesia time of the two concurrent cases, the teaching CRNA can only be involved with those two concurrent cases and may not perform services for other patients.

(b) *Level of payment.* The allowance for the service of the teaching CRNA, furnished under paragraph (a) of this section, is determined in the same way as for a physician who personally performs the anesthesia service alone as specified in § 414.46(c) of this subpart.

[74 FR 62006, Nov. 25, 2009]

**§ 414.62 Fee schedule for clinical psychologist services.**

The fee schedule for clinical psychologist services is set at 100 percent of the amount determined for corresponding services under the physician fee schedule.

[62 FR 59102, Oct. 31, 1997]

**§ 414.63 Payment for outpatient diabetes self-management training.**

(a) Payment under the physician fee schedule. Except as provided in paragraph (d) of this section, payment for outpatient diabetes self-management training is made under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) To whom payment may be made. Payment may be made to an entity approved by CMS to furnish outpatient diabetes self-management training in accordance with part 410, subpart H of this chapter.

(c) Limitation on payment. Payment may be made for training sessions actually attended by the beneficiary and documented on attendance sheets.

(d) Payments made to those not paid under the physician fee schedule. Payments may be made to other entities not routinely paid under the physician fee schedule, such as hospital outpatient departments, ESRD facilities, and DME suppliers. The payment equals the amounts paid under the physician fee schedule.

(e) Other conditions for fee-for-service payment. The beneficiary must meet the following conditions:

(1) Has not previously received initial training for which Medicare payment was made under this benefit.

(2) Is not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home.

(3) Is not receiving services as an outpatient in an RHC or FQHC.

[65 FR 83153, Dec. 29, 2000]

**§ 414.64 Payment for medical nutrition therapy.**

(a) *Payment under the physician fee schedule.* Medicare payment for medical nutrition therapy is made under the physician fee schedule in accordance with subpart B of this part. Payment to nonphysician professionals, as

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specified in paragraph (b) of this section, is 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charges or 85 percent of the physician fee schedule amount.

(b) *To whom payment may be made.* Payment may be made to a registered dietician or nutrition professional qualified to furnish medical nutrition therapy in accordance with part 410, subpart G of this chapter.

(c) *Effective date of payment.* Medicare pays suppliers of medical nutrition therapy on or after the effective date of enrollment of the supplier at the carrier.

(d) *Limitation on payment.* Payment is made only for documented nutritional therapy sessions actually attended by the beneficiary.

(e) *Other conditions for fee-for-service payment.* Payment is made only if the beneficiary:

(1) Is not an inpatient of a hospital, SNF, nursing home, or hospice.

(2) Is not receiving services in an RHC, FQHC or ESRD dialysis facility.

[66 FR 55332, Nov. 1, 2001, as amended at 86 FR 65668, Nov. 19, 2021]

### § 414.65 Payment for telehealth services.

(a) *Professional service.* The Medicare payment amount for telehealth services described under § 410.78 of this chapter is equal to the current fee schedule amount applicable for the service of the physician or practitioner, subject to paragraphs (a)(1) and (2) of this section, but must be made in accordance with the following limitations:

(1) Only the physician or practitioner at the distant site may bill and receive payment for the professional service via an interactive telecommunications system.

(2) Payments made to the physician or practitioner at the distant site, including deductible and coinsurance, for the professional service may not be shared with the referring practitioner or telepresenter.

(b) *Originating site facility fee.* For telehealth services furnished on or after October 1, 2001:

(1) For services furnished on or after October 1, 2001 through December 31, 2002, the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of \$20. For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act.

(2) Only the originating site may bill for the originating site facility fee and only on an assignment-related basis. The distant site physician or practitioner may not bill for or receive payment for facility fees associated with the professional service furnished via an interactive telecommunications system.

(3) No originating site facility fee payment is made to an originating site described in § 410.78(b)(3)(x), (xi), or (xii); or to an originating site for services furnished under the exception at § 410.78(b)(4)(iv)(A) or (B) of this chapter.

(c) *Deductible and coinsurance apply.* The payment for the professional service and originating site facility fee is subject to the coinsurance and deductible requirements of sections 1833(a)(1) and (b) of the Act.

(d) *Assignment required for physicians, practitioners, and originating sites.* Payment to physicians, practitioners, and originating sites is made only on an assignment-related basis.

(e) *Sanctions.* A distant site practitioner or originating site facility may be subject to the applicable sanctions provided for in chapter IV, part 402 and chapter V, parts 1001, 1002, and 1003 of this title if he or she does any of the following:

(1) Knowingly and willfully bills or collects for services in violation of the limitation of this section.

(2) Fails to timely correct excess charges by reducing the actual charge billed for the service in an amount that does not exceed the limiting charge for the service or fails to timely refund excess collections.

(3) Fails to submit a claim on a standard form for services provided for

which payment is made on a fee schedule basis.

(4) Imposes a charge for completing and submitting the standard claims form.

[66 FR 55332, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2003; 69 FR 66424, Nov. 15, 2004; 70 FR 70332, Nov. 21, 2005; 72 FR 66401, Nov. 27, 2007; 73 FR 69936, Nov. 19, 2008; 74 FR 62006, Nov. 25, 2009; 75 FR 73617, Nov. 29, 2010; 76 FR 73471, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 78 FR 74812, Dec. 10, 2013; 83 FR 60074, Nov. 23, 2018]

**§ 414.66 Incentive payments for physician scarcity areas.**

(a) *Definition.* As used in this section, the following definitions apply.

*Physician scarcity area* is defined as an area with a shortage of primary care physicians or specialty physicians to the Medicare population in that area.

*Primary care physician* is defined as a general practitioner, family practice practitioner, general internist, obstetrician or gynecologist.

(b) Physicians' services furnished to a beneficiary in a Physician Scarcity Area (PSA) for primary or specialist care are eligible for a 5 percent incentive payment.

(c) Primary care physicians furnishing services in primary care PSAs are entitled to an additional 5 percent incentive payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

(d) Physicians, as defined in section 1861(r)(1) of the Act, furnishing services in specialist care PSAs are entitled to an additional 5 percent payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

[69 FR 66424, Nov. 15, 2004]

**§ 414.67 Incentive payments for services furnished in Health Professional Shortage Areas.**

(a) *Health Professional Shortage Area (HPSA) physician bonus program.* A HPSA physician incentive payment will be made subject to the following:

(1) HPSA bonuses are payable for services furnished by physicians as de-

fined in section 1861(r) of the Act in areas designated as of December 31 of the prior year as geographic primary medical care HPSAs as defined in section 332(a)(1)(A) of the Public Health Service Act.

(2) HPSA bonuses are payable for services furnished by psychiatrists in areas designated as of December 31 of the prior year as geographic mental health HPSAs if the services are not already eligible for the bonus based on being in a geographic primary care HPSA.

(3) Physicians eligible for the HPSA physician bonus are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(4) Physicians furnishing services in areas that are designated as geographic HPSAs prior to the beginning of the year but not included on the published list of zip codes for which automated HPSA bonus payments are made must use the AQ modifier to receive the HPSA physician bonus payment.

(b) *HPSA surgical incentive payment program.* A HPSA surgical incentive payment will be made subject to the following:

(1) A major surgical procedure as defined in § 414.2 of this part is furnished by a general surgeon on or after January 1, 2011 and before January 1, 2016 in an area recognized for the HPSA physician bonus program under paragraph (a)(1) of this section.

(2) Payment will be made on a quarterly basis in an amount equal to 10 percent of the Part B payment amount for major surgical procedures furnished as described in paragraph (b)(1) of this section, in addition to the amount the physician would otherwise be paid.

(3) Physicians furnishing services in areas that are designated as geographic HPSAs eligible for the HPSA physician bonus program under paragraph (a)(1) of this section prior to the beginning of the year but not included on the published list of zip codes for which automated HPSA surgical incentive payments are made should report HCPCS modifier -AQ to receive the HPSA surgical incentive payment.

(4) The payment described in paragraph (b)(2) of this section is made to

the surgeon or, where the surgeon has reassigned his or her benefits to a critical access hospital (CAH) paid under the optional method, to the CAH based on an institutional claim.

[75 FR 73617, Nov. 29, 2010]

**§ 414.68 Imaging accreditation.**

(a) *Scope and purpose.* Section 1834(e) of the Act requires the Secretary to designate and approve independent accreditation organizations for purposes of accrediting suppliers furnishing the technical component (TC) of advanced diagnostic imaging services and establish procedures to ensure that the criteria used by an accreditation organization is specific to each imaging modality. Suppliers of the TC of advanced diagnostic imaging services for which payment is made under the fee schedule established in section 1848(b) of the Act must become accredited by an accreditation organization designated by the Secretary beginning January 1, 2012.

(b) *Definitions.* As used in this section, the following definitions are applicable:

*Accredited supplier* means a supplier that has been accredited by a CMS-designated accreditation organization as specified in this part.

*Advanced diagnostic imaging service* means any of the following diagnostic services:

- (i) Magnetic resonance imaging.
- (ii) Computed tomography.
- (iii) Nuclear medicine.
- (iv) Positron emission tomography.

*CMS-approved accreditation organization* means an accreditation organization designated by CMS to perform the accreditation functions specified in section 1834(e) of the Act.

(c) *Application and reapplication procedures for accreditation organizations.* An independent accreditation organization applying for approval or reapproval of authority to survey suppliers for purposes of accrediting suppliers furnishing the TC of advanced diagnostic imaging services is required to furnish CMS with all of the following:

(1) A detailed description of how the organization's accreditation criteria satisfy the statutory standards authorized by section 1834(e)(3) of the Act, specifically—

(i) Qualifications of medical personnel who are not physicians and who furnish the TC of advanced diagnostic imaging services;

(ii) Qualifications and responsibilities of medical directors and supervising physicians (who may be the same person), such as their training in advanced diagnostic imaging services in a residency program, expertise obtained through experience, or continuing medical education courses;

(iii) Procedures to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by the supplier, including a thorough evaluation of equipment performance and safety;

(iv) Procedures to ensure the safety of persons who furnish the TC of advanced diagnostic imaging services and individuals to whom such services are furnished;

(v) Procedures to assist the beneficiary in obtaining the beneficiary's imaging records on request; and

(vi) Procedures to notify the accreditation organization of any changes to the modalities subsequent to the organization's accreditation decision.

(2) An agreement to conform accreditation requirements to any changes in Medicare statutory requirements authorized by section 1834(e) of the Act. The accreditation organization must maintain or adopt standards that are equal to, or more stringent than, those of Medicare.

(3) Information that demonstrates the accreditation organization's knowledge and experience in the advanced diagnostic imaging arena.

(4) The organization's proposed fees for accreditation for each modality in which the organization intends to offer accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.

(5) Any specific documentation requirements and attestations requested by CMS as a condition of designation under this part.

(6) A detailed description of the organization's survey process, including the following:

(i) Type and frequency of the surveys performed.



(ii) The ability of the organization to conduct timely reviews of accreditation applications, to include the organization's national capacity.

(iii) Description of the organization's audit procedures, including random site visits, site audits, or other strategies for ensuring suppliers maintain compliance for the duration of accreditation.

(iv) Procedures for performing unannounced site surveys.

(v) Copies of the organization's survey forms.

(vi) A description of the accreditation survey review process and the accreditation status decision-making process, including the process for addressing deficiencies identified with the accreditation requirements, and the procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vii) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(viii) Detailed information about the individuals who perform evaluations for the accreditation organization, including all of the following information:

(A) The number of professional and technical staff that are available for surveys.

(B) The education, employment, and experience requirements surveyors must meet.

(C) The content and length of the orientation program.

(ix) The frequency and types of in-service training provided to survey personnel.

(x) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(xi) The policies and procedures regarding an individual's participation in the survey or accreditation decision process of any organization with which the individual is professionally or financially affiliated.

(xii) The policies and procedures used when an organization has a dispute regarding survey findings or an adverse decision.

(7) Detailed information about the size and composition of survey teams

for each category of advanced medical imaging service supplier accredited.

(8) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(9) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and CMS.

(10) The organization's policies and procedures for the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements. These policies and procedures must include notifying CMS of Medicare facilities that fail to meet the requirements of the accrediting organization.

(11) A list of all currently accredited suppliers, the type and category of accreditation currently held by each supplier, and the expiration date of each supplier's current accreditation.

(12) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(13) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(14) A statement acknowledging that, as a condition for approval of designation, the organization agrees to carry out the following activities:

(i) Prioritize surveys for those suppliers needing to be accredited by January 1, 2012.

(ii) Notify CMS, in writing, of any Medicare supplier that had its accreditation revoked, withdrawn, revised, or any other remedial or adverse action taken against it by the accreditation organization within 30 calendar days of any such action taken.

(iii) Notify all accredited suppliers within 10 calendar days of the organization's removal from the list of designated accreditation organizations.

(iv) Notify CMS, in writing, at least 30 calendar days in advance of the effective date of any significant proposed changes in its accreditation requirements.

(v) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(vi) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accreditation supplier from any source where the deficiency poses an immediate jeopardy to the supplier's beneficiaries or a hazard to the general public.

(vii) Provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditations and trends.

(viii) Attest that the organization will not perform any accreditation surveys of Medicare-participating suppliers with which it has a financial relationship in which it has an interest.

(ix) Conform accreditation requirements to changes in Medicare requirements.

(x) If CMS withdraws an accreditation organization's approved status, work collaboratively with CMS to direct suppliers to the remaining accreditation organizations within a reasonable period of time.

(d) *Determination of whether additional information is needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for designation, the organization must be notified and afforded an opportunity to provide the additional information.

(e) *Visits to the organization's office.* CMS may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, reviewing documents and interviewing the organization's staff.

(f) *Formal notice from CMS.* The accreditation organization will receive a formal notice from CMS stating whether the request for designation has been approved or denied. If approval was de-

nied the notice includes the basis for denial and reconsideration and re-application procedures.

(g) *Ongoing responsibilities of a CMS-approved accreditation organization.* An accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(1) Provide CMS with all of the following in written format (either electronic or hard copy):

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers.

(iv) Information about all accredited suppliers against which the accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days after a change in CMS requirements, the accreditation organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(3) The accreditation organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 business days of identifying a deficiency of an accredited supplier that poses immediate jeopardy to a beneficiary or to the general public, the accreditation organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS' notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, the accreditation organization must provide written notice

of the withdrawal to all of the organization's accredited suppliers.

(6) The organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(h) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved accreditation organization.

(1) *Validation audits.* (i) CMS or its contractor may conduct an audit of an accredited supplier to validate the survey accreditation process of approved accreditation organizations for the TC of advanced diagnostic imaging services.

(ii) The audits must be conducted on a representative sample of suppliers who have been accredited by a particular accrediting organization or in response to allegations of supplier non-compliance with the standards.

(A) When conducted on a representative sample basis, the audit is comprehensive and addresses all of the standards, or may focus on a specific standard in issue.

(B) When conducted in response to an allegation, CMS audits any standards that CMS determines are related to the allegations.

(2) *Notice of intent to withdraw approval.* (i) If, during the audit specified in paragraph (h)(1) of this section, CMS identifies any accreditation programs for which validation audit results indicate—

(A) A 10 percent or greater rate of disparity between findings by the accreditation organization and findings by CMS on standards that do not constitute immediate jeopardy to patient health and safety if unmet; or

(B) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or,

(C) Irrespective of the rate of disparity, widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance

that suppliers meet or exceed the Medicare requirements; then CMS will give the organization written notice of its intent to withdraw approval as specified in paragraph (h)(3) of this section.

(ii) CMS may also provide the organization written notice of its intent to withdraw approval if an equivalency review, onsite observation, or CMS' daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this section.

(3) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Accreditation by the organization no longer adequately assures that the suppliers furnishing the technical component of advanced diagnostic imaging service are meeting the established industry standards for each modality and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(i) *Reconsideration.* An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the accreditation organization meet the applicable quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of designation to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(1) *Filing requirements.* (i) The request must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(ii) The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(iii) A requestor may withdraw its request for reconsideration at any time

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before the issuance of a reconsideration determination.

(2) *CMS response to a filing request.* In response to a request for reconsideration, CMS provides the accreditation organization with—

(i) The opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(ii) Written notice of the time and place of the informal hearing at least 10 business days before the scheduled date.

(3) *Hearing requirements and rules.* (i) The informal reconsideration hearing is open to all of the following:

(A) CMS.

(B) The organization requesting the reconsideration including—

(1) Authorized representatives;

(2) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(3) Legal counsel.

(ii) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(iii) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(iv) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(v) Within 45 calendar days of the close of the hearing, the hearing officer presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(vi) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(vii) The hearing officer's decision is final.

(j) *Change of ownership.* An accreditation organization whose accreditation program(s) is (are) approved and recog-

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nized by CMS that wishes to undergo a change of ownership are subject to the requirements set out at § 488.5(f) of this chapter.

[74 FR 62006, Nov. 25, 2009, as amended at 87 FR 25427, Apr. 29, 2022]

### § 414.80 Incentive payment for primary care services.

(a) *Definitions.* As defined in this section—

*Eligible primary care practitioner* means one of the following:

(i) A physician (as defined in section 1861(r)(1) of the Act) who meets all of the following criteria:

(A) Enrolled in Medicare with a primary specialty designation of 08-family practice, 11-internal medicine, 37-pediatrics, or 38-geriatrics.

(B) At least 60 percent of the physician's allowed charges under the physician fee schedule (excluding hospital inpatient care and emergency department visits) during a reference period specified by the Secretary are for primary care services.

(ii) A nurse practitioner, clinical nurse specialist, or physician assistant (as defined in section 1861(aa)(5) of the Act) who meets all of the following criteria:

(A) Enrolled in Medicare with a primary specialty designation of 50-nurse practitioner, 89-certified clinical nurse, or 97-physician assistant.

(B) At least 60 percent of the practitioner's allowed charges under the physician fee schedule (excluding hospital inpatient care and emergency department visits) during a reference period specified by the Secretary are for primary care services.

*Primary care services* means—

(i) New and established patient office or other outpatient evaluation and management (E/M) visits;

(ii) Initial, subsequent, discharge, and other nursing facility E/M services;

(iii) New and established patient domiciliary, rest home (for example, boarding home), or custodial care E/M services;

(iv) Domiciliary, rest home (for example, assisted living facility), or home care plan oversight services; and

(v) New and established patient home E/M visits.

(b) *Payment.* (1) For primary care services furnished by an eligible primary care practitioner on or after January 1, 2011 and before January 1, 2016, payment is made on a quarterly basis in an amount equal to 10 percent of the payment amount for the primary care services under Part B, in addition to the amount the primary care practitioner would otherwise be paid for the primary care services under Part B.

(2) The payment described in paragraph (b)(1) of this section is made to the eligible primary care practitioner or, where the physician has reassigned his or her benefits to a critical access hospital (CAH) paid under the optional method, to the CAH based on an institutional claim.

[75 FR 73617, Nov. 29, 2010]

#### § 414.84 Payment for MDPP services.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 424.205(a) of this chapter, the following definitions apply to this section.

*Bridge payment* means a one-time payment to an MDPP supplier for furnishing its first MDPP session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier.

*Performance goal* means an attendance or weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment.

*Performance payment* means a payment made to an MDPP supplier for furnishing certain MDPP services to an MDPP beneficiary when the MDPP beneficiary achieves the applicable performance goal.

(b) *Performance payment.* CMS makes one or more types of performance payments to an MDPP supplier as specified in this paragraph (b). Each type of performance payment is made only if the beneficiary achieves the applicable performance goal and only once per MDPP beneficiary. A performance payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any

amount. CMS will make a performance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The seven types of performance payments are as follows:

(1) *Performance Goal 1: Attends the first core session that initiates the MDPP services period.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends the first core session, which initiates the MDPP services period, and that first core session was furnished by that supplier. An MDPP supplier that has been paid this performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment described in paragraph (c) of this section for that MDPP beneficiary. The amount of this performance payment is determined as follows:

(i) For a first core session furnished January 1, 2022, through December 31, 2022 the amount is \$35.

(ii) For a first core session furnished during a calendar year subsequent to CY 2022. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(2) *Performance Goal 2: Attends four core sessions.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary achieves attendance at the fourth core session upon attendance at a core session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For the fourth core session furnished January 1, 2022, through December 31, 2022 the amount is \$105.

(ii) For a fourth core session furnished during a calendar year subsequent to CY 2022. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(3) *Performance Goal 3: Attends nine core sessions.* CMS makes a performance payment to an MDPP supplier if an

MDPP beneficiary achieves attendance at the ninth core session upon attendance at a core session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For the ninth core session furnished January 1, 2022, through December 31, 2022 the amount is \$175.

(ii) For a ninth core session furnished during a calendar year subsequent to CY 2022. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(4) *Performance Goal 4: Attends two core maintenance sessions during a core maintenance session interval.* CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends two core maintenance sessions in a core maintenance session interval and achieves attendance at the second core maintenance session upon attendance at a core maintenance session furnished by that supplier. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per core maintenance session interval. The amount of this performance payment is determined as follows:

(i) If the beneficiary also achieves or maintains the required minimum weight loss as measured in-person during a core maintenance session furnished during the applicable core maintenance session interval:

(A) For a second core maintenance session January 1, 2022, through December 31, 2022 the amount is \$93.

(B) For a second core maintenance session furnished during a calendar year subsequent to CY 2022. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(ii) If the beneficiary does not achieve or maintain the required minimum weight loss as measured in-person during a core maintenance session furnished during the applicable core maintenance session interval:

(A) For a second core maintenance session January 1, 2022, through December 31, 2022 the amount is \$70.

(B) For a second core maintenance session furnished during a calendar year subsequent to CY 2022. The performance payment amount specified in

this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(5) *Performance Goal 5: Attends two ongoing maintenance sessions and maintains the required minimum weight loss during an ongoing maintenance session interval.* For an MDPP beneficiary who attends his or her first core session on or before December 31, 2021, CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends two ongoing maintenance sessions during an ongoing maintenance session interval, achieves attendance at that second ongoing maintenance session upon attendance at an ongoing maintenance session furnished by that supplier, and achieves or maintains the required minimum weight loss as measured in-person during an ongoing maintenance session furnished during the applicable ongoing maintenance session interval. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per ongoing maintenance session interval. The amount of this performance payment is determined as follows:

(i) For a second ongoing maintenance session furnished in interval 1 (months 13–15 of the MDPP services period), January 1, 2022, through December 31, 2022, the amount is \$52.

(ii) For a second ongoing maintenance session furnished in interval 2 (months 16–18 of the MDPP services period), January 1, 2022, through December 31, 2022, the amount is \$52.

(iii) For a second ongoing maintenance session furnished in interval 3 (months 19–21 of the MDPP services period), January 1, 2022, through December 31, 2022, the amount is \$53.

(iv) For a second ongoing maintenance session furnished in interval 4 (months 22–24 of the MDPP services period), January 1, 2022, through December 31, 2022 the amount is \$53.

(v) For a second ongoing maintenance session furnished during a subsequent year. The performance payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

(6) *Performance Goal 6: Achieves the required minimum weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who

achieves the required minimum weight loss as measured in-person during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2022, through December 31, 2022, the amount is \$169.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(7) *Performance Goal 7: Achieves 9-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person during a core session, core maintenance session, or ongoing maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2022, through December 31, 2022, the amount is \$35.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

(c) *Bridge payment.* CMS makes a bridge payment to an MDPP supplier only for a core session or core maintenance session furnished to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier. An MDPP supplier that has previously been paid either a bridge payment or a performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment for that beneficiary. A bridge payment is made only on an assignment-related basis in accordance with § 424.55 of this subchapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a bridge payment only to an MDPP supplier that complies with all applicable enroll-

ment and program requirements, and only for MDPP services furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The amount of the bridge payment is determined as follows:

(1) For core session or core maintenance session, as applicable, furnished January 1, 2022, through December 31, 2022, the amount is \$35.

(2) For core session and core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2022. The bridge payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

(d) *Updating performance payments and the bridge payment.* The performance payments and bridge payment will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI-U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

[82 FR 53360, Nov. 15, 2017, as amended at 86 FR 65668, Nov. 19, 2021; 86 FR 73159, Dec. 27, 2021]

#### § 414.90 Physician Quality Reporting System (PQRS).

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

(1) 1848(a)—Payment Based on Fee Schedule.

(2) 1848(k)—Quality Reporting System.

(3) 1848(m)—Incentive Payments for Quality Reporting.

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

*Administrative claims* means a reporting mechanism under which an eligible professional or group practice uses claims to report data on PQRS quality

measures. Under this reporting mechanism, CMS analyzes claims data to determine which measures an eligible professional or group practice reports.

*Certified survey vendor* means a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS.

*Covered professional services* means services for which payment is made under, or is based on, the Medicare physician fee schedule as provided under section 1848(k)(3) of the Act and which are furnished by an eligible professional.

*Direct electronic health record (EHR) product* means an electronic health record vendor's product and version that submits data on PQRS measures directly to CMS.

*Electronic health record (EHR) data submission vendor product* means an entity that receives and transmits data on PQRS measures from an EHR product to CMS.

*Eligible professional* means any of the following:

- (i) A physician.
- (ii) A practitioner described in section 1842(b)(18)(C) of the Act.
- (iii) A physical or occupational therapist or a qualified speech-language pathologist.
- (iv) A qualified audiologist (as defined in section 1861(l)(3)(B) of the Act).

*Group practice* means a physician group practice that is defined by a TIN, with 2 or more individual eligible professionals (or, as identified by NPIs) that has reassigned their billing rights to the TIN.

*Group practice reporting option (GPRO) web interface* means a web product developed by CMS that is used by group practices that are selected to participate in the group practice reporting option (GPRO) to submit data on PQRS quality measures.

*Maintenance of Certification Program* means a continuous assessment program, such as qualified American Board of Medical Specialties Maintenance of Certification Program or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the com-

petencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills, and professionalism. Such a program must include the following:

- (i) The program requires the physician to maintain a valid unrestricted license in the United States.
- (ii) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.
- (iii) The program requires a physician to demonstrate, through a formalized secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.
- (iv) The program requires successful completion of a qualified maintenance of certification program practice assessment.

*Maintenance of Certification Program Practice Assessment* means an assessment of a physician's practice that—

- (i) Includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine.
- (ii) Includes a survey of patient experience with care.
- (iii) Requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under paragraph (h) of this section and then to remeasure to assess performance improvement after such intervention.

*Measures group* means a subset of six or more PQRS measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

*Physician Quality Reporting System (PQRS)* means the physician reporting system under section 1848(k) of the Act for the reporting by eligible professionals of data on quality measures and the incentive payment associated with this physician reporting system.

*Performance rate* means the percentage of a defined population who receives a particular process of care or



achieve a particular outcome for a particular quality measure.

*Qualified clinical data registry* means a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A qualified clinical data registry must perform the following functions:

(i) Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. A qualified clinical data registry must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures.

(ii) Submit to CMS, for purposes of demonstrating satisfactory participation, quality measures data on multiple payers, not just Medicare patients.

(iii) Provide timely feedback, at least four times a year, on the measures at the individual participant level for which the qualified clinical data registry reports on the eligible professional's behalf for purposes of the individual eligible professional's satisfactory participation in the clinical quality data registry.

(iv) Possess benchmarking capacity that measures the quality of care an eligible professional provides with other eligible professionals performing the same or similar functions.

*Qualified registry* means a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the PQRS qualification requirements specified by CMS for that program year. The registry may act as a data submission vendor, which has the requisite legal authority to provide PQRS data (as specified by CMS) on behalf of an eligible professional to CMS. If CMS finds that a qualified registry submits grossly inaccurate data for reporting periods occurring in a particular year,

CMS reserves the right to disqualify a registry for reporting periods occurring in the subsequent year.

*Reporting rate* means the percentage of patients that the eligible professional indicated a quality action was or was not performed divided by the total number of patients in the denominator of the measure.

(c) *Incentive payments.* For 2007 to 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, an eligible professional (or in the case of a group practice under paragraph (i) of this section, a group practice) may receive an incentive if—

(1) There are any quality measures that have been established under the PQRS that are applicable to any such services furnished by such professional (or in the case of a group practice under paragraph (i) of this section, such group practice) for such reporting period; and

(2) If the eligible professional (or in the case of a group practice under paragraph (j) of this section, the group practice) satisfactorily submits (as determined under paragraph (g) of this section for the eligible professional and paragraph (i) of this section for the group practice) to the Secretary data on such quality measures in accordance with the PQRS for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act or, in the case of a group practice under paragraph (i) of this section, to the group practice) from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable quality percent (as specified in paragraph (c)(3) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (i) of this section, by the group practice) during the reporting period.

(3) The applicable quality percent is as follows:

- (i) For 2007 and 2008, 1.5 percent.
- (ii) For 2009 and 2010, 2.0 percent.
- (iii) For 2011, 1.0 percent.
- (iv) For 2012, 2013, and 2014, 0.5 percent.

(4) For purposes of this paragraph (c)—

(i) The eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(ii) In the case of the eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(iii) Incentive payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the PQRS to eligible professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals. For any program year in which the group practice (as identified by the TIN) is selected to participate in the PQRS group practice reporting option, the eligible professional cannot individually qualify for a PQRS incentive payment by meeting the requirements specified in paragraph (g) of this section.

(iv) Incentive payments earned by the eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(5) The Secretary must treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (g) of this section), if the eligible professional is satisfactorily participating (as determined under paragraph (h) of this section), in a qualified clinical data registry.

(d) *Additional incentive payment.*

Through 2014, if an eligible professional meets the requirements described in paragraph (d)(2) of this section, the applicable percent for such year, as described in paragraphs (c)(3)(iii) and (iv) of this section, must be increased by 0.5 percentage points.

(1) In order to qualify for the additional incentive payment described in paragraph (d) of this section, an eligible professional must meet all of the following requirements:

(i) Satisfactorily submits data on quality measures, or, for 2014, in lieu of satisfactory reporting, satisfactorily participates in a qualified clinical data registry for purposes of this section for the applicable incentive year.

(ii) Have such data submitted on their behalf through a Maintenance of Certification program that meets:

(A) The criteria for a registry (as specified by CMS); or

(B) An alternative form and manner determined appropriate by the Secretary.

(iii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(A) Participates in a maintenance of certification program for a year; and

(B) Successfully completes a qualified maintenance of certification program practice assessment for such year.

(2) In order for an eligible professional to receive the additional incentive payment, a Maintenance of Certification Program must submit to the Secretary, on behalf of the eligible professional, information—

(i) In a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of paragraph (d)(1)(iii) of this section, which may be in the form of a structural measure.

(ii) If requested by the Secretary, on the survey of patient experience with care.

(iii) As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(e) *Payment adjustments.* For 2015 through 2018, with respect to covered professional services furnished by an eligible professional, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under section 1848(m)(3)(A) of the Act), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes for determining a payment based on such amount) must be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this paragraph (e).

(1) The applicable percent is as follows:

(i) For 2015, 98.5 percent.

(ii) For 2016 through 2018, 98 percent.

(2) The Secretary must treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (h) of this section), if the eligible professional is satisfactorily participating, in a qualified clinical data registry.

(f) *Use of appropriate and consensus-based quality measures.* For measures selected for inclusion in the PQRS quality measure set, CMS will use group practice measures determined appropriate by CMS and consensus-based quality measures that meet one of the following criteria:

(1) Be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(2) For each quality measure adopted by the Secretary under this paragraph, the Secretary ensures that eligible professionals have the opportunity to provide

input during the development, endorsement, or selection of quality measures applicable to services they furnish.

(g) *Use of quality measures for satisfactory participation in a qualified clinical data registry.* For measures selected for reporting to meet the criteria for satisfactory participation in a qualified clinical data registry, CMS will use measures selected by qualified clinical data registries based on parameters set by CMS.

(h) *Satisfactory reporting requirements for the incentive payments.* In order to qualify to earn a PQRS incentive payment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory reporting specified by CMS under paragraph (h)(3) of (h)(5) of this section for such year by reporting on either individual PQRS quality measures or PQRS measures groups identified by CMS during a reporting period specified in paragraph (h)(1) of this section, using one of the reporting mechanisms specified in paragraph (h)(2) or (4) of this section, and using one of the reporting criteria specified in paragraph (h)(3) or (5) of this section.

(1) *Reporting periods.* For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 of such program year.

(ii) A 6-month period from July 1 through December 31 of such program year.

(A) For 2011, such 6-month reporting period is not available for EHR-based reporting of individual PQRS quality measures.

(B) For 2012 and subsequent program years, such 6-month reporting period from July 1 through December 31 of such program year is only available for registry-based reporting of PQRS measures groups by eligible professionals.

(2) *Reporting mechanisms for individual eligible professionals.* An individual eligible professional who wishes to participate in the PQRS must report information on PQRS quality measures

identified by CMS in one of the following manners:

(i) *Claims*. Reporting PQRS quality measures or PQRS measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for re-processing, the eligible professional may not attach a G-code at that time for reporting on individual PQRS measures or measures groups.

(B) [Reserved]

(ii) *Registry*. Reporting PQRS quality measures or PQRS measures groups to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product*. Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor*. Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) Although an eligible professional may attempt to qualify for the PQRS incentive payment by reporting on both individual PQRS quality measures and measures groups, using more than one reporting mechanism (as specified in paragraph (g)(2) of this section), or reporting for more than one reporting period, he or she will receive only one PQRS incentive payment per TIN/NPI combination for a program year.

(3) *Satisfactory reporting criteria for individual eligible professionals for the 2014 PQRS incentive*. An individual eligible professional who wishes to qualify for the 2014 PQRS incentive must report information on PQRS quality measures data in one of the following manners:

(i) *Via Claims*. For the 12-month 2014 PQRS incentive reporting period—

(A) Report at least 9 measures covering at least 3 National Quality Strategy domains, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 National Quality Strategy domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(B) [Reserved]

(ii) *Via Qualified Registry*. (A) For the 12-month 2014 PQRS incentive reporting period—

(1) Report at least 9 measures covering at least 3 of the National Quality Strategy domains report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains for which there is Medicare patient data and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an

eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the eligible professional will be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(2) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(B) For the 6-month 2014 PQRS incentive reporting period, report at least 1 measures group and report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2014 PQRS incentive reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2014 PQRS incentive reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(4) *Reporting mechanisms for group practices.* With the exception of a group practice who wishes to participate in

the PQRS using the certified survey vendor mechanism (as specified in paragraph (h)(4)(v) of this section), a group practice must report information on PQRS quality measures identified by CMS in one of the following reporting mechanisms:

(i) *Web interface.* For 2013 and subsequent years, reporting PQRS quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

(ii) *Registry.* For 2013 and subsequent years, reporting on PQRS quality measures to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* For 2014 and subsequent years, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* For 2014 and subsequent years, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *Certified survey vendors.* For 2014 and subsequent years, reporting CAHPS for PQRS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional group practice reporting mechanism in order to meet the criteria for satisfactory reporting for the incentive payments.

(vi) Although a group practice may attempt to qualify for the PQRS incentive payment by using more than one reporting mechanism (as specified in paragraph (g)(3) of this section), or reporting for more than one reporting period, the group practice will receive only one PQRS incentive payment for a program year.

(5) *Satisfactory reporting criteria for group practices for the 2014 PQRS incentive.* A group practice who wishes to qualify for the 2014 PQRS incentive must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* (A) For the 12-month 2014 PQRS incentive reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

(B) For the 12-month 2014 PQRS incentive reporting period, for a group practice of 100 or more eligible professionals, report on all measures included in the web interface and populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, for the 12-month 2014 PQRS incentive reporting period, the group practice must report all CAHPS for PQRS survey measures via a CMS-certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, or EHR data submission vendor.

(ii) *Via Qualified Registry.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report at least 9 measures, covering at least 3 of the National Quality Strategy domains

and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or, if less than 9 measures covering at least 3 NQS domains apply to the group practice, then the group practice must report 1–8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether a group practice should have reported on additional measures and/or measures covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified survey vendor, in addition to the GPRO web interface, qualified registry, direct EHR product, or EHR*

*data submission vendor reporting mechanisms.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 25 or more eligible professionals, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface.

(i) *Satisfactory participation requirements for the incentive payments for individual eligible professionals.* To qualify for the 2014 PQRS incentive using a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory participation as specified under paragraph (i)(3) of this section by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (i)(1) of this section, and using the reporting mechanism specified in paragraph (i)(2) of this section.

(1) *Reporting period.* For purposes of this paragraph, the reporting period is the 12-month period from January 1 through December 31.

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

(3) *Satisfactory participation criteria for individual eligible professionals for the 2014 PQRS incentive.* An individual eligible professional who wishes to qualify for the 2014 PQRS incentive through satisfactory participation in a qualified clinical data registry must report information on quality measures identified by the qualified clinical data registry in the following manner:

(i) For the 12-month 2014 PQRS incentive reporting period, report at least 9 measures designated for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients. Of the measures reported via a qualified

clinical data registry, the eligible professional must report on at least 1 outcome measure.

(ii) [Reserved]

(j) *Satisfactory reporting requirements for the payment adjustments.* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, or a group practice must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual PQRS measures or PQRS measures groups identified by CMS during a reporting period specified in paragraph (j)(1) of this section, using one of the reporting mechanisms specified in paragraph (j)(2) or (4) of this section, and using one of the reporting criteria specified in section (j)(3) or (5) of this section.

(1) For purposes of this paragraph (j), the reporting period for the payment adjustment, with respect to a payment adjustment year, is the 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(i) For the 2015 and 2016 PQRS payment adjustments only, an alternative 6-month reporting period, from July 1–December 31 that fall 2 years prior to the year in which the payment adjustment is applied, is also available.

(ii) *Secondary Reporting Period for the 2017 PQRS payment adjustment for certain eligible professionals or group practices—*Individual eligible professionals or group practices, who bill under the TIN of an ACO participant if the ACO failed to report data on behalf of such EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment, may separately report during a secondary reporting period for the 2017 PQRS payment adjustment. The secondary reporting period for the 2017 PQRS payment adjustment for the affected individual eligible professionals or group practices is January 1, 2016 through December 31, 2016.

(2) *Reporting mechanisms for individual eligible professionals.* An individual eligible professional participating in the PQRS must report information on

PQRS quality measures identified by CMS in one of the following manners:

(i) *Claims*. Reporting PQRS quality measures or PQRS measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for re-processing, the eligible professional may not attach a G-code at that time for reporting on individual PQRS measures or measures groups.

(B) [Reserved]

(ii) *Registry*. Reporting PQRS quality measures or PQRS measures groups to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product*. Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor*. Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *Administrative claims*. For 2015, reporting data on PQRS quality measures via administrative claims during the applicable reporting period. Eligible professionals that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Elect to participate in the PQRS using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the eligible professional has performed services applicable to certain individual PQRS quality measures.

(3) *Satisfactory reporting criteria for individual eligible professionals for the 2016 PQRS payment adjustment*. An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via Claims*. (A) For the 12-month 2016 PQRS payment adjustment reporting period—

(1)(i) Report at least 9 measures covering at least 3 National Quality Strategy domains and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1–8 measures covering 1–3 National Quality Strategy domains, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional National Quality Strategy domains; or

(ii) Report at least 3 measures covering at least 1 NQS domain, or, if less than 3 measures covering at least 1 NQS domain apply to the eligible professional, report 1–2 measures covering at least 1 NQS domain; and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(2) Measures with a 0 percent performance rate would not be counted.



(ii) *Via Qualified Registry.* (A) For the 12-month 2016 PQRS payment adjustment reporting period—

(1)(i) Report at least 9 measures covering at least 3 of the National Quality Strategy domains; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains for which there is Medicare patient data, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional National Quality Strategy domains; or

(ii) Report at least 3 measures covering at least 1 of the NQS domains; or if less than 3 measures covering at least 1 NQS domain apply to the eligible professional, report 1 to 2 measures covering 1 National Quality Strategy domain for which there is Medicare patient data, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 3 measures covering 1 NQS domain via the registry-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures; or

(iii) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(2) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(B) For the 6-month 2016 PQRS payment adjustment reporting period—

(1) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(4) *Satisfactory Reporting Criteria for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via Claims.* (A) For the 12-month 2017 PQRS payment adjustment reporting period—

(1)(i) Report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the 9 measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-

face encounter, the eligible professional must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the eligible professional, report up to 8 measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

(ii) [Reserved]

(ii) *Via Qualified Registry.* (A) For the 12-month 2017 PQRS payment adjustment reporting period—

(1)(i) Report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the 9 measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the eligible professional, report up to 8 measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(ii) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(2) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2017 PQRS payment

adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(v) Paragraphs (j)(8)(ii), (iii), and (iv) of this section apply to individuals reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

(5) *Reporting mechanisms for group practices.* With the exception of a group practice who wishes to participate in the PQRS using the certified survey vendor mechanism, a group practice participating in the PQRS must report information on PQRS quality measures identified by CMS in one of the following reporting mechanisms:

(i) *Web interface.* For the 2015 payment adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

(ii) *Registry.* For the 2015 subsequent adjustment and subsequent payment adjustments, reporting on PQRS quality measures to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* For the 2016 subsequent adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* For the 2016 subsequent adjustment and

subsequent payment adjustments, reporting PQRs quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the group practice during the applicable reporting period.

(v) *Administrative claims.* For 2015, reporting data on PQRs quality measures via administrative claims during the applicable reporting period. Group practices that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Elect to participate in the PQRs using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the group practice has performed services applicable to certain individual PQRs quality measures.

(vi) *Certified Survey Vendors.* For 2016 and subsequent years, reporting CAHPS for PQRs survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional group practice reporting mechanism in order to meet the criteria for satisfactory reporting for the payment adjustment.

(6) *Satisfactory reporting criteria for group practices for the 2016 PQRs payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2016 PQRs payment adjustment must report information on PQRs quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* (A) For the 12-month 2016 PQRs payment adjustment reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned bene-

ficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

(B) For the 12-month 2016 PQRs payment adjustment reporting period, for a group practice of 100 or more eligible professionals, report on all measures included in the Web interface and populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, the group practice must also report all CAHPS for PQRs survey measures via certified survey vendor.

(ii) *Via Qualified Registry.* (A) For the 12-month 2016 PQRs payment adjustment reporting period, for a group practice of 2 or more eligible professionals—

(1) Report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or If less than 9 measures covering at least 3 NQS domains apply to the eligible professional, then the group practices must report 1-8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether a group practice should have reported on additional measures. Measures with a 0 percent performance rate would not be counted; or

(2) Report at least 3 measures, covering at least 1 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 3 measures covering at least

1 NQS domain apply to the group practice, then the group practice must report 1–2 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 3 measures covering at least 1 NQS domain via the registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether a group practice should have reported on additional measures. Measures with a 0 percent performance rate would not be counted.

(iii) *Via EHR Direct Product.* For a group practice of 2 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified survey vendor, in addition to the GPRO Web interface, qualified registry, direct EHR product, or EHR data submission vendor reporting mechanisms.* For a group practice of 25 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least

6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO Web interface.

(7) *Satisfactory reporting criteria for group practices for the 2017 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* For the 12-month 2017 PQRS payment adjustment reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(ii) *Via Qualified Registry.* For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, then the group practice must report up to 8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. Measures with a 0 percent performance rate would not be counted; or

(iii) *Via EHR Direct Product.* For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a group practice's direct EHR product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a group practice's EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified Survey Vendor in addition to a Qualified Registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 additional measures covering at least 2 of the NQS domains using a qualified registry. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set specified by CMS.

(vi) *Via a Certified Survey Vendor in addition a Direct EHR Product or EHR Data Submission Vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey

vendor and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product that is CEHRT or EHR data submission vendor product that is CEHRT. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, the group practice must report on at least 1 measure for which there is Medicare patient data.

(vii) *Via a Certified Survey Vendor in addition to the GPRO Web interface.* (A) For a group practice of 25 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(B) [Reserved]

(viii) Paragraphs (j)(9)(ii), (iii), and (iv) of this section apply to group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

(8) *Satisfactory reporting criteria for individual eligible professionals for the 2018 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via claims.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(1)(i) Report at least 6 measures and report each measure for at least 50 percent of the eligible professional's Medicare Part B Fee-for-Service patients seen during the reporting period to

which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

(ii) [Reserved]

(2) [Reserved]

(B) [Reserved]

(ii) *Via qualified registry.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(1)(i) Report at least 6 measures and report each measure for at least 50 percent of the eligible professional's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies.

(ii) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.

(2) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

(B) [Reserved]

(iii) *Via EHR direct product.* For the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For the 12-month 2018 PQRS payment

adjustment reporting period, report at least 6 measures. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(9) *Satisfactory reporting criteria for group practices for the 2018 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* For the 12-month 2018 PQRS payment adjustment reporting period, for a group practice of 25 or more eligible professionals, report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In some instances, the sampling methodology will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(ii) *Via qualified registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures and report each measure for at least 50 percent of the group practice's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the

group practice must report on each measure that is applicable, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(iii) *Via EHR direct product.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a certified survey vendor in addition to a qualified registry.* For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a qualified registry for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the qualified registry and report each measure for at least 50 percent of the group practice's Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 3 measures apply to the group practice, the group practice must report on each measure that is applica-

ble, and report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(vi) *Via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor.* For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the direct EHR product or EHR data submission vendor product. If less than 3 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 3 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice must report on at least 1 measure for which there is Medicare patient data.

(vii) *Via a certified survey vendor in addition to the GPRO web interface.* (A) For a group practice of 25 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data.

(B) [Reserved]

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more eligible professionals that register to participate in the GPRO may administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected.

(k) *Satisfactory participation requirements for the payment adjustments for individual eligible professionals and group practices.* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year through participation in a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, or group practice must meet the criteria for satisfactory participation as specified in paragraph (k)(3) of this section for such year, by reporting on quality measures identified by a qualified 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.

(1) Reporting period. For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(ii) [Reserved]

(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.

(3) *Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment.* Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment. An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2016 PQRS payment adjustment must report information on quality measures identified by the qualified clinical data registry in one of the following manners:

(i) For the 12-month 2016 PQRS payment adjustment reporting period—

(A) Report at least 9 measures available for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients; or

(B) Report at least 3 measures available for reporting under a qualified clinical data registry covering at least 1 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients.

(4) *Satisfactory participation criteria for individual eligible professionals for the 2017 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment must report information on quality measures identified by the QCDR in one of the following manner:

(i) For the 12-month 2017 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 2 outcome measures, or, if 2 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, efficiency/appropriate use or patient safety.

(ii) Section 414.90(k)(5) applies to individuals and group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

(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) *Individual eligible professional.* For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR and report each measure for at least 50 percent of the eligible professional's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, and report each measure for at least 50 percent of the eligible professional's patients.

(ii) *Group practices.* For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR and report each measure for at least 50 percent of the group practice's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, and report each measure for at least 50 percent of the group practice's patients. If a group practice reports the CAHPS for PQRS survey measures, apply reduced criteria as follows: 3 measures, as applicable.

(1) *Requirements for group practices.* Under the PQRS, a group practice must meet all of the following requirements:

(1) Meet the participation requirements specified by CMS for the PQRS group practice reporting option.

(2) Report measures in the form and manner specified by CMS.

(3) Meet other requirements for satisfactory reporting specified by CMS.

(4) Meet participation requirements.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a group practice (as identified by the TIN) selected to participate in the PQRS group practice reporting option for a program year, then for that program year the eligible professional must participate in the PQRS via the group practice reporting option.

(ii) If, for the program year, the eligible professional participates in the PQRS as part of a group practice (as identified by the TIN) that is not selected to participate in the PQRS group practice reporting option for that program year, then the eligible

professional may individually participate and qualify for a PQRS incentive by meeting the requirements specified in paragraph (g) of this section under that TIN.

(m) *Informal review.* Eligible professionals or group practices may seek an informal review of the determination that an eligible professional or group practices did not satisfactorily submit data on quality measures under the PQRS, or, for individual eligible professionals, in lieu of satisfactory reporting, did not satisfactorily participate in a qualified clinical data registry.

(1) To request an informal review for reporting periods that occur prior to 2014, an eligible professional or group practice must submit a request to CMS within 90 days of the release of the feedback reports. To request an informal review for reporting periods that occur in 2014 and subsequent years, an eligible professional or group practice must submit a request to CMS within 60 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) CMS will provide a written response within 90 days of the receipt of the original request.

(i) All decisions based on the informal review will be final.

(ii) There will be no further review or appeal.

(3) If, during the informal review process, CMS finds errors in data that was submitted by a third-party vendor on behalf of an eligible professional or group practice using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may allow for the resubmission of data to correct these errors.

(i) CMS will not allow resubmission of data submitted via claims, direct EHR, and the GPRO web interface reporting mechanisms.

(ii) CMS will only allow resubmission of data that was already previously submitted to CMS.

(iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

(n) *Limitations on review.* Except as specified in paragraph (i) of this section, there is no administrative or judicial review under section 1869 or 1879 of the Act, or otherwise of—

(1) The determination of measures applicable to services furnished by eligible professionals under the PQRS;

(2) The determination of satisfactory reporting; and

(3) The determination of any Physician Quality Reporting System incentive payment and the PQRS payment adjustment.

(o) *Public reporting of an eligible professional's or group practice's PQRS data.* For each program year, CMS will post on a public Web site, in an easily understandable format, a list of the names of eligible professionals (or in the case of reporting under paragraph (g) of this section, group practices) who satisfactorily submitted PQRS quality measures.

[78 FR 74812, Dec. 10, 2013, as amended at 79 FR 68003, Nov. 13, 2014; 81 FR 34913, June 1, 2016; 81 FR 77537, Nov. 4, 2016; 81 FR 80554, Nov. 15, 2016; 82 FR 53362, Nov. 15, 2017]

**§ 414.92 Electronic Prescribing Incentive Program.**

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

(1) Section 1848(a)—Payment Based on Fee Schedule.

(2) Section 1848(m)—Incentive Payments for Quality Reporting.

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

*Certified electronic health record technology* means an electronic health record vendor's product and version as described in 45 CFR 170.102.

*Covered professional services* means services for which payment is made under, or is based on, the Medicare physician fee schedule which are furnished by an eligible professional.

*Electronic Prescribing Incentive Program* means the incentive payment program established under section 1848(m) of the Act for the adoption and use of electronic prescribing technology by eligible professionals.

*Eligible professional* means any of the following healthcare professionals who have prescribing authority:

(i) A physician.

(ii) A practitioner described in section 1842(b)(18)(C) of the Act.

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) A qualified audiologist (as defined in section 1861(11)(3)(B) of the Act).

*Group practice* means a group practice that is—

(i)(A) Defined at § 414.90(b), that is participating in the Physician Quality Reporting System; or

(B) In a Medicare-approved demonstration project or other Medicare program, under which Physician Quality Reporting System requirements and incentives have been incorporated; and

(ii) Has indicated its desire to participate in the electronic prescribing group practice option.

*Qualified electronic health record product* means an electronic health record product and version that, with respect to a particular program year, is designated by CMS as a qualified electronic health record product for the purpose of the Physician Quality Reporting System (as described in § 414.90) and the product's vendor has indicated a desire to have the product qualified for purposes of the product's users to submit information related to the electronic prescribing measure.

*Qualified registry* means a medical registry or a Maintenance of Certification Program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, is designated by CMS as a qualified registry for the purpose of the Physician Quality Reporting System (as described in § 414.90) and that has indicated its desire to be qualified to submit the electronic prescribing measure on behalf of eligible professionals for the purposes of the Electronic Prescribing Incentive Program.

(c) *Incentive payments and payment adjustments.* (1) *Incentive payments.* Subject to paragraph (c)(3) of this section, with respect to covered professional services furnished during a reporting period by an eligible professional, if the eligible professional is a successful electronic prescriber for such reporting

period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act) or, in the case of a group practice under paragraph (e) of this section, to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable electronic prescribing percent (as specified in paragraph (c)(1)(ii) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (e) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (e) of this section, by the group practice) during the applicable reporting period.

(i) For purposes of paragraph (c)(1) of this section,

(A) The eligible professional's (or, in the case of a group practice under paragraph (e) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(B) In the case of an eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(C) Incentive payments earned by an eligible professional (or in the case of a group practice under paragraph (e) of this section, by a group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(ii) *Applicable electronic prescribing percent.* The applicable electronic prescribing percent is as follows:

(A) For the 2011 and 2012 program years, 1.0 percent.

(B) For the 2013 program year, 0.5 percent.

(iii) *Limitation with respect to electronic health record (EHR) incentive pay-*

*ments.* The provisions of this paragraph do not apply to an eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) if, for the electronic health record reporting period the eligible professional (or group practice) receives an incentive payment under section 1848(o)(1)(A) of the Act with respect to a certified electronic health record technology (as defined in section 1848(o)(4) of the Act) that has the capability of electronic prescribing.

(2) *Payment adjustment.* Subject to paragraphs (c)(1)(ii) and (c)(3) of this section, with respect to covered professional services furnished by an eligible professional during 2012, 2013, or 2014, if the eligible professional (or in the case of a group practice under paragraph (e) of this section, the group practice) is not a successful electronic prescriber (as specified by CMS for purposes of the payment adjustment) for an applicable reporting period (as specified by CMS) the fee schedule amount for such services furnished by such professional (or group practice) during the program year (including the fee schedule amount for purposes of determining a payment based on such amount) is equal to the applicable percent (as specified in paragraph (c)(2)(i) of this section) of the fee schedule amount that would otherwise apply to such services under section 1848 of the Act.

(i) *Applicable percent.* The applicable percent is as follows:

(A) For 2012, 99 percent;

(B) For 2013, 98.5 percent; and

(C) For 2014, 98 percent.

(ii) *Significant hardship exception.* CMS may, on a case-by-case basis, exempt an eligible professional (or in the case of a group practice under paragraph (e) of this section, a group practice) from the application of the payment adjustment under paragraph (c)(2) of this section if, CMS determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. Eligible professionals (or, in the case of a group practice under paragraph (e) of this section, a group practice) may request consideration for a significant

hardship exemption from a eRx payment adjustment if one of the following circumstances apply:

(A) From the 2012 payment adjustments by meeting one of the following:

(1) The practice is located in a rural area without high speed internet access.

(2) The practice is located in an area without sufficient available pharmacies for electronic prescribing.

(3) Registration to participate in the Medicare or Medicaid EHR Incentive Program and adoption of Certified EHR Technology.

(4) Inability to electronically prescribe due to local, State or Federal law or regulation.

(5) Eligible professionals who achieve meaningful use during the respective 6 or 12-month payment adjustment reporting periods.

(6) Eligible professionals who have registered to participate in the EHR Incentive Program and adopted Certified EHR Technology prior to application of the respective payment adjustment.

(B) From the 2013 and 2014 payment adjustments by meeting one of the following:

(1) The eligible professional or group practice is located in a rural area without high speed internet access.

(2) The eligible professional or group practice is located in an area without sufficient available pharmacies for electronic prescribing.

(3) The eligible professional or group practice is unable to electronically prescribe due to local, State, or Federal law or regulation.

(4) The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.

(iii) *Other limitations to the payment adjustment.* An eligible professional (or in the case of a group practice under paragraph (b) of this section, a group practice) is exempt from the application of the payment adjustment under paragraph (c)(2) of this section if one of the following applies:

(A) The eligible professional is not an MD, DO, podiatrist, nurse practitioner, or physician assistant.

(B) The eligible professional does not have at least 100 cases containing an encounter code that falls within the denominator of the electronic prescribing measure for dates of service during the 6-month reporting period specified in paragraph (f)(1) of this section.

(3) *Limitation with respect to electronic prescribing quality measures.* The provisions of paragraphs (c)(1) and (c)(2) of this section do not apply to an eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) if for the reporting period the allowed charges under section 1848 of the Act for all covered professional services furnished by the eligible professional (or group, as applicable) for the codes to which the electronic prescribing measure applies are less than 10 percent of the total of the allowed charges under section 1848 of the Act for all such covered professional services furnished by the eligible professional (or the group practice, as applicable).

(d) *Requirements for individual eligible professionals to qualify to receive an incentive payment.* In order to be considered a successful electronic prescriber and qualify to earn an electronic prescribing incentive payment (subject to paragraph (c)(3) of this section), an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber under section 1848(m)(3)(B) of the Act and as specified by CMS during the reporting period specified in paragraph (d)(1) of this section and using one of the reporting mechanisms specified in paragraph (d)(2) of this section. Although an eligible professional may attempt to qualify for the electronic prescribing incentive payment using more than one reporting mechanism (as specified in paragraph (d)(2) of this section), the eligible professional will receive only one electronic prescribing incentive payment per TIN/NPI combination for a program year.

(1) *Reporting period.* For purposes of this paragraph, the reporting period with respect to a program year is the entire calendar year.

(2) *Reporting mechanisms.* An eligible professional who wishes to participate in the Electronic Prescribing Incentive

Program must report information on the electronic prescribing measure identified by CMS to—

(i) CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section;

(ii) A qualified registry (as defined in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected qualified registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section to CMS on the eligible professional's behalf; or

(iii) CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified electronic health record product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (d)(1) of this section. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing real or dummy clinical quality data extracted from the qualified electronic health record product selected by the eligible professional using a secure data submission method, as required by CMS.

(e) *Requirements for group practices to qualify to receive an incentive payment.*

(1) A group practice (as defined in paragraph (b) of this section) will be treated as a successful electronic prescriber for covered professional services for a reporting period if the group practice meets the criteria for successful electronic prescriber specified by CMS in the form and manner and at the time specified by CMS.

(2) *No double payments.* Payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the Electronic Prescribing Incentive Program to eligible professionals in the

group practice for being a successful electronic prescriber.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a TIN selected to participate in the electronic prescribing group practice reporting option for a program year, then for that program year the eligible professional must participate in the Electronic Prescribing Incentive Program via the group practice reporting option. For any program year in which the TIN is selected to participate in the Electronic Prescribing Incentive Program group practice reporting option, the eligible professional cannot individually qualify for an electronic prescribing incentive payment by meeting the requirements specified in paragraph (d) of this section.

(ii) If, for the program year, the eligible professional participates in the Electronic Prescribing Incentive Program under a TIN that is not selected to participate in the Electronic Prescribing Incentive Program group practice reporting option for that program year, then the eligible professional may individually qualify for an electronic prescribing incentive by meeting the requirements specified in paragraph (d) of this section under that TIN.

(f) *Requirements for individual eligible professionals and group practices for the payment adjustment.* In order to be considered a successful electronic prescriber for the electronic prescribing payment adjustment, an individual eligible professional (or, in the case of a group practice under paragraph (b) of this section, a group practice), as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber specified by CMS, in the form and manner specified in paragraph (f)(2) of this section, and during the reporting period specified in paragraph (f)(1) of this section.

(1) *Reporting periods.* (i) For purposes of this paragraph (f), the reporting period for the 2013 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2011 through December 31, 2011.

(B) The 6-month period from January 1, 2012 through June 30, 2012.

(ii) For purposes of this paragraph (f), the reporting period for the 2014 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2012 through December 31, 2012.

(B) The 6-month period from January 1, 2013 through June 30, 2013.

(2) *Reporting mechanisms.* An eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) who wishes to participate in the Electronic Prescribing Incentive Program must report information on the electronic prescribing measure identified by CMS to one of the following:

(i) For the 6- and 12-month reporting periods under paragraph (f)(1) of this section, CMS, by no later than 2 months after the end of the applicable 12-month reporting period or by no later than 1 month after the end of the applicable 6-month reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section.

(A) If an eligible professional re-submits a Medicare Part B claim for re-processing, the eligible professional may not attach a G-code at that time for reporting on the electronic prescribing measure.

(B) [Reserved]

(ii) For the 12-month reporting period under paragraph (f)(1) of this section, a qualified registry (as defined in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected qualified registry submits information, as required by CMS, for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section to CMS on the eligible professional's behalf.

(iii) For the 12-month reporting period under paragraph (f)(1) of this section, CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified electronic health record product (as defined in paragraph (b) of this section) by the deadline specified by CMS for

covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing dummy clinical quality data extracted from the qualified electronic health record product selected by the eligible professional using a secure data submission method, as required by CMS.

(g) *Informal review.* Eligible professionals (or in the case of reporting under paragraph (e) of this section, group practices) may seek an informal review of the determination that an eligible professional (or in the case of reporting under paragraph (e) of this section, group practices) did not meet the requirements for the 2012 and 2013 incentives or the 2013 and 2014 payment adjustments.

(1) To request an informal review for the 2012 and 2013 incentives, an eligible professional or group practice must submit a request to CMS via email within 90 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) To request an informal review for the 2013 and 2014 payment adjustments, an eligible professional or group practices must submit a request to CMS via email by February 28 of the year in which the eligible professional is receiving the applicable payment adjustment. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(3) CMS will provide a written response of CMS' determination.

(i) All decisions based on the informal review will be final.

(ii) There will be no further review or appeal.

(h) *Public reporting of an eligible professional's or group practice's Electronic Prescribing Incentive Program data.* For each program year, CMS will post on a public Web site, in an easily understandable format, a list of the names of

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 individ-

uals 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 non-traumatic).

(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.