SUBCHAPTER B—MEDICARE PROGRAM (CONTINUED)

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

Subpart A—General Provisions

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CONDITIONS FOR PAYMENT

PAYMENT SYSTEM

AUTHORITY: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

SOURCE: 55 FR 23441, June 8, 1990, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 414 appear at 60 FR 50442, Sept. 29, 1995, and 60 FR 53877, Oct. 18, 1995.

Subpart A—General Provisions

§ 414.1 Basis and scope.

This part implements the following provisions of the Act:

1802—Rules for private contracts by Medicare beneficiaries.

1833—Rules for payment for most Part B services.

1834(a) and (h)—Amounts and frequency of payments for durable medical equipment and for prosthetic devices and orthotics and prosthetics.

1834(l)—Establishment of a fee schedule for ambulance services.

1834(m)—Rules for Medicare reimbursement for telehealth services.

1834A—Improving policies for clinical diagnostic laboratory tests

1842(o)—Rules for payment of certain drugs and biologicals.

1847(a) and (b)—Competitive bidding for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

1848—Fee schedule for physician services.

1881(b)—Rules for payment for services to ESRD beneficiaries.

1887—Payment of charges for physician services to patients in providers.

[67 FR 9132, Feb. 27, 2002, as amended at 69 FR 1116, Jan. 7, 2004; 71 FR 48409, Aug. 18, 2006; 81 FR 41098, June 23, 2016]

§ 414.2 Definitions.

As used in this part, unless the context indicates otherwise—

AA stands for anesthesiologist assistant.

AHPB stands for adjusted historical payment basis.

CF stands for conversion factor.

CRNA stands for certified registered nurse anesthetist.

CY stands for calendar year.

FY stands for fiscal year.

GAF stands for geographic adjustment factor.

GPCI stands for geographic practice cost index.

HCPCS stands for CMS Common Procedure Coding System.

Health Professional Shortage Area (HPSA) means an area designated under section 332(a)(1)(A) of the Public Health Service Act as identified by the Secretary prior to the beginning of such year.

Major surgical procedure means a surgical procedure for which a 10-day or 90-day global period is used for payment under the physician fee schedule and section 1848(b) of the Act.

Physician services means the following services to the extent that they are covered by Medicare:

(1) Professional services of doctors of medicine and osteopathy (including osteopathic practitioners), doctors of optometry, doctors of podiatry, doctors of dental surgery and dental medicine, and chiropractors.

(2) Supplies and services covered ''incident to'' physician services (excluding drugs as specified in § 414.36).

(3) Outpatient physical and occupational therapy services if furnished by a person or an entity that is not a Medicare provider of services as defined in § 400.202 of this chapter.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding diagnostic laboratory tests paid under the fee schedule established under section 1833(h) of the Act).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens, as described in section 1861(s)(2)(G) of the Act.

(7) Bone mass measurement.

RVU stands for relative value unit.

(8) Screening mammography services.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63686, Dec. 2, 1993; 59 FR 63463, Dec. 8, 1994; 60 FR 63177, Dec. 8, 1995; 63 FR 34328, June 24, 1998; 66 FR 55322, Nov. 1, 2001; 75 FR 73616, Nov. 29, 2010]

§ 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]

§ 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. 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 rulemaking 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

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 nonlabor 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

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.

(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 postoperative 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 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

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 anesthetist 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

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 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

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 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

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 defined 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 organizations 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 denied the notice includes the basis for denial and reconsideration and reapplication 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 noncompliance 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

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 recognized 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 enrollment 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(ll)(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 competencies 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 reprocessing, 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 much 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 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 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 reprocessing, 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 beneficiaries 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 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).

(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.

(l) *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(ll)(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 payments.* 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 reprocessing, 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 individuals as appropriate. The PLE must document the following information and make it available in timely fashion to a public request, for a period of not less than 5 years after the most recent published update of the relevant AUC:

(A) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations including the PLE and any other party participating in AUC development or modification that may financially benefit from the AUC. These financial relationships may include, for example, compensation arrangements such as salary, grant, speaking or consulting fees, contract, or collaboration agreements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) Priority clinical areas include the following:

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

(ii) Suspected pulmonary embolism.

(iii) Headache (traumatic and nontraumatic).

(iv) Hip pain.

(v) Low back pain.

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

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

(viii) Cervical or neck pain.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(xii) Notify ordering professionals upon de-qualification.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Insufficient internet access.

(ii) EHR or CDSM vendor issues.

(iii) Extreme and uncontrollable circumstances.

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

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

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

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

(2) Information indicating:

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

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

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

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

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

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

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

§ 414.100 Purpose.

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

[78 FR 72252, Dec. 2, 2013]

§ 414.102 General payment rules.

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

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

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

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

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

(c) *Updating the fee schedule amounts.* For the years 2003 through 2010 for PEN items and services, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year. For each year subsequent to 2010 for PEN items and services and for each year subsequent to 2014 for splints and casts, and IOLs inserted in a physician's office, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

[66 FR 45176, Aug. 28, 2001, as amended at 78 FR 72252, Dec. 2, 2013]

§ 414.104 PEN Items and Services.

(a) *Payment rules.* Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) *Fee schedule amount.* The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

§ 414.105 Application of competitive bidding information.

For enteral nutrients, equipment and supplies furnished on or after January 1, 2011, the fee schedule amounts may be adjusted based on information on the payment determined as part of implementation of the programs under subpart F using the methodologies set forth at § 414.210(g).

[79 FR 66262, Nov. 6, 2014]

§ 414.106 Splints and casts.

(a) *Payment rules.* Payment is made in a lump sum for splints and casts.

(b) *Fee schedule amount.* The fee schedule amount for payment for an item or service furnished in 2014 is the reasonable charge amount for 2013, updated by the percentage increase in the CPI–U for the 12-month period ending with June of 2013.

[78 FR 72253, Dec. 2, 2013]

§ 414.108 IOLs inserted in a physician's office.

(a) *Payment rules.* Payment is made in a lump sum for IOLs inserted in a physician's office.

(b) *Fee schedule amount.* The fee schedule amount for payment for an IOL furnished in 2014 is the national average allowed charge for the IOL furnished from in calendar year 2012, updated by the percentage increase in the CPI–U for the 24-month period ending with June of 2013.

[78 FR 72253, Dec. 2, 2013]

§ 414.110 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General Rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different

items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

[84 FR 60806, Nov. 8, 2019]

§ 414.112 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI–U minus current CPI–U) divided by current CPI–U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in § 414.102(c).

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new supplier or commercial prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

[84 FR 60806, Nov. 8, 2019]

§ 414.114 Procedures for making benefit category determinations and payment determinations for new PEN items and services covered under the prosthetic device benefit; splints and casts; and IOLs inserted in a physician's office covered under the prosthetic device benefit.

(a) *Definitions.* For the purpose of this subpart:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of a prosthetic device at section 1861(s)(8) of the Act or is a splint, cast, or device used for reduction of fractures or dislocations subject to section 1842(s) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other

means meet the definition of items and services that may be covered and paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit.

(2) If a preliminary determination is made that the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(4) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

[86 FR 73910, Dec. 28, 2021]

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§ 414.200 Purpose.

This subpart implements sections 1834(a), (h) and (i) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment, prosthetic and orthotic devices, and surgical dressings for Medicare beneficiaries.

[78 FR 72253, Dec. 2, 2013]

§ 414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Complex rehabilitative power-driven wheelchair means a power-driven wheelchair that is classified as—

(1) Group 2 power wheelchair with power options that can accommodate rehabilitative features (for example, tilt in space); or

(2) Group 3 power wheelchair.

Covered item update means the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) for the 12-month period ending with June of the previous year.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

Prosthetic and orthotic devices means—

(1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;

(2) One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; and

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.

The following are neither prosthetic nor orthotic devices—

(1) Parenteral and enteral nutrients, supplies, and equipment;

(2) Intraocular lenses;

(3) Medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by an HHA as part of home health services under § 409.40(e) of this chapter;

(4) Dental prostheses.

Region means, for the purpose of implementing §414.210(g), geographic areas defined by the Bureau of Economic Analysis in the United States Department of Commerce for economic analysis purposes, and, for the purpose of implementing §414.228, those contractor service areas administered by CMS regional offices.

Rural area means, for the purpose of implementing §414.210(g), a geographic area represented by a postal zip code if at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). A rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at §414.210(g) are applied.

[57 FR 57689, Dec. 7, 1992, as amended at 75 FR 73622, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011; 79 FR 66262, Nov. 6, 2014]

§414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c), (d), and (g) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§414.220 through 414.232

(b) *Payment classification.* (1) The carrier determines fee schedules for the following classes of equipment and devices:

(i) Inexpensive or routinely purchased items, as specified in §414.220.

(ii) Items requiring frequent and substantial servicing, as specified in §414.222.

(iii) Certain customized items, as specified in §414.224.

(iv) Oxygen and oxygen equipment, as specified in §414.226.

(v) Prosthetic and orthotic devices, as specified in §414.228.

(vi) Other durable medical equipment (capped rental items), as specified in §414.229.

(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in §414.232.

(2) CMS designates the items in each class of equipment or device through its program instructions.

(c) *Exception for certain HHAs.* Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in §413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provision of §§414.220 through 414.230.

(d) *Prohibition on special limits.* For items furnished on or after January 1, 1989 and before January 1, 1991, neither CMS nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in §405.502(g) of this chapter.

(e) *Maintenance and servicing*—(1) *General rule.* Except as provided in paragraph (e)(3) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing of beneficiary-owned equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made for replacement parts in a lump sum based on the carrier's consideration of the item. The carrier establishes a reasonable fee for labor associated with repairing, maintaining, and servicing the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for oxygen equipment described in paragraph (e)(2) of this section or for other durable medical equipment as described in §414.229(e).

(2) *Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period from January 1, 2009 through June 30, 2010.* The carrier makes a maintenance and servicing payment for oxygen equipment other than liquid and gaseous equipment (stationary and portable) as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with § 414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for 30 minutes of labor for routine maintenance and servicing of the equipment in the beneficiary's home (including an institution used as the beneficiary's home).

(iii) The supplier must visit the beneficiary's home (including an institution used as the beneficiary's home) to inspect the equipment during the first month of the 6-month period.

(3) *Exception to maintenance and servicing payments.* For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in § 414.222(a);

(ii) Capped rental items, as defined in § 414.229(a), that are not beneficiary-owned in accordance with § 414.229(d), § 414.229(f)(2), or § 414.229(h); and

(iii) Capped rental items, as defined in § 414.229(a), that are not beneficiary-owned in § 414.229(d), § 414.229(f)(2), or § 414.229(h); and

(iv) Oxygen equipment, as described in § 414.226.

(4) *Supplier replacement of beneficiary-owned equipment based on accumulated repair costs.* A supplier that transfers title to a capped rental item to a beneficiary in accordance with § 414.229(f)(2) is responsible for furnishing replacement equipment at no cost to the beneficiary or to the Medicare program if the carrier determines that the item furnished by the supplier will not last for the entire reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1). In making this determination, the carrier may consider whether the accumulated costs of repair exceed 60 percent of the cost to replace the item.

(5) *Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period and on or after July 1, 2010.* For oxygen equipment other than liquid and gaseous equipment (stationary and portable), the carrier makes payment as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with § 414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for routine maintenance and servicing of the equipment in the beneficiary's home (including an institution used as the beneficiary's home).

(iii) Payment for maintenance and servicing is made based on a reasonable fee not to exceed 10 percent of the purchase price for a stationary oxygen concentrator. This payment includes payment for maintenance and servicing of all oxygen equipment other than liquid or gaseous equipment (stationary or portable).

(iv) The supplier must visit the beneficiary's home (including an institution used as the beneficiary's home) to inspect the equipment during the first month of the 6-month period.

(f) *Payment for replacement of equipment.* If an item of DME or a prosthetic or orthotic device paid for under this subpart has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost, stolen, or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement oxygen equipment, payment is made in accordance with § 414.226(a).

(3) If the beneficiary elects to obtain a replacement capped rental item, payment is made in accordance with § 414.229(a)(2) or (a)(3).

(4) For all other beneficiary-owned items, if the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

(g) *Application of Competitive Bidding Information and Limitation of Inherent Reasonableness Authority.* For items furnished on or after January 1, 2011, the fee schedule amounts may be adjusted, and for DME items furnished on or after January 1, 2016, the fee schedule amounts shall be adjusted, based on information on the payment determined as part of implementation of the programs under subpart F, of this part, excluding information on the payment determined in accordance with the special payment rules at §414.409. In the case of such adjustments, the rules at §405.502(g) and (h) of this chapter shall not be applied. The methodologies for adjusting fee schedule amounts are provided below. In any case where application of these methodologies results in an increase in the fee schedule amount, the adjustment to the fee schedule amount is not made.

(1) *Payment adjustments for areas within the contiguous United States using information from competitive bidding programs.* For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for such item or service for areas within the contiguous United States shall be adjusted as follows:

(i) CMS determines a regional price for each state in the contiguous United States and the District of Columbia equal to the un-weighted average of the single payment amounts for an item or service established in accordance with §414.416 for competitive bidding areas that are fully or partially located in the same region that contains the state or District of Columbia.

(ii) CMS determines a national average price equal to the un-weighted average of the regional prices determined under paragraph (g)(1)(i) of this section.

(iii) A regional price determined under paragraph (g)(1)(i) of this section cannot be greater than 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section nor less than 90 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(iv) The fee schedule amount for all areas within a state that are not defined as rural areas for purposes of this subpart is adjusted to the regional price determined under paragraphs (g)(1)(i) and (iii) of this section.

(v) For items and services furnished before February 28, 2022, the fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) Payment adjustments for areas outside the contiguous United States and for items furnished on or after February 28, 2022 in rural areas within the contiguous United States using information from competitive bidding programs.

(i) For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States (Alaska, Hawaii, and U.S. territories) for items and services furnished from January 1, 2016, through December 31, 2020 are reduced to the greater of—

(A) The average of the single payment amounts for the item or service for CBAs outside the contiguous United States.

(B) 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section.

(ii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for areas outside the contiguous United States for items and services furnished on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of the greater of the average of the single payment amounts for the item or service for CBAs outside the contiguous United States or 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

(iii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for rural areas within the contiguous United States for items and services furnished on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

(3) *Payment adjustments for items and services included in no more than ten competitive bidding programs.* Notwithstanding paragraph (g)(1) of this section, for an item or service that is included in ten or fewer competitive bidding programs as defined at §414.402, the fee schedule amounts applied for all areas within and outside the contiguous United States are reduced to 110 percent of the un-weighted average of the single payment amounts from the ten or fewer competitive bidding programs for the item or service in the areas where the ten or fewer competitive bidding programs are in place.

(4) *Payment adjustments using data on items and services included in competitive bidding programs no longer in effect.* In the case where adjustments to fee schedule amounts are made using any of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the fee schedule amounts. The single payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustments to the fee schedule amounts, if the adjustments continue to be based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts used to reduce the fee schedule amounts are updated every 12 months using the percentage change in the CPI–U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

(5) *Adjusted payment amounts for accessories used with different types of base equipment.* In situations where a HCPCS code that describes an item used with different types of base equipment is included in more than one product category in a CBA under competitive bidding, a weighted average of the single payment amounts for the code is computed for each CBA based on the total number of allowed services for the item on a national basis for the code from each product category prior to applying the payment adjustment methodologies in this section.

(6) *Adjustments of single payment amounts resulting from price inversions under the DMEPOS Competitive Bidding Program.* (i) In situations where a price inversion defined in §414.402 occurs under the DMEPOS Competitive Bidding Program in a competitive bidding area (CBA) following a competition for a grouping of similar items identified in paragraph (g)(6)(ii) of this section, prior to adjusting the fee schedule amounts under paragraph (g) of this section the single payment amount for each item in the grouping of similar items in the CBA is adjusted to be

equal to the weighted average of the single payment amounts for the items in the grouping of similar items in the CBA.

(ii) The groupings of similar items subject to this rule include—

(A) Hospital beds (HCPCS codes E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, and E0304).

(B) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373)

(C) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, and K0823).

(D) Seat lift mechanisms (HCPCS codes E0627 and E0629).

(E) TENS devices (HCPCS codes E0720 and E0730).

(F) Walkers (HCPCS codes E0130, E0135, E0141, and E0143).

(iii) The weight for each item (HCPCS code) used in calculating the weighted average described in paragraph (g)(6)(ii) of this section is equal to the proportion of total nationwide allowed services furnished in calendar year 2012 for the item (HCPCS code) in the grouping of similar items, relative to the total nationwide allowed services furnished in calendar year 2012 for each of the other items (HCPCS codes) in the grouping of similar items.

(7) *Payment adjustments for mail order items furnished in the Northern Mariana Islands.* The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program. Beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph no longer applies.

(8) *Updating adjusted fee schedule amounts.* The adjusted fee schedule amounts are revised each time a single payment amount for an item or service is updated following one or more new competitions and as other items are added to programs established under Subpart F of this part.

(9) *Transition rules.* The payment adjustments described above are phased in as follows:

(i) For applicable items and services furnished with dates of service from January 1, 2016 through December 31, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(ii) For items and services furnished with dates of service from January 1, 2017, through May 31, 2018, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(iii) For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through December 31, 2020 or through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(iv) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from June 1, 2018 through March 5, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(v) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount. For items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(vi) For items and services furnished in all areas with dates of service on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, based on the fee schedule amount for the area is equal to the adjusted payment amount established under paragraph (g) of this section.

(10) *Payment adjustments for items and services furnished in former competitive bidding areas during temporary gaps in the DMEPOS CBP*. During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.

[57 FR 57689, Dec. 7, 1992, as amended at 71 FR 65932, Nov. 9, 2006; 73 FR 69936, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 74 FR 62009, Nov. 25, 2009; 79 FR 66262, Nov. 6, 2013; 81 FR 77965, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57070, Nov. 14, 2018; 85 FR 27623, May 8, 2020; 86 FR 73911, Dec. 28, 2021; 87 FR 199, Jan. 4, 2022]

§ 414.220 Inexpensive or routinely purchased items.

(a) *Definitions*. (1) *Inexpensive equipment* means equipment the average purchase price of which did not exceed $150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(3) *Accessories*. Effective January 1, 1994, accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from § 414.222 meet the definitions of ''inexpensive equipment'' and ''routinely purchased equipment'' in paragraphs (a)(1) and (a)(2) of this section, respectively.

(b) *Payment rules*. (1) Subject to the limitation in paragraph (b)(3) of this section, payment for inexpensive and routinely purchased items is made on a rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount.

(2) Effective January 1, 1994, payment for ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician's professional service or furnished by an HHA is made using the methodology for the inexpensive and routinely purchased class.

(3) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

(c) *Fee schedule amount for 1989 and 1990*. The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the local payment amounts for years after 1990*. For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) *Calculating the fee schedule amounts for years after 1990*. For years after 1990, the fee schedule amounts are

equal to the national limited payment amount.

(f) *Calculating the national limited payment amount.* The national limited payment amount is computed as follows:

(1) The 1991 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(3) For 1993, the national limited payment amount is equal to one of the following:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts.

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts.

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:

(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.

(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.

(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.

(g) *Payment for surgical dressings.* For surgical dressings furnished after December 31, 1993, the national limited payment amount is computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates for 1993 and 1994.

[57 FR 57689, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators (except those that are either continuous airway pressure devices or respiratory assist devices with bi-level pressure capability with or without a backup rate, previously referred to as ''intermittent assist devices with continuous airway pressure devices'').

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other items specified in CMS program instructions.

(5) Other items identified by the carrier.

(b) *Payment rule.* Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier adjusts the amounts determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedules are determined using the methodology contained in paragraphs (d), (e), and (f) of § 414.220.

(e) *Transition to other payment classes.* For purposes of calculating the 15-month rental period, beginning January 1, 1994, if an item has been paid for under the frequent and substantial servicing class and is subsequently paid for under another payment class, the rental period begins with the first month of continuous rental, even if that period began before January 1, 1994. For example, if the rental period began on July 1, 1993, the carrier must use this date as beginning the first month of rental. Likewise, for purposes of calculating the 10-month purchase option, the rental period begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August 1993, the 10-month purchase option must be offered to the beneficiary in May 1994, the tenth month of continuous rental.

(f) *Multi-function ventilators*—(1) Definition. For the purpose of this paragraph (f), a multi-function ventilator is a ventilator as defined in paragraph (a)(1) of this section that also performs medically necessary functions for the patient at the same time that would otherwise be performed by one or more different items classified under § 414.220, § 414.226, or § 414.229.

(2) *Payment rule.* Effective for dates of service on or after January 1, 2019, the monthly rental fee schedule amount for a multi-function ventilator described in paragraph (f)(1) of this section is equal to the monthly rental fee schedule amount for the ventilator established in paragraph (c) and paragraph (d) of this section plus the average of the lowest monthly cost for one additional function determined under paragraph (f)(3) of this section and the monthly cost of all additional functions determined under paragraph (f)(3) of this section, increased by the annual covered item updates of section 1834(a)(14) of the Act.

(3) *Monthly cost for additional functions.* (i) For functions performed by items classified under this section prior to 1994, the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.

(ii) For functions performed by items classified under § 414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in § 414.220(c), (d), (e), and (f), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

(iii) For functions performed by items classified under § 414.226, the monthly cost is equal to the monthly payment amount established in § 414.226(e) and (f), adjusted in accordance with § 414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.

(iv) For functions performed by items classified under § 414.229, the monthly cost is equal to the purchase price established in § 414.229(c), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

[57 FR 57690, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995; 71 FR 4525, Jan. 27, 2006; 83 FR 57071, Nov. 14, 2018]

§ 414.224 Customized items.

(a) *Criteria for a customized item.* To be considered a customized item for payment purposes under paragraph (b) of this section, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a

specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

(b) *Payment rule.* Payment is made on a lump sum basis for the purchase of a customized item based on the carrier's individual consideration and judgment of a reasonable payment amount for each customized item. The carrier's individual consideration takes into account written documentation on the costs of the item including at least the cost of labor and materials used in customizing an item.

[56 FR 65998, Dec. 20, 1991, as amended at 58 FR 34919, June 30, 1993]

§414.226 Oxygen and oxygen equipment.

(a) *Payment rules*—(1) *Oxygen equipment.* Payment for rental of oxygen equipment is made based on a monthly fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 36 months. A period of continuous use is determined under the provisions in §414.230.

(2) *Oxygen contents.* Payment for purchase of oxygen contents is made based on a monthly fee schedule amount until medical necessity ends.

(b) *Monthly fee schedule amount for items furnished prior to 2007.* (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(i) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(ii) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the change in the CPI-U for the six-month period ending December 1987.

(3) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(iii) and (iv) of this section are determined using the methodology contained in §414.220(d), (e), and (f).

(4) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(i) and (ii) of this section are determined using the methodology contained in §414.220(d), (e), and (f).

(5) For 2005 and 2006, the fee schedule amounts determined under paragraph (b)(4) of this section are reduced using the methodology described in section 1834(a)(21)(A) of the Act.

(c) *Monthly fee schedule amount for items furnished from 2007 through 2018.* (1) For 2007, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable equipment only (gaseous or liquid tanks).

(iii) Oxygen generating portable equipment only.

(iv) Stationary oxygen contents only.

(v) Portable oxygen contents only.

(2) The national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section is equal to the weighted average fee schedule amount established under paragraph (b)(5) of this section reduced by $1.44.

(3) The national limited monthly payment rate for items described in paragraph (c)(1)(ii) of this section is equal to the weighted average of the

fee schedule amounts established under paragraph (b)(5) of this section.

(4) The national limited monthly payment rate for items described in paragraph (c)(1)(iii) of this section is equal to the national limited monthly payment rate established under paragraph (c)(5) of this section, multiplied by 24, and divided by 36.

(5) The national limited monthly payment rate for items described in paragraphs (c)(1)(iv) and (c)(1)(v) of this section is equal to 50 percent of the weighted average fee schedule amounts established under paragraph (b)(3) of this section for items described in paragraph (b)(1)(iii) of this section.

(6) For 2008 through 2018, CMS makes an annual adjustment to the national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(d) *Application of monthly fee schedule amounts for items furnished from 2007 through 2018.* (1) The fee schedule amount for items described in paragraph (c)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (c)(1)(ii) and (c)(1)(iii) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (c)(1)(iv) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (c)(1)(v) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in (c)(1)(ii) of this section;

(ii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(e) *Monthly fee schedule amount for items furnished for years after 2018.* (1) For 2019, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable gaseous equipment only.

(iii) Portable liquid equipment only.

(iv) Oxygen generating portable equipment only.

(v) Stationary oxygen contents only.

(vi) Portable oxygen contents only, except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute.

(vii) Portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute.

(2) The monthly payment rate for items described in paragraphs (e)(1)(i), (ii), (iv), (v), and (vi) of this section are determined using the applicable methodologies contained in § 414.210(g).

(3) The monthly payment rate for items described in paragraph (e)(1)(iii) of this section is determined initially based on the monthly payment rate for items described in paragraph (e)(1)(iv) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(4) The monthly payment rate for items described in paragraph (e)(1)(vii) of this section is determined initially based on 150 percent of the monthly payment rate for items described in paragraph (e)(1)(vi) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(5) Beginning in 2019, CMS makes an annual adjustment to the monthly payment rate for items described in paragraphs (e)(1)(i) through (e)(1)(vii) of

this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(f) *Application of monthly fee schedule amounts for items furnished for years after 2018.* (1) The fee schedule amount for items described in paragraph (e)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (e)(1)(ii), (iii), and (iv) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (e)(1)(v) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (e)(1)(vi) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section; or Code of Federal Regulations/Title 42—Public Health/Vol. 3/2017–10–0166

(ii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(5) The fee schedule amount for items described in paragraph (e)(1)(vii) of this section is paid when the beneficiary has a prescribed flow rate of more than 4 liters per minute and—

(i) Owns portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section; or Code of Federal Regulations/Title 42—Public Health/Vol. 3/2017–10–0166

(ii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(g) *Volume adjustments.* (1) The fee schedule amount for an item described in paragraph (c)(1)(i) of this section is adjusted as follows:

(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (g)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (c)(1)(i) and (c)(1)(ii) or (c)(1)(iii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (g)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

(h) *Furnishing oxygen and oxygen equipment after the 36-month rental cap.* (1) The supplier that furnishes oxygen equipment for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen equipment with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(2) The supplier that furnishes liquid or gaseous oxygen equipment (stationary or portable) for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the oxygen contents necessary for the effective use of the liquid or gaseous equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen contents with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(i) *Additional supplier requirements for rentals that begin on or after January 1, 2007.* (1) The supplier that furnishes oxygen equipment for the first month during which payment is made under this section must continue to furnish the equipment for the entire 36-month period of continuous use, unless medical necessity ends or—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain oxygen equipment from a different supplier prior to the expiration of the 36-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) Oxygen equipment furnished under this section may not be replaced by the supplier prior to the expiration of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1) unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the order is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing oxygen equipment, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

[57 FR 57690, Dec. 7, 1992, as amended at 71 FR 65933, Nov. 9, 2006; 73 FR 69936, Nov. 19, 2008; 78 FR 72253, Dec. 2, 2013; 83 FR 57071, Nov. 14, 2018]

§ 414.228 Prosthetic and orthotic devices.

(a) *Payment rule.* Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

(b) *Fee schedule amounts.* The fee schedule amount for prosthetic and orthotic devices is determined as follows:

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier determines a local purchase price equal to the following:

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991. For 1992 and 1993, the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(iii) For 1994 and 1995, the applicable percentage increase is 0 percent.

(iv) For all subsequent years the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(3) CMS determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) CMS determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, CMS determines a national average purchase price equal to the unweighted average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

(6) CMS determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(c) *Payment for therapeutic shoes.* The payment rules specified in paragraphs (a) and (b) of this section are applicable to custom molded and extra depth shoes, modifications, and inserts (therapeutic shoes) furnished after December 31, 2004.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 73 FR 69937, Nov. 19, 2008]

§ 414.229 Other durable medical equipment—capped rental items.

(a) *General payment rule.* Payment is made for other durable medical equipment that is not subject to the payment provisions set forth in § 414.220 through § 414.228 as follows:

(1) For items furnished prior to January 1, 2006, payment is made on a rental or purchase option basis in accordance with the rules set forth in paragraphs (b) through (e) of this section.

(2) For items other than power-driven wheelchairs furnished on or after January 1, 2006, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(3) For power-driven wheelchairs furnished on or after January 1, 2006 through December 31, 2010, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(4) For power-driven wheelchairs that are not classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(5) For power-driven wheelchairs classified as complex rehabilitative

power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(b) *Fee schedule amounts for rental.* (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under § 405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(3) For power-driven wheelchairs furnished on or after January 1, 2011, the monthly fee schedule amount for rental equipment equals 15 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 6 percent of the purchase price for each of the remaining months.

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

(1) For *1989 and 1990.* (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986.

(ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For *1991.* (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by the percentage by which the average of the reasonable charges for claims paid for all other items described in § 414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in § 414.220(f).

(3) *For years after 1991.* The purchase price is determined using the methodology contained in paragraphs (d) through (f) of § 414.220.

(d) *Purchase option.* Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the amount established in paragraph (c) of this section.

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in § 414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13

months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) *Payment for maintenance and servicing.* (1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following:

(i) For the first 6-month period, no payments are to be made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) *Rules for capped rental items furnished beginning on or after January 1, 2006.* (1) For items furnished on or after January 1, 2006, payment is made based on a monthly rental fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 13 months. A period of continuous use is determined under the provisions in §414.230.

(2) The supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made under paragraph (f)(1) of this section.

(3) Payment for maintenance and servicing of beneficiary-owned equipment is made in accordance with §414.210(e).

(g) *Additional supplier requirements for capped rental items that are furnished beginning on or after January 1, 2007.* (1) The supplier that furnishes an item for the first month during which payment is made using the methodology described in paragraph (f)(1) of this section must continue to furnish the equipment until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier, unless—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain the equipment from a different supplier prior to the expiration of the 13-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) A capped rental item furnished under this section may not be replaced by the supplier prior to the expiration of the 13-month rental period unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the need for different equipment is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing a capped rental item, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

(4) No later than two months before the date on which the supplier must transfer title to a capped rental item to the beneficiary, the supplier must

disclose to the beneficiary whether it can maintain and service the item after the beneficiary acquires title to it. CMS or its carriers may make exceptions to this requirement on a case-by-case basis.

(h) *Purchase of power-driven wheelchairs furnished on or after January 1, 2006.* (1) Suppliers must offer beneficiaries the option to purchase power-driven wheelchairs at the time the equipment is initially furnished.

(2) Payment is made on a lump-sum purchase basis if the beneficiary chooses this option.

(3) On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 71 FR 65934, Nov. 9, 2006; 75 FR 73622, Nov. 29, 2010]

§ 414.230 Determining a period of continuous use.

(a) *Scope.* This section sets forth the rules that apply in determining a period of continuous use for rental of durable medical equipment.

(b) *Continuous use.* (1) A period of continuous use begins with the first month of medical need and lasts until a beneficiary's medical need for a particular item of durable medical equipment ends.

(2) In the case of a beneficiary receiving oxygen equipment on December 31, 2005, the period of continuous use for the equipment begins on January 1, 2006.

(c) *Temporary interruption.* (1) A period of continuous use allows for temporary interruptions in the use of equipment.

(2) An interruption of not longer than 60 consecutive days plus the days remaining in the rental month in which use ceases is temporary, regardless of the reason for the interruption.

(3) Unless there is a break in medical necessity that lasts longer than 60 consecutive days plus the days remaining in the rental month in which use ceases, medical necessity is presumed to continue.

(d) *Criteria for a new rental period.* If an interruption in the use of equipment continues for more than 60 consecutive days plus the days remaining in the rental month in which use ceases, a new rental period begins if the supplier submits all of the following information—

(1) A new prescription.

(2) New medical necessity documentation.

(3) A statement describing the reason for the interruption and demonstrating that medical necessity in the prior episode ended.

(e) *Beneficiary moves.* A permanent or temporary move made by a beneficiary does not constitute an interruption in the period of continuous use.

(f) *New equipment.* (1) If a beneficiary changes equipment or requires additional equipment based on a physician's prescription, and the new or additional equipment is found to be necessary, a new period of continuous use begins for the new or additional equipment. A new period of continuous use does not begin for base equipment that is modified by an addition.

(2) A new period of continuous use does not begin when a beneficiary changes from one stationary oxygen equipment modality to another or from one portable oxygen equipment modality to another.

(g) *New supplier.* If a beneficiary changes suppliers, a new period of continuous use does not begin.

(h) *Oxygen equipment furnished after the 36-month rental period.* A new period of continuous use does not begin under any circumstance in the case of oxygen equipment furnished after the 36-month rental period in accordance with § 414.226(h) until the end of the reasonable useful lifetime established for such equipment in accordance with § 414.210(h).

[56 FR 50823, Oct. 9, 1991, as amended at 57 FR 57111, Dec. 3, 1992; 71 FR 65935, Nov. 9, 2006; 73 FR 69937, Nov. 19, 2008; 83 FR 57072, Nov. 14, 2018]

§ 414.232 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) *General payment rule.* Except as provided in paragraph (b) of this section, payment for TENS is made on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in § 414.220. The payment amount for

TENS computed under § 414.220(c)(2) is reduced according to the following formula:

(1) Effective April 1, 1990—the original payment amount is reduced by 15 percent.

(2) Effective January 1, 1991—the reduced payment amount in paragraph (a)(1) is reduced by 15 percent.

(3) Effective January 1, 1994—the reduced payment amount in paragraph (a)(1) is reduced by 45 percent.

(b) *Exception.* In order to permit an attending physician time to determine whether the purchase of the TENS is medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

[57 FR 57692, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

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

Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item is furnished to the beneficiary and before the claim is submitted for processing.

Provisional affirmation is a preliminary finding that a future claim meets Medicare's coverage, coding, and payment rules.

Required Prior Authorization List is a list of DMEPOS items selected from the Master List and subject to the requirements of prior authorization as a condition of payment.

Unnecessary utilization means the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules.

(b) *Master List of Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements.*(1) Master List Inclusion Criteria are as follows:

(i) Any DMEPOS items included in the DMEPOS Fee Schedule that have an average purchase fee of $500 (adjusted annually for inflation using consumer price index for all urban consumers (CPI–U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or an average monthly rental fee schedule of $50 (adjusted annually for inflation using consumer price index for all urban consumers (CPI–U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a 12-month period that are:

(A) Identified as having a high rate of potential fraud or unnecessary utilization in an Office of Inspector General (OIG) or Government Accountability Office (GAO) report that is national in scope and published in 2015 or later, or

(B) Listed in the 2018 or later Comprehensive Error Rate Testing (CERT) Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report as having a high improper payment rate, or

(ii) The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

(A) Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or

(B) Exceeding a 30 percent increase in payment, or

(iii) Any item statutorily requiring a face-to-face encounter, a written order

prior to delivery, or prior authorization.

(2) The Master List is self-updating at a minimum annually, and is published in the FEDERAL REGISTER.

(3) DMEPOS items identified as having a high rate of fraud or unnecessary utilization in any of the following reports that are national in scope and meeting the payment threshold criteria set forth in paragraph (b)(1) of this section are added to the Master List:

(i) OIG reports published after 2020.

(ii) GAO reports published after 2020.

(iii) Listed in the CERT Medicare FFS Supplemental Improper Payment Data report(s) published after 2020 as having a high improper payment rate.

(4) Items are removed from the Master List after 10 years from the date the item was added to the Master List, unless the item was identified in an OIG report, GAO report, or having been identified in the CERT Medicare FFS Supplemental Improper Payment Data report as having a high improper payment rate, within the 5-year period preceding the anticipated date of expiration.

(5) Items that are discontinued or are no longer covered by Medicare are removed from the Master List.

(6) An item is removed from the list if the cost drops below the payment threshold criteria set forth in paragraph (b)(1)(i) of this section.

(7) An item is removed from the Master List and replaced by its equivalent when the Healthcare Common Procedure Coding System (HCPCS) code representing the item has been discontinued and cross-walked to an equivalent item.

(c) *Condition of payment*—(1) *Items requiring prior authorization.* CMS publishes in the FEDERAL REGISTER and posts on the CMS Prior Authorization Web site a list of items, the Required Prior Authorization List, that require prior authorization as a condition of payment.

(i) The Required Prior Authorization List specified in paragraph (c)(1) of this section is selected from the Master List. CMS may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis and may implement prior authorization nationally or locally.

(ii) CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region. CMS may elect to exempt suppliers from prior authorization upon demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process.

(iii) The Required Prior Authorization List is effective no less than 60 days after publication and posting.

(2) *Denial of claims.* (i) CMS or its contractors denies a claim for an item that requires prior authorization if the claim has not received a provisional affirmation.

(ii) Claims receiving a provisional affirmation may be denied based on either of the following:

(A) Technical requirements that can only be evaluated after the claim has been submitted for formal processing.

(B) Information not available at the time of a prior authorization request.

(d) *Submission of prior authorization requests.* A prior authorization request must do the following:

(1) Include all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules, including those outlined in § 410.38 and all of the following:

(i) Written order/prescription.

(ii) Relevant information from the beneficiary's medical record.

(iii) Relevant supplier produced documentation.

(2) Be submitted before the item is furnished to the beneficiary and before the claim is submitted for processing.

(e) *Review of prior authorization requests.* (1) After receipt of a prior authorization request, CMS or its contractor reviews the prior authorization request for compliance with applicable Medicare coverage, coding, and payment rules.

(2) If applicable Medicare coverage, coding, and payment rules are met, CMS or its contractor issues a provisional affirmation to the requester.

(3) If applicable Medicare coverage, coding, and payment rules are not met, CMS or its contractor issues a non-affirmation decision to the requester.

(4) If the requester receives a non-affirmation decision, the requester may resubmit a prior authorization request before the item is furnished to the beneficiary and before the claim is submitted for processing.

(5) A prior authorization request for an expedited review must include documentation that shows that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function. If CMS or its contractor agrees that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function, then CMS or its contractor expedites the review of the prior authorization request and communicates the decision following the receipt of all applicable Medicare required documentation.

(f) *Suspension of prior authorization requests.* (1) CMS may suspend prior authorization requirements generally or for a particular item or items at any time and without undertaking rulemaking.

(2) CMS provides notification of the suspension of the prior authorization requirements via—

(i) FEDERAL REGISTER notice; and

(ii) Posting on the CMS prior authorization Web site.

[80 FR 81706, Dec. 30, 2015, as amended at 84 FR 60807, Nov. 8, 2019]

§ 414.236 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

[84 FR 60808, Nov. 8, 2019]

§ 414.238 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and

additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI–U minus current CPI–U) divided by current CPI–U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME, section 1834(h)(4) of the Act for prosthetic devices, prosthetics, orthotics, and therapeutic shoes and inserts, and section 1834(i)(1)(B) of the Act for surgical dressings.

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

[84 FR 60808, Nov. 8, 2019]

§ 414.240 Procedures for making benefit category determinations and payment determinations for new durable medical equipment, prosthetic devices, orthotics and prosthetics, surgical dressings, and therapeutic shoes and inserts.

(a) *Definitions.* For the purpose of this subpart—

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of durable medical equipment at section 1861(n) of the Act, a prosthetic device at section 1861(s)(8) of the Act and further defined under section 1834(h)(4) of the Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is durable medical equipment, a prosthetic device as further defined under section 1834(h)(4) of the Act, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert.

(2) If a preliminary determination is made that the item or service is durable medical equipment, a prosthetic device, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment

determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(4) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

[86 FR 73911, Dec. 28, 2021]

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§ 414.300 Scope of subpart.

This subpart sets forth criteria and procedures for payment of the following services furnished to ESRD patients:

(a) Physician services related to renal dialysis.

(b) Physician services related to renal transplantation.

(c) Home dialysis equipment, supplies, and support services.

(d) Epoetin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

[55 FR 23441, June 8, 1990, as amended at 56 FR 43710, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994]

§ 414.310 Determination of reasonable charges for physician services furnished to renal dialysis patients.

(a) *Principle.* Physician services furnished to renal dialysis patients are subject to payment if the services are otherwise covered by the Medicare program and if they are considered reasonable and medically necessary in accordance with section 1862(a)(1)(A) of the Act.

(b) *Scope and applicability*—(1) *Scope.* This section pertains to physician services furnished to the following patients:

(i) Outpatient maintenance dialysis patients who dialyze—

(A) In an independent or hospital-based ESRD facility, or

(B) At home.

(ii) Hospital inpatients for which the physician elects to continue payment under the monthly capitation payment (MCP) method described in § 414.314.

(2) *Applicability.* These provisions apply to routine professional services of physicians. They do not apply to administrative services performed by physicians, which are paid for as part of a prospective payment for dialysis services made to the facility under § 413.170 of this chapter.

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

Administrative services are physician services that are differentiated from routine professional services and other physician services because they are supervision, as described in the definition of ''supervision of staff'' of this section, or are not related directly to the care of an individual patient, but are supportive of the facility as a whole and of benefit to patients in general. Examples of administrative services include supervision of staff, staff training, participation in staff conferences and in the management of the facility, and advising staff on the procurement of supplies.

Dialysis session is the period of time that begins when the patient arrives at the facility and ends when the patient departs from the facility. In the case of home dialysis, the period begins when the patient prepares for dialysis and generally ends when the patient is disconnected from the machine. In this context, a dialysis facility includes only those parts of the building used as a facility. It does not include any areas used as a physician's office.

Medical direction, in contrast to supervision of staff, is a routine professional service that entails substantial direct involvement and the physical presence of the physician in the delivery of services directly to the patient.

Routine professional services include all physicians' services furnished during a dialysis session and all services listed in paragraph (d) of this section that meet the following requirements:

(1) They are personally furnished by a physician to an individual patient.

(2) They contribute directly to the diagnosis or treatment of an individual patient.

(3) They ordinarily must be performed by a physician.

Supervision of staff, in contrast to medical direction, is an administrative service that does not necessarily require the physician to be present at the dialysis session. It is a general activity primarily concerned with monitoring performance of and giving guidance to other health care personnel (such as nurses and dialysis technicians) who deliver services to patients.

(d) *Types of routine professional services.* Routine professional services include at least all of the following services when medically appropriate:

(1) Visits to the patient during dialysis, and review of laboratory test results, nurses' notes and any other medical documentation, as a basis for—

(i) Adjustment of the patient's medication or diet, or the dialysis procedure;

(ii) Prescription of medical supplies; and

(iii) Evaluation of the patient's psychosocial status and the appropriateness of the treatment modality.

(2) Medical direction of staff in delivering services to a patient during a dialysis session.

(3) Pre-dialysis and post-dialysis examinations, or examinations that could have been furnished on a pre-dialysis or post-dialysis basis.

(4) Insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(e) *Payment for routine professional services.* Beginning August 7, 1990, routine professional services furnished by physicians may be paid under either the ''initial method'' of payment described in § 414.313, (if all of the physicians at the facility elect the initial method) or under the ''physician MCP method'' described in § 414.314. Physician services furnished after July 31, 1983 and before August 6, 1990, are payable only under the MCP method described in § 414.314.

§ 414.313 Initial method of payment.

(a) *Basic rule.* Under this method, the intermediary pays the facility for routine professional services furnished by physicians. Payment is in the form of an add-on to the facility's composite rate payment, which is described in part 413, subpart H of this subchapter.

(b) *Services for which payment is not included in the add-on payment.* (1) Physician administrative services are considered to be facility services and are paid for as part of the facility's composite rate.

(2) The carrier pays the physician or the beneficiary (as appropriate) under the reasonable charge criteria set forth in subpart E of part 405 of this chapter for the following services:

(i) Physician services that must be furnished at a time other than during the dialysis session (excluding pre-dialysis and post-dialysis examinations and examinations that could have been furnished on a pre-dialysis or post-dialysis basis), such as monthly and semi-annual examinations to review health status and treatment.

(ii) Physician surgical services other than insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(iii) Physician services furnished to hospital inpatients who were not admitted solely to receive maintenance dialysis.

(iv) Administration of hepatitis B vaccine.

(c) *Physician election of the initial method.* (1) Each physician in a facility must submit to the appropriate carrier and intermediary that serve the facility a statement of election of the initial method of payment for all the ESRD facility patients that he or she attends.

(2) The initial method of payment applies to dialysis services furnished beginning with the second calendar month after the month in which all physicians in the facility elect the initial method and continues until the effective date of a termination of the election described in paragraph (d) of this section.

(d) *Termination of the initial method.* (1) Physicians may terminate the initial method of payment by written notice to the carrier(s) that serves each physician and to the intermediary that serves the facility.

(2) If the notice terminating the initial method is received by the carrier(s) and intermediary—

(i) On or before November 1, the effective date of the termination is January 1 of the year following the calendar year in which the termination notice is received by the carrier(s) and intermediary; or

(ii) After November 1, the effective date of the termination is January 1 of the second year after the calendar year in which the notice is received by the carrier(s) and intermediary.

(e) *Determination of payment amount.* The factors used in determining the add-on amount are related to program experience. They are re-evaluated periodically and may be adjusted, as determined necessary by CMS, to maintain the payment at a level commensurate with the prevailing charges of other physicians for comparable services.

(f) *Publication of payment amount.* Revisions to the add-on amounts are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[55 FR 23441, June 8, 1990, as amended at 62 FR 43674, Aug. 15, 1997]

§414.314 Monthly capitation payment method.

(a) *Basic rules.* (1) Under the monthly capitation payment (MCP) method, the carrier pays an MCP amount for each patient, to cover all professional services furnished by the physician, except those listed in paragraph (b) of this section.

(2) The carrier pays the MCP amount, subject to the deductible and coinsurance provisions, either to the physician if the physician accepts assignment or to the beneficiary if the physician does not accept assignment.

(3) The MCP method recognizes the need of maintenance dialysis patients for physician services furnished periodically over relatively long periods of time, and the capitation amounts are consistent with physicians' charging patterns in their localities.

(4) Payment of the capitation amount for any particular month is contingent upon the physician furnishing to the patient all physician services required by the patient during the month, except those listed in paragraph (b) of this section.

(5) Payment for physician administrative services (§414.310) is made to the dialysis facility as part of the facility's composite rate (part 413, subpart H of this subchapter) and not to the physician under the MCP.

(b) *Services not included in the MCP.* (1) Services that are not included in the MCP and which may be paid in accordance with the reasonable charge rules set forth in subpart E of part 405 of this chapter are limited to the following:

(i) Administration of hepatitis B vaccine.

(ii) Covered physician services furnished by another physician when the patient is not available to receive, or the attending physician is not available to furnish, the outpatient services as usual (see paragraph (b)(3) of this section).

(iii) Covered physician services furnished to hospital inpatients, including services related to inpatient dialysis, by a physician who elects not to continue to receive the MCP during the period of inpatient stay.

(iv) Surgical services, including declotting of shunts, other than the insertion of catheters for patients on maintenance peritoneal dialysis who do not have indwelling catheters.

(v) Needed physician services that are—

(A) Furnished by the physician furnishing renal care or by another physician;

(B) Not related to the treatment of the patient's renal condition; and

(C) Not furnished during a dialysis session or an office visit required because of the patient's renal condition.

(2) For the services described in paragraph (b)(1)(v) of this section, the following rules apply:

(i) The physician must provide documentation to show that the services are not related to the treatment of the patient's renal condition and that additional visits are required.

(ii) The carrier's medical staff, acting on the basis of the documentation and appropriate medical consultation obtained by the carrier, determines whether additional payment for the additional services is warranted.

(3) The MCP is reduced in proportion to the number of days the patient is—

(i) Hospitalized and the physician elects to bill separately for services furnished during hospitalization; or

(ii) Not attended by the physician or his or her substitute for any reason, including when the physician is not available to furnish patient care or when the patient is not available to receive care.

(c) *Determination of payment amount.* The amount of payment for the MCP is determined under the Medicare physician fee schedule described in this part 414.

[55 FR 23441, June 8, 1990, as amended at 59 FR 63463, Dec. 8, 1994; 62 FR 43674, Aug. 15, 1997]

§ 414.316 Payment for physician services to patients in training for self-dialysis and home dialysis.

(a) For each patient, the carrier pays a flat amount that covers all physician services required to create the capacity for self-dialysis and home dialysis.

(b) CMS determines the amount on the basis of program experience and reviews it periodically.

(c) The payment is made at the end of the training course, is subject to the deductible and coinsurance provisions, and is in addition to any amounts payable under the initial or MCP methods set forth in §§ 414.313 and 414.314, respectively.

(d) If the training is not completed, the payment amount is proportionate to the time spent in training.

§ 414.320 Determination of reasonable charges for physician renal transplantation services.

(a) *Comprehensive payment for services furnished during a 60-day period.* (1) The comprehensive payment is subject to the deductible and coinsurance provisions and is for all surgeon services furnished during a period of 60 days in connection with a renal transplantation, including the usual preoperative and postoperative care, and for immunosuppressant therapy if supervised by the transplant surgeon.

(2) Additional sums, in amounts established on the basis of program experience, may be included in the comprehensive payment for other surgery performed concurrently with the transplant operation.

(3) The amount of the comprehensive payment may not exceed the lower of the following:

(i) The actual charges made for the services.

(ii) Overall national payment levels established under the ESRD program and adjusted to give effect to variations in physician's charges throughout the nation. (These adjusted amounts are the maximum allowances in a carrier's service area for renal transplantation surgery and related services by surgeons.)

(4) Maximum allowances computed under these instructions are revised at the beginning of each calendar year to the extent permitted by the lesser of the following:

(i) Changes in the economic index as described in § 405.504(a)(3)(i) of this chapter.

(ii) Percentage changes in the weighted average of the carrier's prevailing charges (before adjustment by the economic index) for—

(A) A unilateral nephrectomy; or

(B) Another medical or surgical service designated by CMS for this purpose.

(b) *Other payments.* Payments for covered medical services furnished to the transplant beneficiary by other specialists, as well as for services by the transplant surgeon after the 60-day period covered by the comprehensive payment, are made under the reasonable charge criteria set forth in § 405.502 (a) through (d) of this chapter. The payments for physicians' services in connection with renal transplantations are changed on the basis of program experience and the expected advances in the medical art for this operation.

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) *Equipment and supplies*—(1) *Basic rule.* Except as provided in paragraph (a)(2) of this section, Medicare pays for home dialysis equipment and supplies only under the prospective payment rates established at § 413.210.

(2) *Exception for equipment and supplies furnished prior to January 1, 2011.* If the conditions in subparagraphs (a)(2)(i) through (iv) of this section are met, Medicare pays for home analysis equipment and supplies on a reasonable

charge basis in accordance with subpart E (Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians) of part 405, but the amount of payment may not exceed the limit for equipment and supplies in paragraph (c)(2) of this section.

(i) The patient elects to obtain home dialysis equipment and supplies from a supplier that is not a Medicare approved dialysis facility.

(ii) The patient certifies to CMS that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on CMS Form 382 (the ''ESRD Beneficiary Selection'' form).

(iii) In writing, the supplier—

(A) Agrees to receive Medicare payment for home dialysis supplies and equipment only on an assignment-related basis; and

(B) Certifies to CMS that it has a written agreement with one Medicare approved dialysis facility or, if the beneficiary is also entitled to military or veteran's benefits, one military or Veterans Administration hospital, for each patient. (See part 494 of this chapter for the requirements for a Medicare approved dialysis facility.) Under the agreement, the facility or military or VA hospital agrees to the following:

(*1*) To furnish all home dialysis support services for each patient in accordance with part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. (§410.52 sets forth the scope and conditions of Medicare Part B coverage of home dialysis services, supplies, and equipment.)

(*2*) To furnish institutional dialysis services and supplies. (§410.50 sets forth the scope and conditions for Medicare Part B coverage of institutional dialysis services and supplies.)

(*3*) To furnish dialysis-related emergency services.

(*4*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are covered under the composite rate established at §413.170 and to arrange for the laboratory to seek payment from the facility. The facility then includes these laboratory services in its claim for payment for home dialysis support services.

(*5*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are not covered under the composite rate established at §413.170 and for which the laboratory files a Medicare claim directly.

(*6*) To furnish all other necessary dialysis services and supplies (that is, those which are not home dialysis equipment and supplies).

(*7*) To satisfy all documentation, recordkeeping and reporting requirements in part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. This includes maintaining a complete medical record of ESRD related items and services furnished by other parties. The facility must report, on the forms required by CMS or the ESRD network, all data for each patient in accordance with subpart U.

(iv) The facility with which the agreement is made must be located within a reasonable distance from the patient's home (that is, located so that the facility can actually furnish the needed services in a practical and timely manner, taking into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, and the usual distances traveled by patients in the area to obtain health care services).

(C) Agrees to report to the ESRD facility providing support services, at least every 45 days, all data (meaning information showing what supplies and services were provided to the patient and when each was provided) for each patient regarding services and items furnished to the patient in accordance with §494.100(c)(2) of this chapter.

(b) *Support services*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, Medicare pays for support services only under the prospective payment rates established in §413.210 of this chapter.

(2) *Exception for home support services furnished prior to January 1, 2011.* If the patient elects to obtain home dialysis equipment and supplies from a supplier that is not an approved ESRD facility, Medicare pays for support services, other than support services furnished

by military or VA hospitals referred to in paragraph (a)(2)(iii)(B) of this section, under paragraphs (b)(2) (i) and (ii) of this section but in no case may the amount of payment exceed the limit for support services in paragraph (c)(1) of this section:

(i) For support services furnished by a hospital-based ESRD facility, Medicare pays on a reasonable cost basis in accordance with part 413 of this chapter.

(ii) For support services furnished by an independent ESRD facility, Medicare pays on the basis of reasonable charges that are related to costs and allowances that are reasonable when the services are furnished in an effective and economical manner.

(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

(1) *Support services.* The amount of payment for home dialysis support services is limited to the national average Medicare-allowed charge per patient per month for home dialysis support services, as determined by CMS, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by CMS, multiplied by the national average number of treatments per month.

(2) *Equipment and supplies.* Payment for home dialysis equipment and supplies is limited to an amount equal to the result obtained by subtracting the support services payment limit in paragraph (c)(1) of this section from the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent) of the national median payment as determined by CMS that would have been made under the prospective payment rates established in §413.170 of this chapter for hospital-based facilities.

(3) *Notification of changes to the payment limits.* Updated data are incorporated into the payment limits when the prospective payment rates established at §413.170 of this chapter are updated, and changes are announced by notice in the FEDERAL REGISTER without a public comment period. Revisions of the methodology for determining the limits are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[57 FR 54187, Nov. 17, 1992, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49202, Aug. 12, 2010]

§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in §413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in §413.230

[75 FR 49202, Aug. 12, 2010]

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

§ 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

[72 FR 18084, Apr. 10, 2007]

§ 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

Affected party means a contract supplier that has been notified that their DMEPOS CBP contract will be terminated for a breach of contract.

Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

Bidding entity means the entity whose legal business name is identified in the ''Form A: Business Organization Information'' section of the bid.

Breach of contract means any deviation from contract requirements, including a failure to comply with a governmental agency or licensing organization requirements, constitutes a breach of contract.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart.

Competitive bidding program means a program established under this subpart within a designated CBA.

Composite bid means the bid submitted by the supplier for the lead item in the product category.

Contract supplier means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

Corrective action plan (CAP) means a contract supplier's written document with supporting information that describes the actions the contract supplier will take within a specified timeframe to remedy a breach of contract.

Covered document means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards.

Covered document review date means the later of—

(1) The date that is 30 days before the final date for the closing of the bid window; or

(2) The date that is 30 days after the opening of the bid window.

DMEPOS stands for durable medical equipment, prosthetics, orthotics, and supplies.

Grandfathered item means all rented items within a product category for which payment was made prior to the implementation of a competitive bidding program to a grandfathered supplier that chooses to continue to furnish the items in accordance with §414.408(j) of this subpart and that fall within the following payment categories for competitive bidding:

(1) An inexpensive or routinely purchased item described in §414.220 of this part.

(2) An item requiring frequent and substantial servicing, as described in §414.222 of this part.

(3) Oxygen and oxygen equipment described in §414.226 of this part.

(4) Other DME described in §414.229 of this part.

Grandfathered supplier means a noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

Hearing officer means an individual, who was not involved with the CBIC recommendation to take action for a breach of a DMEPOS Competitive Bidding Program contract, who is designated by CMS to review and make an unbiased and independent recommendation when there is an appeal of CMS's initial determination to take action for a breach of a DMEPOS Competitive Bidding Program contract.

Hospital has the same meaning as in section 1861(e) of the Act.

Item means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes and/or modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are:

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in §414.202, group 3 complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs, and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in §414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in §414.222(a).

(iii) Oxygen and oxygen equipment, as specified in §414.226(c)(1).

(iv) Other DME (capped rental items), as specified in §414.229.

(2) Supplies necessary for the effective use of DME other than inhalation and infusion drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category.

Lead item is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

Mail order contract supplier is a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Mail order item means any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary's home, regardless of the method of delivery.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.

National mail order DMEPOS competitive bidding program means a program whereby contracts are awarded to suppliers for the furnishing of mail order items across the nation.

Nationwide competitive bidding area means a CBA that includes the United States, its Territories, and the District of Columbia.

Nationwide mail order contract supplier means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.

Network means a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire CBA.

Noncontract supplier means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.

Non-mail order item means any item (for example, diabetic testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront.

Parties to the hearing means the DMEPOS contract supplier and CMS.

Physician has the same meaning as in section 1861(r) of the Act.

Pivotal bid means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

Price inversion means any situation where the following occurs: One item (HCPCS code) in a grouping of similar items (*e.g.*, walkers, enteral infusion pumps, or power wheelchairs) in a product category includes a feature that another, similar item in the same product category does not have (*e.g.*, wheels, alarm, or Group 2 performance); the average of the 2015 fee schedule amounts (or initial, unadjusted fee schedule amounts for subsequent years for new items) for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and, following a competition, the SPA for the code with the feature is lower than the SPA for the code without that feature.

Product category means a grouping of related items that are used to treat a similar medical condition.

Regional competitive bidding area means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.

Regional mail order contract supplier means a mail order contract supplier that furnishes items in a regional competitive bidding area.

Single payment amount means the allowed payment for an item furnished under a competitive bidding program.

Small supplier means, a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue.

Supplier means an entity with a valid Medicare supplier number, including

an entity that furnishes an item through the mail.

Total nationwide allowed services means the total number of services allowed for an item furnished in all states, territories, and the District of Columbia where Medicare beneficiaries reside and can receive covered DMEPOS items and services.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

Weighted bid means the item weight multiplied by the bid price submitted for that item.

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73622, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011; 81 FR 77966, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018; 86 FR 42422, Aug. 4, 2021]

§ 414.404 Scope and applicability.

(a) *Applicability*. Except as specified in paragraph (b) of this section, this subpart applies to all suppliers that furnish the items defined in § 414.402 to beneficiaries, including providers, physicians, treating practitioners, physical therapists, and occupational therapists that furnish such items under Medicare Part B.

(b) *Exceptions*. (1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

(i) The items furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME, and off-the-shelf (OTS) orthotics.

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

(2) A physical therapist in private practice (as defined in § 410.60(c) of this chapter) or an occupational therapist in private practice (as defined in § 410.59(c) of this chapter) may furnish competitively bid off-the-shelf orthotics without submitting a bid and being awarded a contract under this subpart, provided that the items are furnished only to the therapist's own patients as part of the physical or occupational therapy service.

(3) Payment for items furnished in accordance with paragraphs (b)(1) and (b)(2) of this section will be paid in accordance with § 414.408(a).

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011]

§ 414.406 Implementation of programs.

(a) *Implementation contractor*. CMS designates one or more implementation contractors for the purpose of implementing this subpart.

(b) *Competitive bidding areas*. CMS designates through program instructions or by other means, such as the request for bids, each CBA in which a competitive bidding program may be implemented under this subpart.

(c) *Revisions to competitive bidding areas*. CMS may revise the CBAs designated under paragraph (b) of this section.

(d) *Competitively bid items*. CMS designates the items that are included in a competitive bidding program through program instructions or by other means

(e) *Claims processing*. The Durable Medical Equipment Medicare Administrative Contractor designated to process DMEPOS claims for a particular geographic region also processes claims for items furnished under a competitive bidding program in the same geographic region.

[71 FR 48409, Aug. 18, 2006, as amended at 72 FR 18085, Apr. 10, 2007]

§ 414.408 Payment rules.

(a) *Payment basis*. (1) The payment basis for an item furnished under a

competitive bidding program is 80 percent of the single payment amount calculated for the item under § 414.416 for the CBA in which the beneficiary maintains a permanent residence.

(2) If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item is 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item, as determined under subpart C or subpart D.

(b) *No changes to the single payment amount.* The single payment amount calculated for each item under each competitive bidding program is paid for the duration of the competitive bidding program and will not be adjusted by any update factor.

(c) *Payment on an assignment-related basis.* Payment for an item furnished under this subpart is made on an assignment-related basis.

(d) *Applicability of advanced beneficiary notice.* Implementation of a program in accordance with this subpart does not preclude the use of an advanced beneficiary notice.

(e) *Requirement to obtain competitively bid items from a contract supplier.* (1) *General rule.* Except as provided in paragraph (e)(2) of this section, all items that are included in a competitive bidding program must be furnished by a contract supplier for that program.

(2) *Exceptions.* (i) A grandfathered supplier may furnish a grandfathered item to a beneficiary in accordance with paragraph (j) of this section.

(ii) Medicare may make a secondary payment for an item furnished by a noncontract supplier that the beneficiary is required to use under his or her primary insurance policy. The provisions of this paragraph do not supersede Medicare secondary payer statutory and regulatory provisions, including the Medicare secondary payment rules located in §§ 411.32 and 411.33 of this subchapter, and payment will be calculated in accordance with those rules.

(iii) If a beneficiary is outside of the CBA in which he or she maintains a permanent residence, he or she may obtain an item from a—

(A) Contract supplier, if the beneficiary obtains the item in another CBA and the item is included in the competitive bidding program for that CBA; or

(B) Supplier with a valid Medicare billing number, if the beneficiary obtains the item in an area that is not a CBA, or if the beneficiary obtains the item in another CBA but the item is not included in the competitive bidding program for that CBA.

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with § 414.404(b) of this subpart.

(3) Unless paragraph (e)(2) of this section applies:

(i) Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section, and

(ii) A beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA in violation of paragraph (e)(1) of this section, unless the beneficiary has signed an advanced beneficiary notice.

(4) CMS separately designates the Medicare billing number of all noncontract suppliers to monitor compliance with paragraphs (e)(1) and (e)(2) of this section.

(f) *Purchased equipment.* (1) The single payment amounts for new purchased durable medical equipment, including power wheelchairs that are purchased when the equipment is initially furnished and enteral nutrition equipment are calculated based on the bids submitted and accepted for these items. For contracts entered into beginning on or after January 1, 2011, payment on a lump sum purchase basis is only available for power wheelchairs classified as complex rehabilitative power wheelchairs.

(2) Payment for used purchased durable medical equipment and enteral nutrition equipment is made in an amount equal to 75 percent of the single payment amounts calculated for new purchased equipment under paragraph (f)(1) of this section.

(g) *Purchased supplies and orthotics.* The single payment amounts for the following purchased items are calculated based on the bids submitted and accepted for the following items:

(1) Supplies used in conjunction with durable medical equipment.

(2) Enteral nutrients.

(3) Enteral nutrition supplies.

(4) OTS orthotics.

(h) *Rented equipment*—(1) *Capped rental DME.* Subject to the provisions of paragraph (h)(2) of this section, payment for capped rental durable medical equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(2) For contracts entered into beginning on or after January 1, 2011, the monthly fee schedule amount for rental of power wheelchairs equals 15 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 6 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(3) *Additional payment to certain contract suppliers for capped rental DME.* (i) Except as specified in paragraph (h)(3)(ii) of this section, Medicare makes 13 monthly payments to a contract supplier that furnishes capped rental durable medical equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section. Payment is made using the methodology described in paragraph (h)(1) of this section. The contract supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made in accordance with this paragraph.

(ii) Medicare does not make payment to a contract supplier under paragraph (h)(3)(i) of this section if the contract supplier furnishes capped rental durable medical equipment to a beneficiary who previously rented the equipment from another contract supplier.

(4) *Maintenance and servicing of rented DME.* Separate maintenance and servicing payments are not made for any rented durable medical equipment.

(5) *Payment for rented enteral nutrition equipment.* Payment for rented enteral nutrition equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new enteral nutrition equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amount calculated for these items under paragraph (f)(1) of this section for each of the remaining months 4 through 15. The contract supplier to which payment is made in month 15 for furnishing enteral nutrition equipment on a rental basis must continue to furnish, maintain and service the equipment until a determination is made by the beneficiary's physician or treating practitioner that the equipment is no longer medically necessary.

(6) *Maintenance and servicing of rented enteral nutrition equipment.* Payment for the maintenance and servicing of rented enteral nutrition equipment beginning 6 months after 15 months of rental payments is made in an amount equal to 5 percent of the single payment amounts calculated for these items under paragraph (f)(1) of this section.

(7) *Payment for inexpensive or routinely purchased durable medical equipment.* Payment for inexpensive or routinely purchased durable medical equipment furnished on a rental basis is made in an amount equal to 10 percent of the single payment amount calculated for new purchased equipment.

(8) *Payment amounts for rented DME requiring frequent and substantial servicing*—(i) *General rule.* Except as provided in paragraph (h)(7)(ii) of this section, the single payment amounts for rented durable medical equipment requiring frequent and substantial servicing are calculated based on the rental bids submitted and accepted for the furnishing of these items on a monthly basis.

(ii) *Exception.* The single payment amounts for continuous passive motion exercise devices are calculated based

on the bids submitted and accepted for the furnishing of these items on a daily basis.

(i) *Monthly payment amounts for oxygen and oxygen equipment*—(1) *Basic payment amount.* Subject to the provisions of paragraph (i)(2) of this section, the single payment amounts for oxygen and oxygen equipment are calculated based on the bids submitted and accepted for the furnishing on a monthly basis of each of the five classes of oxygen and oxygen equipment described in § 414.226(c)(1).

(2) *Additional payment to certain contract suppliers.* (i) Except as specified in paragraph (i)(2)(iii) of this section, Medicare makes monthly payments to a contract supplier that furnishes oxygen equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section as follows:

(A) If Medicare made 26 or less monthly payments to the former supplier, Medicare makes a monthly payment to the contract supplier for up to the number of months equal to the difference between 36 and the number of months for which payment was made to the former supplier.

(B) If Medicare made 27 or more monthly payments to the former supplier, Medicare makes 10 monthly payments to the contract supplier.

(ii) Payment is made using the methodology described in paragraph (i)(1) of this section. On the first day after the month in which the final rental payment is made under paragraph (i)(2)(i) of this section, the contract supplier must transfer title of the oxygen equipment to the beneficiary.

(iii) Medicare does not make payment to a contract supplier under paragraph (i)(2) of this section if the contract supplier furnishes oxygen equipment to a beneficiary who previously rented the equipment from another contract supplier.

(j) *Special rules for certain rented durable medical equipment and oxygen and oxygen equipment*—(1) *Supplier election.* (i) A supplier that is furnishing durable medical equipment or is furnishing oxygen or oxygen equipment on a rental basis to a beneficiary prior to the implementation of a competitive bidding program in the CBA where the beneficiary maintains a permanent residence may elect to continue furnishing the item as a grandfathered supplier.

(ii) A supplier that elects to be a grandfathered supplier must continue to furnish the grandfathered items to all beneficiaries who elect to continue receiving the grandfathered items from that supplier for the remainder of the rental period for that item.

(2) *Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA.* Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA is made as follows:

(i) For inexpensive and routinely purchased items described in § 414.220(a), payment is made in the amount determined under § 414.220(b).

(ii) For other durable medical equipment or capped rental items described in § 414.229, payment is made in the amount determined under § 414.229(b).

(iii) For items requiring frequent and substantial servicing described in § 414.222, payment is made in accordance with paragraph (a)(1) of this section.

(iv) For oxygen and oxygen equipment described in § 414.226(c)(1), payment is made in accordance with paragraph (a)(1) of this section.

(3) *Payment for grandfathered items furnished during all subsequent competitive bidding programs in a CBA.* Beginning with the second competitive bidding program implemented in a CBA, payment is made for grandfathered items in accordance with paragraph (a)(1) of this section.

(4) *Choice of suppliers.* (i) Beneficiaries who are renting an item that meets the definition of a grandfathered item in § 414.402 of this subpart may elect to obtain the item from a grandfathered supplier.

(ii) A beneficiary who is otherwise entitled to obtain a grandfathered item from a grandfathered supplier under paragraph (j) of this section may elect to obtain the same item from a contract supplier at any time after a competitive bidding program is implemented.

(iii) If a beneficiary elects to obtain the same item from a contract supplier, payment is made for the item accordance with paragraph (a)(1) of this section.

(5) *Notification of beneficiaries and CMS by suppliers that choose to become grandfathered suppliers.* (i) *Notification of beneficiaries by suppliers.* (A) *Requirements of notification.* A noncontract supplier that elects to become a grandfathered supplier must provide a 30-day written notification to each Medicare beneficiary that resides in a competitive bidding area and is currently renting a competitively bid item from that supplier. The 30-day notification to the beneficiary must meet the following requirements:

(*1*) Be sent by the supplier to the beneficiary at least 30 business days before the start date of the implementation of the competitive bidding program for the CBA in which the beneficiary resides.

(*2*) Identify the grandfathered items that the supplier is willing to continue to rent to the beneficiary.

(*3*) Be in writing (for example, by letter or postcard) and the supplier must maintain proof of delivery.

(*4*) State that the supplier is willing to continue to furnish certain rented Durable Medical Equipment (DME), oxygen and oxygen equipment, and supplies that the supplier is currently furnishing to the beneficiary (that is, before the start of the competitive bidding program) and is willing to continue to provide these items to the beneficiary for the remaining rental months.

(*5*) State that the beneficiary has the choice to continue to receive a grandfathered item(s) from the grandfathered supplier or may elect to receive the item(s) from a contract supplier after the end of the last month for which a rental payment is made to the noncontract supplier.

(*6*) Provide the supplier's telephone number and instruct the beneficiary to call the supplier with any questions and to notify the supplier of his or her decision to use or not use the supplier as a grandfathered supplier.

(*7*) State that the beneficiary can obtain information about the competitive bidding program by calling 1–800–MEDICARE or on the Internet at *http://www.Medicare.gov*.

(B) *Record of beneficiary's choice.* The supplier should obtain an election from the beneficiary regarding whether to use or not use the supplier as a grandfathered supplier. The supplier must maintain a record of its attempts to communicate with the beneficiary to obtain the beneficiary's election regarding grandfathering. When the supplier obtains such an election, the supplier must maintain a record of the beneficiary decision including the date the choice was made, and how the beneficiary communicated his or her choice to the supplier.

(C) *Notification.* If the beneficiary chooses not to continue to receive a grandfathered item(s) from their current supplier, the supplier must provide the beneficiary with 2 more notices in addition to the 30-day notice prior to the supplier picking up its equipment.

(*1*) *10-day notification:* Ten business days prior to picking up the item, the supplier should have direct contact (for example, a phone call) with the beneficiary or the beneficiary's caregiver and receive acknowledgement that the beneficiary understands their equipment will be picked up. This should occur on the first anniversary date after the start of the CBP or on another date agreed to by the beneficiary or the beneficiary's caregiver. The beneficiary's anniversary date occurs every month and is the date of the month on which the item was first delivered to the beneficiary by the current supplier. When a date other than the anniversary date is chosen by the beneficiary or the beneficiary's caregiver, the noncontract supplier will still receive payment up to the anniversary date after the start of the CBP, and the new contract supplier may not bill for any period of time before the anniversary date.

(*2*) *2-day notification:* Two business days prior to picking up the item the supplier should contact the beneficiary or the beneficiary's caregiver by phone to notify the beneficiary of the date the supplier will pick up the item. This date should not be before the beneficiary's first anniversary date that occurs after the start of the competitive

bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(D) *Pickup procedures.* (*1*) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(*2*) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(*3*) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are suitable to the beneficiary.

(*4*) The contract supplier may not submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP, and the contract supplier may not begin billing until the first anniversary date that occurs after the beginning of the CBP.

(*5*) The noncontract supplier must submit a claim to be paid up to the first anniversary date that occurs after the beginning of the CBP. Therefore, they should not pick up the equipment before that date unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(ii) *Notification to CMS by suppliers.* A noncontract supplier that elects to become a grandfathered supplier must provide a written notification to CMS of this decision. This notification must meet the following requirements:

(A) State that the supplier agrees to continue to furnish certain rented DME, oxygen and oxygen equipment that it is currently furnishing to beneficiaries (that is, before the start of the competitive bidding program) in a CBA and will continue to provide these items to these beneficiaries for the remaining months of the rental period.

(B) Include the following information:

(*1*) Name and address of the supplier.

(*2*) The 6-digit NSC number of the supplier.

(*3*) Product category(s) by CBA for which the supplier is willing to be a grandfathered supplier.

(C) State that the supplier agrees to meet all the terms and conditions pertaining to grandfathered suppliers.

(D) Be provided by the supplier to CMS in writing at least 30 business days before the start date of the implementation of the Medicare DMEPOS Competitive Bidding Program.

(6) *Suppliers that choose not to become grandfathered suppliers.* (i) *Requirement for non-grandfathered supplier.* A noncontract supplier that elects not to become a grandfathered supplier is required to pick up the item it is currently renting to the beneficiary from the beneficiary's home after proper notification.

(ii) *Notification.* Proper notification includes a 30-day, a 10-day, and a 2-day notice of the supplier's decision not to become a grandfathered supplier to its Medicare beneficiaries who are currently renting certain DME competitively bid item(s) and who reside in a CBA.

(iii) *Requirements of notification.* These notifications must meet all of the requirements listed in paragraph (j)(5)(i) of this section for the 30-day, 10-day and 2-day notices that must be sent by suppliers who decide to be grandfathered suppliers, with the following exceptions for the 30-day notice.

(A) State that, for those items for which the supplier has decided not to be a grandfathered supplier, the supplier will only continue to rent these competitively bid item(s) to its beneficiaries up to the first anniversary date that occurs after the start of the Medicare DMEPOS Competitive Bidding Program.

(B) State that the beneficiary must select a contract supplier for Medicare to continue to pay for these items.

(C) Refer the beneficiary to the contract supplier locator tool on and to 1–800–MEDICARE to obtain information

about the availability of contract suppliers for the beneficiary's area.

(iv) *Pickup procedures.* (A) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(B) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(C) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are agreeable to the beneficiary.

(D) The contract supplier cannot submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP.

(7) *Payment for accessories and supplies for grandfathered items.* Accessories and supplies that are used in conjunction with and are necessary for the effective use of a grandfathered item may be furnished by the same grandfathered supplier that furnishes the grandfathered item. Payment is made in accordance with paragraph (a)(1) of this section.

(k) *Payment for maintenance, servicing and replacement of beneficiary-owned items.* (1) Payment is made for the maintenance and servicing of beneficiary-owned items, provided the maintenance and servicing is performed by a contract supplier or a noncontract supplier having a valid Medicare billing number, as follows:

(i) Payment for labor is made in accordance with §414.210(e)(1) of subpart D.

(ii) Payment for parts that are not items (as defined in §414.402) is made in accordance with §414.210(e)(1) of subpart D.

(iii) Payment for parts that are items (as defined in §414.402) is made in accordance with paragraph (a)(1) of this section.

(2) Additional payments are made in accordance with §414.210(e)(2), (e)(3) and (e)(5) of this part for the maintenance and servicing of oxygen equipment if performed by a contract supplier or a noncontract supplier having a valid Medicare billing number.

(3) Beneficiaries must obtain a replacement of a beneficiary-owned item, other than parts needed for the repair of beneficiary-owned equipment from a contract supplier. Payment is made for the replacement item in accordance with paragraph (a)(1) of this section.

(l) *Exceptions for certain items and services paid in accordance with special payment rules.* The payment rules in paragraphs (f) thru (h), (j)(2), (j)(3), and (j)(7), and (k) of this section do not apply to items and services paid in accordance with the special payment rules at §414.409.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014]

§414.409 Special payment rules.

(a) *Payment on a bundled, continuous rental basis.* In no more than 12 CBAs, in conjunction with competitions that begin after January 1, 2015, payment is made on a bundled, continuous monthly rental basis for standard power wheelchairs and continuous positive airway pressure (CPAP) devices. The CBAs and competitions where these payment rules apply are announced in advance of each competition, with the payment rules in this section used in lieu of the payment rules at §414.408(f) thru (h), (j)(2), (j)(3), and (j)(7), and (k). The single payment amounts are established based on bids submitted and accepted for furnishing rented standard power wheelchairs and CPAP devices on a monthly basis for each month of medical need during the contract period. The single payment amount for the monthly rental of the DME includes payment for the rented equipment, maintenance and servicing of the rented equipment, and replacement of supplies and accessories necessary for

the effective use of the rented equipment. Separate payment for replacement of equipment, repair or maintenance and servicing of equipment, or for replacement of accessories and supplies necessary for the effective use of equipment is not allowed under any circumstance.

(b) *Payment for grandfathered DME items paid on a bundled, continuous rental basis.* Payment to a supplier that elects to be a grandfathered supplier of DME furnished in CBPs where these special payment rules apply is made in accordance with § 414.408(a)(1).

(c) *Supplier transitions for DME paid on a bundled, continuous rental basis.* Changes from a non-contract supplier to a contract supplier at the beginning of a CBP where payment is made on a bundled, continuous monthly rental basis results in the contract supplier taking on responsibility for meeting all of the monthly needs for furnishing the covered DME. In the event that a beneficiary relocates from a CBA where these special payment rules apply to an area where rental cap rules apply, a new period of continuous use begins for the capped rental item as long as the item is determined to be medically necessary.

(d) *Responsibility for repair and maintenance and servicing of power wheelchairs.* In no more than 12 CBAs where payment for power wheelchairs is made on a capped rental basis, for power wheelchairs furnished in conjunction with competitions that begin after January 1, 2015, contract suppliers that furnish power wheelchairs under contracts awarded based on these competitions shall continue to repair power wheelchairs they furnish following transfer of title to the equipment to the beneficiary. The responsibility of the contract supplier to repair, maintain and service beneficiary-owned power wheelchairs does not apply to power wheelchairs that the contract supplier did not furnish to the beneficiary. For power wheelchairs that the contract supplier furnishes during the contract period, the responsibility of the contract supplier to repair, maintain and service the power wheelchair once it is owned by the beneficiary continues until the reasonable useful lifetime of the equipment expires, coverage for the power wheelchair ends, or the beneficiary relocates outside the CBA where the item was furnished. The contract supplier may not charge the beneficiary or the program for any necessary repairs or maintenance and servicing of a beneficiary-owned power wheelchair it furnished during the contract period.

[79 FR 66264, Nov. 6, 2014]

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs—

(1) In CY 2009, in Cincinnati—Middletown (Ohio, Kentucky and Indiana), Cleveland—Elyria—Mentor (Ohio), Charlotte—Gastonia—Concord (North Carolina and South Carolina), Dallas—Fort Worth—Arlington (Texas), Kansas City (Missouri and Kansas), Miami—Fort Lauderdale—Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside—San Bernardino—Ontario (California).

(2) In CY 2011, in an additional 91 MSAs (the additional 70 MSAs selected by CMS as of June 1, 2008, and the next 21 largest MSAs by total population based on 2009 population estimates, and not already phased in as of June 1, 2008). CMS may subdivide any of the 91 MSAs with a population of greater than 8,000,000 into separate CBAs, thereby resulting in more than 91 CBAs.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

(4) For competitions (other than for national mail order items and services) after CY 2011 and prior to CY 2015, the following areas are excluded:

(i) Rural areas.

(ii) MSAs not selected under paragraphs (a)(1) or (a)(2) of this section with a population of less than 250,000.

(iii) An area with low population density within an MSA not selected under paragraphs (a)(1) or (a)(2) of this section.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating CBAs in CY 2007 and CY 2009 by considering the following variables:

(1) The total population of an MSA.

(2) The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.

(3) The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.

(4) An MSA's geographic location.

(c) *Exclusions from a CBA.* CMS may exclude from a CBA a rural area (as defined in §412.64(b)(1)(ii)(C) of this subchapter), or an area with low population density based on one or more of the following factors—

(1) Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare fee-for-service beneficiaries relative to similar geographic areas.

(d) *Selection of additional CBAs after CY 2009.* (1) Beginning after CY 2009, CMS designates through program instructions or by other means additional CBAs based on CMS' determination that the implementation of a competitive bidding program in a particular area would be likely to result in significant savings to the Medicare program.

(2) Beginning after CY 2009, CMS may designate through program instructions or by other means a nationwide CBA or one or more regional CBAs for purposes of implementing competitive bidding programs for items that are furnished through the mail by nationwide or regional mail order contract suppliers.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011]

§414.411 Special rule in case of competitions for diabetic testing strips conducted on or after January 1, 2011.

(a) *National mail order competitions.* A supplier must demonstrate that their bid submitted as part of a national mail order competition for diabetic testing strips covers the furnishing of a sufficient number of different types of diabetic testing strip products that, in the aggregate, and taking into account volume for the different products, includes at least 50 percent of all the different types of products on the market. A type of diabetic testing strip means a specific brand and model of testing strips.

(b) *Other competitions.* CMS may apply this special rule to non-mail order or local competitions for diabetic testing strips.

[75 FR 73623, Nov. 29, 2010]

§414.412 Submission of bids under a competitive bidding program.

(a) *Requirement to submit a bid.* Except as provided under §414.404(b), in order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must submit a bid to furnish those items and be awarded a contract under this subpart.

(b) *Grouping of items into product categories.* (1) Composite bids, as defined in §414.402, are submitted for lead items, as defined in §414.402.

(2) The bid submitted for each lead item and product category cannot exceed the payment amount that would otherwise apply to the lead item under subpart C of this part, without the application of §414.210(g), or subpart D of this part, without the application of §414.105.

(3) The bids submitted for standard power wheelchairs paid in accordance with the special payment rules at §414.409(a) cannot exceed the average monthly payment for the bundle of items and services that would otherwise apply to the item under subpart D of this part.

(4) The bids submitted for continuous positive airway pressure (CPAP) devices paid in accordance with the special payment rules at §414.409(a) cannot exceed the 1993 fee schedule amounts for these items, increased by the covered item update factors provided for these items in section 1834(a)(14) of the Act.

(5) Suppliers shall take into consideration the special payment rules at §414.409(d) when submitting bids for furnishing power wheelchairs under competitions where these rules apply.

(c) *Furnishing of items.* A bid must include all costs related to furnishing all

items in the product category, including all services directly related to the furnishing of the items.

(d) *Commonly-owned or controlled suppliers.* (1) For purposes of this paragraph—

(i) An ownership interest is the possession of equity in the capital, stock or profits of another supplier;

(ii) A controlling interest exists if one or more of owners of a supplier is an officer, director or partner in another supplier; and

(iii) Two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s).

(2) A supplier must disclose in its bid each supplier in which it has an ownership or controlling interest and each supplier which has an ownership or controlling interest in it.

(3) Commonly-owned or controlled suppliers must submit a single bid to furnish a product category in a CBA. Each commonly-owned or controlled supplier that is located in the CBA for which the bid is being submitted must be included in the bid. The bid must also include any commonly-owned or controlled supplier that is located outside of the CBA but would furnish the product category to the beneficiaries who maintain a permanent residence in the CBA.

(e) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in a CBA in which a mail order competitive bidding program that includes the items is implemented.

(2) Suppliers that submit one or more bids under (e)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(f) *Applicability of the mail order competitive bidding program.* Suppliers that do not furnish items through the mail are not required to participate in a nationwide or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A CBA, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a CBA.

(g) *Requiring bid surety bonds for bidding entities*—(1) *Bidding requirements.* For competitions beginning on or after January 1, 2017, and no later than January 1, 2019, a bidding entity may not submit a bid(s) for a CBA unless it obtains a bid surety bond for the CBA from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provides proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission.

(2) *Bid surety bond requirements.* (i) The bid surety bond issued must include at a minimum:

(A) The name of the bidding entity as the principal/obligor;

(B) The name and National Association of Insurance Commissioners number of the authorized surety;

(C) CMS as the named obligee;

(D) The conditions of the bond as specified in paragraph (g)(3) of this section;

(E) The CBA covered by the bond;

(F) The bond number;

(G) The date of issuance; and

(H) The bid bond value of $50,000.00.

(ii) The bid surety bond must be maintained until it is either collected upon due to forfeiture or the liability is returned for not meeting bid forfeiture conditions.

(3) *Forfeiture of bid surety bond.* (i) When a bidding entity is offered a contract for a CBA/product category (''competition'') and its composite bid for the competition is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts within the competition and the bidding entity does not accept the contract offer, its bid surety bond submitted for that CBA will be forfeited and CMS will collect on the bond via Electronic Funds Transfer (EFT) from the respective bonding company. As one bid surety bond is required for each CBA in which the bidding entity is submitting a bid, the failure to accept a contract offer for any product category within the CBA when the entity's bid is at or below the median composite bid rate will result in forfeiture of the bid surety bond for that CBA.

(ii) Where the bid(s) does not meet the specified forfeiture conditions in paragraph (h)(3)(i) of this section, the

bid surety bond liability will be returned within 90 days of the public announcement of contract suppliers for the CBA. CMS will notify the bidding entity that it did not meet the specified forfeiture requirements and the bid surety bond will not be collected by CMS.

(4) *Penalties.* (i) A bidding entity that has been determined to have falsified its bid surety bond may be prohibited from participation in the DMEPOS Competitive Bidding Program for the current round of the Competitive Bidding Program in which it submitted a bid and also from participating in the next round of the Competitive Bidding Program. Offending suppliers will also be referred to the Office of Inspector General and Department of Justice for further investigation.

(ii) A bidding entity, whose composite bid is at or below the median composite bid rate, that—

(A) Accepts a contract award; and

(B) Is found to be in breach of contract for nonperformance of the contract to avoid forfeiture of the bid surety bond will have its contract terminated and will be precluded from participation in the in the next round of the DMEPOS Competitive Bidding Program.

[72 FR 18085, Apr. 10, 2007, as amended at 79 FR 66264, Nov. 6, 2014; 81 FR 77966, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018]

§414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each supplier must meet the enrollment standards specified in §424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids. CMS may not award a contract to any entity in a CBA unless the entity meets applicable State licensure requirements.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in §414.418.

(c) *Quality standards and accreditation.* Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the requirements of §424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards*—(1) *General rule.* Each supplier must submit along with its bid the applicable covered documents (as defined in §414.402) specified in the request for bids.

(2) *Process for reviewing covered documents*—(i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents.* (A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to notify suppliers of any missing covered documents.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of

missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

(e) Evaluation of bids. CMS evaluates composite bids submitted for a lead item within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the lead item in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category;

(3) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(4) Calculating the pivotal bid for the product category; and

(5) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D.

(g) *Special rules for small suppliers*—(1) *Target for small supplier participation.* CMS ensures that small suppliers have the opportunity to participate in a competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under § 414.416 of this subpart.

(h) *Sufficient number of suppliers.* (1) Except as provided in paragraph (h)(3) of this section. CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the product category calculated under paragraph (e)(1) of this section.

(3) The provisions of paragraph (h)(1) of this section do not apply to regional or nationwide mail order CBAs under § 414.410(d)(2) of this subpart.

(i) *Selection of new suppliers after bidding.* (1) Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program. CMS selects additional contract suppliers by—

(i) Referring to the arrayed list of suppliers that submitted bids for the product category included in the competitive bidding program for which beneficiary demand is not being met; and

(ii) Beginning with the supplier whose composite bid is the first composite bid above the pivotal bid for that product category, determining if that supplier is willing to become a contract supplier under the same terms and conditions that apply to other contract suppliers in the CBA.

(2) Before CMS awards additional contracts under paragraph (i)(1) of this section, a supplier must submit updated information demonstrating that the supplier meets the requirements under paragraphs (b) through (d) of this section.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014; 81 FR 77967, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018]

§ 414.416 Determination of competitive bidding payment amounts.

(a) *General rule.* CMS establishes a single payment amount for each item furnished under a competitive bidding program.

(b) *Methodology for setting payment amount.* (1) The single payment amount for a lead item furnished under a competitive bidding program is equal to the maximum bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category.

(2) The single payment amount for a lead item must be less than or equal to the amount that would otherwise be paid for the same item under subpart C or subpart D of this part.

(3) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product category is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, the United States Virgin Islands), for the item to the average of the 2015 fee schedule amounts for all areas for the lead item.

[72 FR 18085, Apr. 10, 2007, as amended at 81 FR 77967, Nov. 4, 2016; 83 FR 57072, Nov. 14, 2018]

§ 414.418 Opportunity for networks.

(a) A network may be comprised of at least 2 but not more than 20 small suppliers.

(b) The following rules apply to networks that seek contracts under this subpart:

(1) Each network must form a single legal entity that acts as the bidder and submits the bid. Any agreement entered into for purposes of forming a network must be submitted to CMS. The network must identify itself as a network and identify all of its members.

(2) Each member of the network must satisfy the requirements in § 414.414(b) through (d).

(3) A small supplier may join one or more networks but cannot submit an individual bid to furnish the same product category in the same CBA as any network in which it is a member. A small supplier may not be a member of more than one network if those networks submit bids to furnish the same product category in the same CBA.

(4) The network cannot be anticompetitive, and this section does not supersede any Federal law or regulation that regulates anticompetitive behavior.

(5) A bid submitted by a network must include a statement from each network member certifying that the network member joined the network because it is unable independently to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.

(6) At the time that a network submits a bid, the network's total market share for each product category that is the subject of the network's bid cannot exceed 20 percent of the Medicare demand for that product category in the CBA.

(c) If the network is awarded a contract, each supplier must submit its own claims and will receive payment directly from Medicare for the items that it furnishes under the competitive bidding program.

[72 FR 18085, Apr. 10, 2007]

§ 414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

(a) *Prescription for a particular brand item or mode of delivery.* (1) A physician or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under

a competitive bidding program, or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary.

(2) When a physician or treating practitioner prescribes a particular brand or mode of delivery of an item under paragraph (a)(1) of this section, the physician or treating practitioner must document the reason in the beneficiary's medical record why the particular brand or mode of delivery is medically necessary to avoid an adverse medical outcome.

(b) *Furnishing of a prescribed particular brand item or mode of delivery.* If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must—

(1) Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;

(2) Consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or

(3) Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

(c) *Payment for a particular brand of item or mode of delivery.* Medicare does not make an additional payment to a contract supplier that furnishes a particular brand or mode of delivery for an item, as directed by a prescription written by the beneficiary's physician or treating practitioner.

(d) *Prohibition on billing for an item different from the particular brand of item or mode of delivery prescribed.* A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner. Payment will not be made to a contract supplier that submits a claim prohibited by this paragraph.

[72 FR 18085, Apr. 10, 2007]

§ 414.422 Terms of contracts.

(a) *Basic rule.* CMS specifies the terms and conditions of the contracts entered into with contract suppliers under this subpart. A contract supplier must comply with all terms of its contract, including any option exercised by CMS, for the full duration of the contract period.

(b) *Recompeting competitive bidding contracts.* CMS recompetes competitive bidding contracts at least once every 3 years.

(c) *Nondiscrimination.* The items furnished by a contract supplier under this subpart must be the same items that the contract supplier makes available to other customers.

(d) *Change of ownership (CHOW).* (1) CMS may transfer a contract to a successor entity that merges with, or acquires, a contract supplier if the successor entity—

(i) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) Submits to CMS the documentation described under §414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously submitted information is not needed to make a financial determination. This documentation must be submitted prior to the effective date of the CHOW; and

(iii) Submits to CMS a signed novation agreement acceptable to CMS stating that it assumes all obligations under the contract. This documentation must be submitted no later than 10 days after the effective date of the CHOW.

(2) Except as specified in paragraph (d)(3) of this section, CMS may transfer the entire contract, including all product categories and competitive bidding areas, to a successor entity.

(3) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company (for example, a subsidiary) that furnishes a specific product category or services a specific CBA, CMS may transfer the

portion of the contract performed by that company to a successor entity, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the successor entity that meets all competitive bidding requirements; that is, financial, accreditation, and licensure;

(ii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iii) All requirements of paragraph (d)(1) of this section are met;

(iv) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(v) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

(e) *Furnishing of items.* Except as otherwise prohibited under section 1877 of the Act, or any other applicable law or regulation:

(1) A contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier.

(2) A skilled nursing facility defined under section 1819(a) of the Act or a nursing facility defined under section 1919(a) of the Act that has elected to furnish items only to its own residents and that is also a contract supplier may furnish items under a competitive bidding program to its own patients to whom it would otherwise furnish Part B services.

(3) Contract suppliers for diabetic testing supplies must furnish the brand of diabetic testing supplies that work with the home blood glucose monitor selected by the beneficiary. The contract supplier is prohibited from influencing or incentivizing the beneficiary by persuading, pressuring, or advising them to switch from their current brand or for new beneficiaries from their preferred brand of glucose monitor and testing supplies. The contract supplier may not furnish information about alternative brands to the beneficiary unless the beneficiary requests such information.

(f) *Disclosure of subcontracting arrangements.* (1) *Initial disclosure.* Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) *Subsequent disclosure.* Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

(g) *Breach of contract.* (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions, which will be specified in the notice of breach of contract:

(i) Suspend the contract supplier's contract;

(ii) Terminate the contract;

(iii) Preclude the contract supplier from participating in the competitive bidding program; or

(iv) Avail itself of other remedies allowed by law.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2881, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014; 81 FR 77967, Nov. 4, 2016; 83 FR 57073, Nov. 14, 2018; 84 FR 60808, Nov. 8, 2019]

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

This section implements an appeals process for suppliers that CMS has determined are in breach of their Medicare DMEPOS Competitive Bidding Program contract and where CMS has issued a notice of breach of contract indicating its intent to take action(s) pursuant to § 414.422(g)(2).

(a) *Breach of contract.* CMS may take one or more of the actions specified in § 414.422(g)(2) as a result of a supplier's breach of their DMEPOS Competitive Bidding Program contract.

(b) *Notice of breach of contract*—(1) *CMS notification.* If CMS determines a supplier to be in breach of its contract, it will notify the supplier of the breach of contract in a notice of breach of contract.

(2) *Content of the notice of breach of contract.* The CMS notice of breach of contract will include the following:

(i) The details of the breach of contract.

(ii) The action(s) that CMS is taking as a result of the breach of the contract pursuant to § 414.422(g)(2), and the duration of or timeframe(s) associated with the action(s), if applicable.

(iii) The right to request a hearing by a CBIC hearing officer and, depending on the nature of the breach, the supplier may also be allowed to submit a corrective action plan (CAP) in lieu of requesting a hearing by a CBIC hearing officer, as specified in paragraph (c)(1)(i) of this section.

(iv) The address to which the written request for a hearing must be submitted.

(v) The address to which the CAP must be submitted, if applicable.

(vi) The effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless:

(A) A timely hearing request has been filed; or

(B) A CAP has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.

(c) *Corrective action plan (CAP)*—(1) *Option for a CAP.* (i) CMS has the option to allow a supplier to submit a written CAP to remedy the deficiencies identified in the notice at its sole discretion, including where CMS determines that the delay in the effective date of the breach of contract action(s) caused by allowing a CAP will not cause harm to beneficiaries. CMS will not allow a CAP if the supplier has been excluded from any Federal program, debarred by a Federal agency, or convicted of a healthcare-related crime, or for any other reason determined by CMS.

(ii) If a supplier chooses not to submit a CAP, if CMS determines that a supplier's CAP is insufficient, or if CMS does not allow the supplier the option to submit a CAP, the supplier may request a hearing on the breach of contract action(s).

(2) *Submission of a CAP.* (i) If allowed by CMS, a CAP must be submitted within 30 days from the date on the notice of breach of contract. If the supplier decides not to submit a CAP the supplier may, within 30 days of the date on the notice, request a hearing by a CBIC hearing officer.

(ii) Suppliers will have the opportunity to submit a CAP when they are first notified that they have been determined to be in breach of contract. If the CAP is not acceptable to CMS or is not properly implemented, suppliers will receive a subsequent notice of breach of contract. The subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant to paragraph (c)(1)(i) of this section.

(d) *The purpose of the CAP.* The purpose of the CAP is:

(1) For the supplier to remedy all of the deficiencies that were identified in the notice of breach of contract.

(2) To identify the timeframes by which the supplier will implement each of the components of the CAP.

(e) *Review of the CAP.* (1) The CBIC will review the CAP. Suppliers may only revise their CAP one time during the review process based on the deficiencies identified by the CBIC. The CBIC will submit a recommendation to CMS for each applicable breach of contract action concerning whether the CAP includes the steps necessary to remedy the contract deficiencies as

identified in the notice of breach of contract.

(2) If CMS accepts the CAP, including the supplier's designated timeframe for its completion, the supplier must provide a follow-up report within 5 days after the supplier has fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS.

(3) If the supplier does not implement a CAP that was accepted by CMS, or if CMS does not accept the CAP submitted by the supplier, then the supplier will receive a subsequent notice of breach of contract, as specified in paragraph (b) of this section.

(f) *Right to request a hearing by the CBIC Hearing Officer.* (1) A supplier who receives a notice of breach of contract (whether an initial notice of breach of contract or a subsequent notice of breach of contract under §414.422(e)(3)) has the right to request a hearing before a CBIC hearing officer who was not involved with the original breach of contract determination.

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be submitted to the CBIC within 30 days from the date of the notice of breach of contract.

(3) A request for hearing must be in writing and submitted by an authorized official of the supplier.

(4) The appeals process for the Medicare DMEPOS Competitive Bidding Program is not to be used in place of other existing appeals processes that apply to other parts of Medicare.

(5) If the supplier is given the opportunity to submit a CAP and a CAP is not submitted and the supplier fails to timely request a hearing, the breach of contract action(s) will take effect 45 days from the date of the notice of breach of contract.

(g) *The CBIC Hearing Officer schedules and conducts the hearing.* (1) Within 30 days from the receipt of the supplier's timely request for a hearing the hearing officer will contact the parties to schedule the hearing.

(2) The hearing may be held in person or by telephone at the parties' request.

(3) The scheduling notice to the parties must indicate the time and place for the hearing and must be sent to the parties at least 30 days before the date of the hearing.

(4) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing, but must give the parties to the hearing 30 days' notice of the change.

(5) The hearing officer's scheduling notice must provide the parties to the hearing the following information:

(i) A description of the hearing procedure.

(ii) The specific issues to be resolved.

(iii) The supplier has the burden to prove it is not in violation of the contract or that the breach of contract action(s) is not appropriate.

(iv) The opportunity for parties to the hearing to submit additional evidence to support their positions, if requested by the hearing officer.

(v) A notification that all evidence submitted, both from the supplier and CMS, will be provided in preparation for the hearing to all affected parties at least 15 days prior to the scheduled date of the hearing.

(h) *Burden of proof and evidence submission.* (1) The burden of proof is on the Competitive Bidding Program contract supplier to demonstrate to the hearing officer with convincing evidence that it has not breached its contract or that the breach of contract action(s) is not appropriate.

(2) The supplier's evidence must be submitted with its request for a hearing.

(3) If the supplier fails to submit the evidence at the time of its submission, the Medicare DMEPOS supplier is precluded from introducing new evidence later during the hearing process, unless permitted by the hearing officer.

(4) CMS also has the opportunity to submit evidence to the hearing officer within 10 days of receiving the scheduling notice.

(5) The hearing officer will share all evidence submitted by the supplier and/or CMS, with all parties to the hearing at least 15 days prior to the scheduled date of the hearing.

(i) *Role of the hearing officer.* The hearing officer will conduct a thorough

and independent review of the evidence including the information and documentation submitted for the hearing and other information that the hearing officer considers pertinent for the hearing. The role of the hearing officer includes, at a minimum, the following:

(1) Conduct the hearing and decide the order in which the evidence and the arguments of the parties are presented;

(2) Determine the rules on admissibility of the evidence;

(3) Examine the witnesses, in addition to the examinations conducted by CMS and the contract supplier;

(4) The CBIC may assist CMS in the appeals process including being present at the hearing, testifying as a witness, or performing other, related ministerial duties;

(5) Determine the rules for requesting documents and other evidence from other parties;

(6) Ensure a complete record of the hearing is made available to all parties to the hearing;

(7) Prepare a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the hearing officer and considered as part of the hearing; and

(8) Comply with all applicable provisions of Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

(j) *Hearing officer recommendation.* (1) The hearing officer will issue a written recommendation(s) to CMS within 30 days of the close of the hearing unless an extension has been granted by CMS because the hearing officer has demonstrated that an extension is needed due to the complexity of the matter or heavy workload. In situations where there is more than one breach of contract action presented at the hearing, the hearing officer will issue separate recommendations for each breach of contract action.

(2) The recommendation(s) will explain the basis and the rationale for the hearing officer's recommendation(s).

(3) The hearing officer must include the record of the hearing, along with all evidence and documents produced during the hearing along with its recommendation(s).

(k) *CMS' final determination.* (1) CMS' review of the hearing officer's recommendation(s) will not allow the supplier to submit new information.

(2) After reviewing the hearing officer's recommendation(s), CMS' decision(s) will be made within 30 days from the date of receipt of the hearing officer's recommendation(s). In situations where there is more than one breach of contract action presented at the hearing, and the hearing officer issues multiple recommendations, CMS will render separate decisions for each breach of contract action.

(3) A notice of CMS' decision will be sent to the supplier and the hearing officer. The notice will indicate:

(i) If any breach of contract action(s) included in the notice of breach of contract, specified in paragraph (b)(1) of this section, still apply and will be effectuated, and

(ii) The effective date for any breach of contract action specified in paragraph (k)(3)(i) of this section.

(4) This decision(s) is final and binding.

(l) *Effect of breach of contract action(s)*—(1) *Effect of contract suspension.* (i) All locations included in the contract cannot furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items for the duration of the contract suspension.

(ii) The supplier must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items on a recurring basis of the suspension of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice.

(B) The notice to the beneficiary must inform the beneficiary that they must select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(2) *Effect of contract termination.* (i) All locations included in the contract can no longer furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items after the effective date of the termination.

(ii) The supplier must notify all beneficiaries, who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice of termination.

(B) The notice to the beneficiary must inform the beneficiary that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(3) *Effect of preclusion.* A supplier who is precluded will not be allowed to participate in a specific round of the Competitive Bidding Program, which will be identified in the original notice of breach of contract, as specified in paragraph (b)(1) of this section.

(4) *Effect of other remedies allowed by law.* If CMS decides to impose other remedies under §414.422(g)(2)(iv), the details of the remedies will be included in the notice of breach of contract, as specified in paragraph (b)(2) of this section.

[81 FR 77967, Nov. 4, 2016, as amended at 83 FR 57073, Nov. 14, 2018; 84 FR 60809, Nov. 8, 2019]

§414.424 Administrative or judicial review.

(a) There is no administrative or judicial review under this subpart of the following:

(1) Establishment of payment amounts.

(2) Awarding of contracts.

(3) Designation of CBAs.

(4) Phase-in of the competitive bidding programs.

(5) Selection of items for competitive bidding.

(6) Bidding structure and number of contract suppliers selected for a competitive bidding program.

(b) A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.

[72 FR 18085, Apr. 10, 2007]

§414.425 Claims for damages.

(a) *Eligibility for filing a claim for damages as a result of the termination of supplier contracts by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).* (1) Any aggrieved supplier, including a member of a network that was awarded a contract for the Round 1 Durable Medical Prosthetics, Orthotics, and Supplies Competitive Bidding Program (DMEPOS CBP) that believes it has been damaged by the termination of its competitive bid contract, may file a claim under this section.

(2) A subcontractor of a contract supplier is not eligible to submit a claim under this section.

(b) *Timeframe for filing a claim.* (1) A completed claim, including all documentation, must be filed within 90 days of January 1, 2010 (the effective date of these damages provisions), unless that day is a Federal holiday or Sunday in which case it will fall to the next business day.

(2) The date of filing is the actual date of receipt by the CBIC of a completed claim that includes all the information required by this rule.

(c) *Information that must be included in a claim.* (1) Supplier's name, name of authorized official, U.S. Post Office mailing address, phone number, email address and bidding number, and National Supplier Clearinghouse Number;

(2) A copy of the signed contract entered into with CMS for the Round 1 DMEPOS Competitive Bidding Program;

(3) A detailed explanation of the damages incurred by this supplier as a direct result of the termination of the Round 1 competitive bid contract by MIPPA. The explanation must include all of the following:

(i) Documentation of the supplier's damages through receipts.

(ii) Records that substantiate the supplier's damages and demonstrate that the damages are directly related to performance of the Round 1 contract and are consistent with information the supplier provided as part of their bid.

(4) The supplier must explain how it would be damaged if not reimbursed.

(5) The claim must document steps the supplier took to mitigate any damages they may have incurred due to the

contract termination, including a detailed explanation of the steps of all attempts to use for other purposes, return or dispose of equipment or other assets purchased or rented for the use in the Round 1 DMEPOS CBP contract performance.

(d) *Items that will not be considered in a claim.* The following items will not be considered in a claim:

(1) The cost of submitting a bid.

(2) Any fees or costs incurred for consulting or marketing.

(3) Costs associated with accreditation or licensure.

(4) Costs incurred before March 20, 2008.

(5) Costs incurred for contract performance after July 14, 2008 except for costs incurred to mitigate damages.

(6) Any profits a supplier may have expected from the contract.

(7) Costs that would have occurred without a contract having been awarded.

(8) Costs for items such as inventory, delivery vehicles, office space and equipment, personnel, which the supplier did not purchase specifically to perform the contract.

(9) Costs that the supplier has recouped by any means, and may include use of personnel, material, suppliers, or equipment in the supplier's business operations.

(e) *Filing a claim.* (1) A claim, with all supporting documentation, must be filed with the CMS Competitive Bidding Implementation Contractor (CBIC).

(2) Claims must include a statement from a supplier's authorized official certifying the accuracy of the information provided on the claim and all supporting documentation.

(3) The CBIC does not accept electronic submissions of claims for damages.

(f) *Review of claim.* (1) *Role of the CBIC.* (i) The CBIC will review the claim to ensure it is submitted timely, complete, and by an eligible claimant. When the CBIC identifies that a claim is incomplete or not filed timely, it will make a recommendation to the Determining Authority not to process the claim further. Incomplete or untimely claims may be dismissed by the Determining Authority without further processing.

(ii) For complete, timely claims, the CBIC will review the claim on its merits to determine if damages are warranted and may seek further information from the claimant when making its recommendation to the Determining Authority. The CBIC may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iii) The CBIC will make a recommendation to the Determining Authority for each claim filed and include an explanation that supports its recommendation.

(iv) The recommendation must be either to award damages for a particular amount (which may not be the same amount requested by the claimant) or that no damages should be awarded.

(A) If the CBIC recommends that damages are warranted, the CBIC will calculate a recommended reasonable amount of damages based on the claim submitted.

(B) The reasonable amount will consider both costs incurred and the contractor's attempts and action to limit the damages;

(v) The recommendation will be sent to the Determining Authority for a final determination.

(2) *CMS' role as the Determining Authority.* (i) The Determining Authority shall review the recommendation of the CBIC.

(ii) The Determining Authority may seek further information from the claimant or the CBIC in making a concurrence or non-concurrence determination.

(iii) The Determining Authority may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iv) If the Determining Authority concurs with the CBIC recommendation, the Determining Authority shall submit a final signed decision to the CBIC and direct the CBIC to notify the claimant of the decision and the reasons for the final decision.

(v) If the Determining Authority non-concurs with the CBIC recommendation, the Determining Authority may return the claim for further processing or the Determining Authority may:

(A) Write a determination granting (in whole or in part) a claim for damages or denying a claim in its entirety;

(B) Direct the CBIC to write said determination for the Determining Authority's signature; or

(C) Return the claim to the CBIC with further instructions.

(vi) The Determining Authority's determination is final and not subject to administrative or judicial review.

(g) *Timeframe for determinations.* (1) Every effort will be made to make a determination within 120 days of initial receipt of the claim for damages by the CBIC or the receipt of additional information that was requested by the CBIC, whichever is later.

(2) In the case of more complex cases, or in the event of a large workload, a decision will be issued as soon as practicable.

(h) *Notification to claimant of damage determination.* The CBIC must mail the Determining Authority's determination to the claimant by certified mail return receipt requested, at the address provided in the claim.

[74 FR 62011, Nov. 25, 2009]

§ 414.426 Adjustments to competitively bid payment amounts to reflect changes in the HCPCS.

If a HCPCS code for a competitively bid item is revised after the contract period for a competitive bidding program begins, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number. Payment for these items will be made in accordance with Subpart C or Subpart D.

[72 FR 18085, Apr. 10, 2007]

Subpart G—Payment for Clinical Diagnostic Laboratory Tests

SOURCE: 71 FR 69786, Dec. 1, 2006, unless otherwise noted.

§ 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act and 1834A of the Act—procedures for determining the basis for, and amount of, payment for a clinical diagnostic laboratory test (CDLT).

[81 FR 41098, June 23, 2016]

§ 414.502 Definitions.

For purposes of this subpart—

Actual list charge means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Advanced diagnostic laboratory test (ADLT) means a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of

that laboratory, and meets one of the following criteria:

(1) The test—

(i) Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;

(ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies);

(iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and

(iv) May include other assays.

(2) The test is cleared or approved by the Food and Drug Administration.

Applicable information, with respect to each CDLT for a data collection period:

(1) Means—

(i) Each private payor rate for which final payment has been made during the data collection period;

(ii) The associated volume of tests performed corresponding to each private payor rate; and

(iii) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

(2) Does not include information about a test for which payment is made on a capitated basis.

Applicable laboratory means an entity that:

(1) Is a laboratory, as defined in § 493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(i) For hospital outreach laboratories—bills Medicare Part B on the CMS 1450 under bill type 14x;

(ii) [Reserved]

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

Blood bank or center means an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2023 through March 31, 2023, the data collection period is January 1, 2019 through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2023 through March 31, 2023.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

New advanced diagnostic laboratory test (ADLT) means an ADLT for which payment has not been made under the clinical laboratory fee schedule prior to January 1, 2018.

New ADLT initial period means a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS.

New clinical diagnostic laboratory test (CDLT) means a CDLT that is assigned a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT.

New test means any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System Code is assigned on or after January 1, 2005.

Private payor means:

(1) A health insurance issuer, as defined in section 2791(b)(2) of the Public Health Service Act.

(2) A group health plan, as defined in section 2791(a)(1) of the Public Health Service Act.

(3) A Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Act.

(4) A Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act.

Private payor rate, with respect to applicable information:

(1) Is the final amount that is paid by a private payor for a CDLT after all private payor price concessions are applied and does not include price concessions applied by a laboratory.

(2) Includes any patient cost sharing amounts, if applicable.

(3) Does not include information about denied payments.

Publicly available rate means the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

Reporting entity is the entity that reports tax-related information to the Internal Revenue Service (IRS) using its Taxpayer Identification Number (TIN) for its components that are applicable laboratories.

Single laboratory, for purposes of an ADLT, means:

(1) The laboratory, as defined in 42 CFR 493.2, which furnishes the test, and that may also design, offer, or sell the test; and

(2) The following entities, which may design, offer, or sell the test:

(i) The entity that owns the laboratory.

(ii) The entity that is owned by the laboratory.

Specific HCPCS code means a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a Not Otherwise Classified (NOC) code, as established by the CMS HCPCS Workgroup.

Substantially Revised Healthcare Common Procedure Coding System Code means a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte specific test).

Successor owner, for purposes of an ADLT, means a single laboratory, that has assumed ownership of the single laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law.

(2) *Unincorporated sole proprietorship.* Transfer of title and property to another party.

(3) *Corporation*. The merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007; 81 FR 41098, June 23, 2016; 83 FR 60074, Nov. 23, 2018; 84 FR 61490, Nov. 12, 2019; 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022]

§ 414.504 Data reporting requirements.

(a) In a data reporting period, a reporting entity must report applicable information for each CDLT furnished by its component applicable laboratories during the corresponding data collection period, as follows—

(1) For CDLTs that are not ADLTs, initially January 1, 2017 and every 3 years beginning January 1, 2023.

(2) For ADLTs that are not new ADLTs, every year beginning January 1, 2017.

(3) For new ADLTs—

(i) Initially, no later than the last day of the second quarter of the new ADLT initial period; and

(ii) Thereafter, every year.

(b) Applicable information must be reported in the form and manner specified by CMS.

(c) A laboratory seeking new ADLT status for its test must, in its new ADLT application, attest to the actual list charge.

(d) To certify data integrity, the President, CEO, or CFO of a reporting entity, or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, must sign the certification statement and be responsible for assuring that the data provided are accurate, complete, and truthful, and meets all the reporting parameters described in this section.

(e) If the Secretary determines that a reporting entity has failed to report applicable information for its applicable laboratories, or made a misrepresentation or omission in reporting applicable information for its applicable laboratories, the Secretary may apply a civil monetary penalty to a reporting entity in an amount of up to $10,000 per day, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74, November 2, 2015), for each failure to report or each such misrepresentation or omission. The provisions for civil monetary penalties that apply in general to the Medicare program under 42 U.S.C. 1320a–7b apply in the same manner to the laboratory data reporting process under this section.

(f) CMS or its contractors will not disclose applicable information reported to CMS under this section in a manner that would identify a specific payor or laboratory, or prices charged or payments made to a laboratory, except to permit the Comptroller General, the Director of the Congressional Budget Office, and the Medicare Payment Advisory Commission, to review the information, or as CMS determines is necessary to implement this subpart, such as disclosures to the HHS Office of Inspector General or the Department of Justice for oversight and enforcement activities.

(g) Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory. For a single laboratory that offers and furnishes an ADLT that is not an applicable laboratory except with respect to its ADLTs, the applicable information of its CDLTs that are not ADLTs may not be reported.

[81 FR 41099, June 23, 2016, as amended at 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022]

§ 414.506 Procedures for public consultation for payment for a new clinical diagnostic laboratory test.

For a new CDLT, CMS determines the basis for and amount of payment after performance of the following:

(a) CMS makes available to the public (through CMS's Internet Web site) a list that includes codes for which establishment of a payment amount is being considered for the next calendar year.

(b) CMS publishes a FEDERAL REGISTER notice of a meeting to receive public comments and recommendations (and data on which recommendations are based) on the appropriate basis, as specified in § 414.508, for establishing payment amounts for the list of codes made available to the public.

(c) Not fewer than 30 days after publication of the notice in the FEDERAL REGISTER, CMS convenes a meeting that includes representatives of CMS officials involved in determining payment amounts, to receive public comments and recommendations (and data on which the recommendations are based).

(d) Considering the comments and recommendations (and accompanying data) received at the public meeting, CMS develops and makes available to the public (through an Internet Web site and other appropriate mechanisms) a list of—

(1) Proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based,

including recommendations from the Advisory Panel on CDLTs described in paragraph (e) of this section, and a request for written public comments within a specified time period on the proposed determination; and

(2) Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

(3) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section, CMS will provide an explanation of how it took into account the recommendations of the Advisory Panel on CDLTs described in paragraph (e) of this section.

(4) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section and § 414.509(b)(2)(i) and (iii) when CMS uses the gapfilling method described in § 414.508(b)(2), CMS will make available to the public an explanation of the payment rate for the test.

(e) CMS will consult with an expert outside advisory panel, called the Advisory Panel on CDLTs, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists researchers, and individuals with expertise in laboratory science or health economics, in issues related to CDLTs. This advisory panel will provide input on the establishment of payment rates under § 414.508 and provide recommendations to CMS under this subpart.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007; 81 FR 41099, June 23, 2016]

§ 414.507 Payment for clinical diagnostic laboratory tests.

(a) *General rule.* Except as provided in paragraph (d) of this section, and §§ 414.508 and 414.522, the payment rate for a CDLT furnished on or after January 1, 2018, is equal to the weighted median for the test, as calculated under paragraph (b) of this section. Each payment rate will be in effect for a period of one calendar year for ADLTs and three calendar years for all other CDLTs, until the year following the next data collection period.

(b) *Methodology.* For each test under paragraph (a) of this section for which applicable information is reported, the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory.

(c) The payment amounts established under this section are not subject to any adjustment, such as geographic, budget neutrality, annual update, or other adjustment.

(d) *Phase-in of payment reductions.* For years 2018 through 2025, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

(1) 2018—10 percent of the national limitation amount for the test in 2017.

(2) 2019—10 percent of the payment rate established in 2018.

(3) 2020—10 percent of the payment rate established in 2019.

(4) 2021—0.0 percent of the payment rate established in 2020.

(5) 2022—0.0 percent of the payment rate established in 2021.

(6) 2023—15 percent of the payment rate established in 2022.

(7) 2024—15 percent of the payment rate established in 2023.

(8) 2025—15 percent of the payment rate established in 2024.

(e) There is no administrative or judicial review under sections 1869 and 1878 of the Social Security Act, or otherwise, of the payment rates established under this subpart.

(f) For a CDLT for which CMS receives no applicable information, payment is made based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2).

(g) For ADLTs that are furnished between April 1, 2014 and December 31, 2017, payment is based on the crosswalking or gapfilling methods described in § 414.508(a).

[81 FR 41099, June 23, 2016, as amended at 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022]

§ 414.508 Payment for a new clinical diagnostic laboratory test.

(a) For a new CDLT that is assigned a new or substantially revised code between January 1, 2005 and December 31, 2017, CMS determines the payment amount based on either of the following:

(1) *Crosswalking.* Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the local fee schedule amounts and national limitation amount of the existing test.

(ii) Payment for the new CDLT code is made at the lesser of the local fee schedule amount or the national limitation amount.

(2) *Gapfilling.* Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the CDLT and routine discounts to charges;

(B) Resources required to perform the CDLT;

(C) Payment amounts determined by other payors; and

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(ii) In the second year, the test code is paid at the national limitation amount, which is the median of the contractor-specific amounts.

(iii) For a new CDLT for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the contractor-specific amounts will pay for the test appropriately. If CMS determines that the contractor-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

(b) For a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, CMS determines the payment amount based on either of the following until applicable information is available to establish a payment amount under the methodology described in § 414.507(b):

(1) *Crosswalking.* Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the payment amount established under § 414.507 of the comparable existing CDLT.

(ii) Payment for the new CDLT code is made at the payment amount established under § 414.507.

(2) *Gapfilling.* Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges;

(B) Resources required to perform the test;

(C) Payment amounts determined by other payors;

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and

(E) Other criteria CMS determines appropriate.

(ii) In the second year, the CDLT code is paid at the median of the Medicare Administrative Contractor-specific amounts.

[81 FR 41100, June 23, 2016]

§ 414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.

For a new CDLT, the following reconsideration procedures apply:

(a) *Reconsideration of basis for payment.* (1) CMS will receive reconsideration requests in written format for 60 days after making a determination of the basis for payment under § 414.506(d)(2) regarding whether CMS should reconsider the basis for payment and why a different basis for payment would be more appropriate. If a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test.

(2)(i) A requestor that submitted a request under paragraph (a)(1) of this

section may also present its reconsideration request at the public meeting convened under §414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (a)(1) of this section.

(ii) If the requestor presents its reconsideration request at the public meeting convened under §414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(3) Considering reconsideration requests and other comments received, CMS may reconsider its determination of the basis for payment. As the result of such a reconsideration, CMS may change the basis for payment from crosswalking to gapfilling or from gapfilling to crosswalking.

(4) If the basis for payment is revised as the result of a reconsideration, the new basis for payment is final and is not subject to further reconsideration.

(b) *Reconsideration of amount of payment*—(1) *Crosswalking.* (i) For 60 days after making a determination under §414.506(d)(2) of the code or codes to which a new test will be crosswalked, CMS receives reconsideration requests in written format regarding whether CMS should reconsider its determination and the recommended code or codes to which to crosswalk the new test.

(ii)(A) A requestor that submitted a request under paragraph (b)(1)(i) of this section may also present its reconsideration request at the public meeting convened under §414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (b)(1)(i) of this section.

(B) If a requestor presents its reconsideration request at the public meeting convened under §414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(iii) Considering comments received, CMS may reconsider its determination of the amount of payment. As the result of such a reconsideration, CMS may change the code or codes to which the new test is crosswalked.

(iv) If CMS changes the basis for payment from gapfilling to crosswalking as a result of a reconsideration, the crosswalked amount of payment is not subject to reconsideration.

(2) *Gapfilling.* (i) By April 30 of the year after CMS makes a determination under §414.506(d)(2) or paragraph (a)(3) of this section that the basis for payment for a CDLT will be gapfilling, CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site.

(ii) For 60 days after CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site, CMS will receive public comments in written format regarding the interim Medicare Administrative Contractor-specific amounts.

(iii) After considering the public comments, CMS will post final Medicare Administrative Contractor-specific amounts on the CMS Web site.

(iv) For 30 days after CMS posts final Medicare Administrative Contractor-specific payment amounts on the CMS Web site, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final Medicare Administrative Contractor-specific payment amount and median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

(v) Considering reconsideration requests received, CMS may reconsider its determination of the amount of payment. As the result of a reconsideration, CMS may revise the median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

(3) For both gapfilled and crosswalked new tests, if CMS revises the amount of payment as the result of a reconsideration, the new amount of payment is final and is not subject to further reconsideration.

(c) *Effective date.* If CMS changes a determination as the result of a reconsideration, the new determination regarding the basis for or amount of payment is effective January 1 of the year following reconsideration. Claims for

services with dates of service prior to the effective date will not be reopened or otherwise reprocessed.

(d) *Jurisdiction for reconsideration decisions.* Jurisdiction for reconsidering a determination rests exclusively with the Secretary. A decision whether to reconsider a determination is committed to the discretion of the Secretary. A decision not to reconsider an initial determination is not subject to administrative or judicial review.

[72 FR 66401, Nov. 27, 2007, as amended at 73 FR 2432, Jan. 15, 2008; 81 FR 41100, June 23, 2016]

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

The date of service for either a clinical laboratory test or the technical component of physician pathology service is as follows:

(a) Except as provided under paragraph (b) of this section, the date of service of the test must be the date the specimen was collected.

(b)(1) If a specimen was collected over a period that spans 2 calendar days, then the date of service must be the date the collection ended.

(2) In the case of a test performed on a stored specimen, if a specimen was stored for—

(i) Less than or equal to 30 calendar days from the date it was collected, the date of service of the test must be the date the test was performed only if—

(A) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

(B) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(D) The results of the test do not guide treatment provided during the hospital stay; and

(E) The test was reasonable and medically necessary for the treatment of an illness.

(ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of service of the test must be the date the specimen was obtained from storage.

(3) In the case of a chemotherapy sensitivity test performed on live tissue, the date of service of the test must be the date the test was performed only if—

(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(iv) The results of the test do not guide treatment provided during the hospital stay; and,

(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, ''chemotherapy sensitivity test'' means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

(5) In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, a test that is a cancer-related protein-based Multianalyte Assays with Algorithmic Analyses, or the test described by CPT code 81490, the date of service of the test must be the date the test was performed only if—

(i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department;

(ii) The specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2 of this chapter);

(iii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

(iv) The results of the test do not guide treatment provided during the hospital outpatient encounter; and

(v) The test was reasonable and medically necessary for the treatment of an illness.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66402, Nov. 27, 2007; 82 FR 52636, Nov. 13, 2017; 82 FR 59496, Dec. 14, 2017; 84 FR 61490, Nov. 12, 2019; 85 FR 86301, Dec. 29, 2020]

§ 414.522 Payment for new advanced diagnostic laboratory tests.

(a) The payment rate for a new ADLT—

(1) During the new ADLT initial period, is equal to its actual list charge.

(2) Prior to the new ADLT initial period, is determined by the Medicare Administrative Contractor based on information provided by the laboratory seeking new ADLT status for its laboratory test.

(b) After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median established under the payment methodology described in § 414.507(b).

(c) If, after the new ADLT initial period, the actual list charge of a new ADLT is greater than 130 percent of the weighted median established under the payment methodology described in § 414.507, CMS will recoup the difference between the ADLT actual list charge and 130 percent of the weighted median.

(d) If CMS does not receive any applicable information for a new ADLT by the last day of the second quarter of the new ADLT initial period, the payment rate for the test is determined either by the gapfilling or crosswalking method as described in § 414.508(b)(1) and (2).

[81 FR 41100, June 23, 2016]

§ 414.523 Payment for laboratory specimen collection fee and travel allowance.

(a) *Specimen collection fee and travel allowance.* In addition to the payment amounts provided under this subpart for CDLTs, new CDLTs, and new ADLTs, CMS pays a specimen collection fee, as set forth in paragraph (a)(1) of this section, and a travel allowance, as set forth in paragraph (a)(2) of this section.

(1) *Payment for specimen collection.* Except as provided in paragraph (a)(1)(v) of this section and subject to the annual update in paragraph (a)(1)(iv) of this section, beginning January 1, 2023, CMS pays $8.57 for all specimens collected in one patient encounter, where the specimen(s) is:

(i) Used to perform a CDLT paid under this subpart G;

(ii) Collected by a trained technician from a Medicare beneficiary who is——

(A) Homebound as described in 42 CFR 424.22(a)(1)(ii).

(B) A non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen;

(iii) Of the following type—

(A) Blood specimen collected through venipuncture.

(B) A urine sample collected by catheterization.

(iv) Beginning January 1, 2024, CMS updates the specimen collection fee amount under paragraph (a)(1) of this section for 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.

(v) For a specimen collected from a Medicare beneficiary.

(2) *Payment for travel allowance*—(i) *General requirement.* CMS pays a travel allowance, as calculated under paragraph (a)(2)(iii) of this section, where the specimen is one for which a specimen collection fee is paid under paragraph (a)(1) of this section.

(ii) *Travel allowance basis.* CMS pays a travel allowance on the following bases:

(A) *Flat-rate travel allowance.* The flat-rate travel allowance applies when the trained technician travels 20 eligible miles or less (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(B) *Per-mile travel allowance.* The per-mile travel allowance applies when:

(*1*) The trained technician travels more than 20 eligible miles (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(*2*) The trained technician travels to more than one location for specimen collection from more than one Medicare beneficiary.

(iii) *Travel allowance amount*—(A) *Eligible miles*. Eligible miles begin at the laboratory or the starting point of the technician's travel for specimen collection as specified in paragraph (a)(1) of this section, and end at the laboratory or the ending point of the technician's travel for specimen collection as specified in paragraph (a)(1) of this section. Eligible miles do not include miles traveled for any purpose unrelated to specimen collection as specified in paragraph (a)(1) of this section, such as collecting specimens from non-Medicare beneficiaries or for personal reasons.

(B) *Travel allowance mileage rate*. The travel allowance mileage rate is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician equal to the most recent median hourly wage for phlebotomists, as published by the United States Bureau of Labor Statistics, divided by 40 to represent an average miles-per-hour driving speed.

(C) *Travel allowance amount calculation*. (*1*) For the flat-rate travel allowance basis specified in paragraph (a)(2)(ii)(A) of this section, the travel allowance amount is the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section multiplied by ten, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(*2*) For the per-mile travel allowance basis specified in paragraph (a)(2)(ii)(B) of this section, the travel allowance amount is the number of eligible miles multiplied by the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(b) [Reserved]

[87 FR 70225, Nov. 18, 2022]

Subpart H—Fee Schedule for Ambulance Services

SOURCE: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

§ 414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule. Section 1834(l)(17) of the Act requires the development of a data collection system to collect cost, revenue, utilization, and other information determined appropriate from providers of services and suppliers of ground ambulance services.

[67 FR 9132, Feb. 27, 2002, as amended at 84 FR 63193, Nov. 15, 2019]

§ 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as ''ground'') ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel.

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures:

(1) Manual defibrillation/cardioversion.

(2) Endotracheal intubation.

(3) Central venous line.

(4) Cardiac pacing.

(5) Chest decompression.

(6) Surgical airway.

(7) Intraosseous line.

Advanced life support (ALS) personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications. The EMT-Paramedic is defined as possessing the qualifications of the EMT-Intermediate and also, in accordance with State and local laws, as having enhanced skills that include being able to administer additional interventions and medications.

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

Conversion factor (CF) is the dollar amount established by CMS that is multiplied by relative value units to produce ground ambulance service base rates.

Emergency response means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call.

Fixed wing air ambulance (FW) means transportation by a fixed wing aircraft that is certified as a fixed wing air ambulance and such services and supplies as may be medically necessary.

Geographic adjustment factor (GAF) means the practice expense (PE) portion of the geographic practice cost index (GPCI) from the physician fee schedule as applied to a percentage of the base rate. For ground ambulance services, the PE portion of the GPCI is applied to 70 percent of the base rate for each level of service. For air ambulance services, the PE portion of the GPCI is applied to 50 percent of the applicable base rate.

Ground ambulance organization means a Medicare provider or supplier of ground ambulance services.

Loaded mileage means the number of miles the Medicare beneficiary is transported in the ambulance vehicle.

Paramedic ALS intercept (PI) means EMT-Paramedic services furnished by an entity that does not furnish the ground ambulance transport, provided the services meet the requirements specified in §410.40(d) of this chapter.

Point of pick-up means the location of the beneficiary at the time he or she is placed on board the ambulance.

Relative value units (RVUs) means a value assigned to a ground ambulance service.

Rotary wing air ambulance (RW) means transportation by a helicopter that is certified as an ambulance and such services and supplies as may be medically necessary.

Rural adjustment factor (RAF) means an adjustment applied to the base payment rate when the point of pick-up is located in a rural area.

Rural area means an area located outside an urban area, or a rural census

tract within a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith modification as determined by the Office of Rural Health Policy of the Health Resources and Services Administration.

Specialty care transport (SCT) means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

Urban area means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003; 71 FR 69787, Dec. 1, 2006; 80 FR 71382, Nov. 16, 2015; 84 FR 63193, Nov. 15, 2019]

§ 414.610 Basis of payment.

(a) *Method of payment.* Medicare payment for ambulance services is based on the lesser of the actual charge or the applicable fee schedule amount. The fee schedule payment for ambulance services equals a base rate for the level of service plus payment for mileage and applicable adjustment factors. Except for services furnished by certain critical access hospitals or entities owned and operated by them, as described in § 413.70(b) of this chapter, all ambulance services are paid under the fee schedule specified in this subpart (regardless of the vehicle furnishing the service).

(b) *Mandatory assignment.* Effective with implementation of the ambulance fee schedule described in § 414.601 (that is, for services furnished on or after April 1, 2002), all payments made for ambulance services are made only on an assignment-related basis. Ambulance suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject the provider or supplier to sanctions, as provided by law (part 402 of this chapter).

(c) *Formula for computation of payment amounts.* The fee schedule payment amount for ambulance services is computed according to the following provisions:

(1) *Ground ambulance service levels.* The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate.

(i) For services furnished during the period July 1, 2004 through December 31, 2006, ambulance services originating in—

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 1 percent higher than otherwise is applicable under this section; and

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.

(ii) For services furnished during the period July 1, 2008 through December 31, 2022, ambulance services originating in:

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 3 percent higher than otherwise is applicable under this section.

(iii) The service-level base rate is then adjusted by the GAF. Compare this amount to the actual charge. The lesser of the actual charge or the GAF adjusted base rate amount is added to the lesser of the actual mileage charges or the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is applied to the ground mileage rate to determine the appropriate payment rates. The RVU scale for the ambulance fee schedule is as follows:

Service level	Relative value units (RVUs)
BLS	1.00
BLS-Emergency	1.60
ALS1	1.20
ALS1-Emergency	1.90
ALS2	2.75
SCT	3.25

Service level	Relative value units (RVUs)
PI	1.75

(2) *Air ambulance service levels.* The base payment rate for the applicable type of air ambulance service is adjusted by the GAF and, when applicable, by the appropriate RAF to determine the amount of payment. Air ambulance services have no CF or RVUs. This amount is compared to the actual charge. The lesser of the charge or the adjusted GAF rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is also applied to the air mileage rate.

(3) *Loaded mileage.* Payment is based on loaded miles. Payment for air mileage is based on loaded miles flown as expressed in statute miles. There are three mileage payment rates: a rate for FW services, a rate for RW services, and a rate for all levels of ground transportation.

(4) *Geographic adjustment factor (GAF).* For ground ambulance services, the PE portion of the GPCI from the physician fee schedule is applied to 70 percent of the base rate for ground ambulance services. For air ambulance services, the PE portion of the physician fee schedule GPCI is applied to 50 percent of the base rate for air ambulance services.

(5) *Rural adjustment factor (RAF).* (i) For ground ambulance services where the point of pickup is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles and, for services furnished before January 1, 2004, by 25 percent for miles 18 through 50. The standard mileage rate applies to every mile over 50 miles and, for services furnished after December 31, 2003, to every mile over 17 miles. For air ambulance services where the point of pickup is in a rural area, the total payment is increased by 50 percent; that is, the rural adjustment factor applies to the sum of the base rate and the mileage rate.

(ii) For services furnished during the period July 1, 2004 through December 31, 2022, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

(6) *Multiple patients.* The allowable amount per beneficiary for a single ambulance transport when more than one patient is transported simultaneously is based on the total number of patients (both Medicare and non-Medicare) on board. If two patients are transported simultaneously, then the payment allowance for the beneficiary (or for each of them if both patients are beneficiaries) is equal to 75 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus 50 percent of the applicable mileage payment allowance. If three or more patients are transported simultaneously, the payment allowance for the beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus the applicable mileage payment allowance divided by the number of patients on board.

(7) *Payment rate for mileage greater than 50 miles.* For services furnished during the period July 1, 2004 through December 31, 2008, each loaded ambulance mile greater than 50 (that is, miles 51 and greater) for ambulance transports originating in either urban areas or in rural areas are paid based on a rate that is 25 percent higher than otherwise is applicable under this section.

(8) *Transport of an individual with end-stage renal disease for renal dialysis services.* For ambulance services furnished during the period October 1, 2013 through September 30, 2018, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the

Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent. For such services furnished on or after October 1, 2018, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 23 percent.

(9) *Payment reduction for failure to report data.* In the case of a ground ambulance organization (as defined at § 414.605) that is selected by CMS under § 414.626(c) for a year that does not sufficiently submit data under § 414.626(b) and is not granted a hardship exemption under § 414.626(d), the payments made under this section are reduced by 10 percent for the applicable period. For purposes of this paragraph, the applicable period is the calendar year that begins following the date that CMS provided written notification to the ground ambulance organization under § 414.626(e)(1) that the ground ambulance did not sufficiently submit the required data.

(d) *Payment.* Payment, in accordance with this subpart, represents payment in full (subject to applicable Medicare Part B deductible and coinsurance requirements as described in subpart G of part 409 of this chapter or in subpart I of part 410 of this chapter) for all services, supplies, and other costs for an ambulance service furnished to a Medicare beneficiary. No direct payment will be made under this subpart if billing for the ambulance service is required to be consolidated with billing for another benefit for which payment may be made under this chapter.

(e) *Point of pick-up.* The zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

(f) *Updates.* The CF, the air ambulance base rates, and the mileage rates are updated annually by an inflation factor established by law. The inflation factor is based on the consumer price index for all urban consumers (CPI–U) (U.S. city average) for the 12-month period ending with June of the previous year and, for 2011 and each subsequent year, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(g) *Adjustments.* The Secretary monitors payment and billing data on an ongoing basis and adjusts the CF and air ambulance rates as appropriate to reflect actual practices under the fee schedule. These rates are not adjusted solely because of changes in the total number of ambulance transports.

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through June 30, 2013.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003; 69 FR 40292, July 1, 2004; 71 FR 69787, Dec. 1, 2006; 73 FR 69937, Nov. 19, 2008; 74 FR 62012, Nov. 25, 2009; 75 FR 73625, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011; 77 FR 69368, Nov. 16, 2012; 78 FR 74820, Dec. 10, 2013; 79 FR 68005, Nov. 13, 2014; 80 FR 71382, Nov. 16, 2015; 83 FR 60074, Nov. 23, 2018; 84 FR 63193, Nov. 15, 2019]

§ 414.615 Transition to the ambulance fee schedule.

The fee schedule for ambulance services will be phased in over 5 years beginning April 1, 2002. Subject to the first sentence in § 414.610(a), payment for services furnished during the transition period is made based on a combination of the fee schedule payment for ambulance services and the amount the program would have paid absent the fee schedule for ambulance services, as follows:

(a) *2002 Payment.* For services furnished in 2002, the payment for the service component, the mileage component and, if applicable, the supply component is based on 80 percent of the reasonable charge for independent suppliers or on 80 percent of reasonable cost for providers, plus 20 percent of the ambulance fee schedule amount for the service and mileage components. The reasonable charge or reasonable cost portion of payment in CY 2002 is equal to the supplier's reasonable

charge allowance or provider's reasonable cost allowance for CY 2001, multiplied by the statutory inflation factor for ambulance services.

(b) *2003 Payment.* For services furnished in CY 2003, payment is based on 60 percent of the reasonable charge or reasonable cost, as applicable, plus 40 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2003 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2002, multiplied by the statutory inflation factor for ambulance services.

(c) *2004 Payment.* For services furnished in CY 2004, payment is based on 40 percent of the reasonable charge or reasonable cost, as applicable, plus 60 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2004 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2003, multiplied by the statutory inflation factor for ambulance services.

(d) *2005 Payment.* For services furnished in CY 2005, payment is based on 20 percent of the reasonable charge or reasonable cost, as applicable, plus 80 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2005 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2004, multiplied by the statutory inflation factor for ambulance services.

(e) *2006 and Beyond Payment.* For services furnished in CY 2006 and thereafter, the payment is based solely on the ambulance fee schedule amount.

(f) *Updates.* The portion of the transition payment that is based on the existing payment methodology (that is, the non-fee-schedule portion) is updated annually for inflation by a factor equal to the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. The CY 2002 inflation update factor used to update the 2001 payment amounts is applied to the annualized (average) payment amounts for CY 2001. For the period January 1, 2001 through June 30, 2001, the inflation update factor is 2.7 percent. For the period July 1, 2001 through December 31, 2001, the inflation update factor is 4.7 percent. The average for the year is 3.7 percent. Thus, the annualized (average) CY 2001 payment amounts used to derive the CY 2002 payment amounts are equivalent to the CY 2001 payment amounts that would have been determined had the inflation update factor for the entire CY 2001 been 3.7 percent. Both portions of the transition payment (that is, the portion that is based on reasonable charge or reasonable cost and the portion that is based on the ambulance fee schedule) are updated annually for inflation by the inflation factor described in §414.610(f).

(g) *Exception.* There will be no blended payment allowance as described in paragraphs (a), (b), (c), and (d) of this section for ground mileage in those States where the Medicare carrier paid separately for all out-of-county ground ambulance mileage, but did not, before the implementation of the Medicare ambulance fee schedule, make a separate payment for any ground ambulance mileage within the county in which the beneficiary was transported. Payment for ground ambulance mileage in that State will be made based on the full ambulance fee schedule amount for ground mileage. This exception applies only to carrier-processed claims and only in those States in which the carrier paid separately for out-of-county ambulance mileage, but did not make separate payment for any in-county mileage throughout the entire State.

§414.617 Transition from regional to national ambulance fee schedule.

For services furnished during the period July 1, 2004 through December 31, 2009, the amount for the ground ambulance base rate is subject to a floor amount determined by establishing nine fee schedules based on each of the nine census divisions using the same methodology as used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is less than or equal to the national ground base rate, then it is not used, and the national FS amount applies. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the FS portion of the base rate for that

census division is equal to a blend of the national rate and the regional rate in accordance with the following schedule:

Time period	Regional percent	National percent
7/1/04–12/31/04	80	20
CY 2005	60	40
CY 2006	40	60
CY 2007–CY 2009	20	80
CY 2010 and thereafter	0	100

[69 FR 40292, July 1, 2004]

§ 414.620 Publication of the ambulance fee schedule.

(a) Changes in payment rates resulting from incorporation of the annual inflation factor and the productivity adjustment as described in § 414.610(f) will be announced by CMS by instruction and on the CMS Web site.

(b) CMS will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than those described in § 414.610(f).

[75 FR 73626, Nov. 29, 2010]

§ 414.625 Limitation on review.

There will be no administrative or judicial review under section 1869 of the Act or otherwise of the amounts established under the fee schedule for ambulance services, including the following:

(a) Establishing mechanisms to control increases in expenditures for ambulance services.

(b) Establishing definitions for ambulance services that link payments to the type of services provided.

(c) Considering appropriate regional and operational differences.

(d) Considering adjustments to payment rates to account for inflation and other relevant factors.

(e) Phasing in the application of the payment rates under the fee schedule in an efficient and fair manner.

§ 414.626 Data reporting by ground ambulance organizations.

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

Data collection period means, with respect to a year, the 12-month period that reflects the ground ambulance organization's annual accounting period.

Data reporting period means, with respect to a year, the 5-month period that begins the day after the last day of the ground ambulance organization's data collection period.

For a year means one of the calendar years from 2020 through 2024.

Medicare Ground Ambulance Data Collection Instrument means the single survey-based data collection instrument that can be accessed by sampled ambulance organizations under this section via a secure web-based system for reporting data under this section.

(b) *Data collection and submission requirement.* Except as provided in paragraph (d) of this section, a ground ambulance organization selected by CMS under paragraph (c) of this section must do the following:

(1) Within 30 days of the date that CMS notifies a ground ambulance organization under paragraph (c)(3) of this section that it has selected the ground ambulance organization to report data under this section, the ground ambulance organization must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to CMS or its contractor.

(2) Collect during its selected data collection period the data necessary to complete the Medicare Ground Ambulance Data Collection Instrument.

(3) Submit to CMS a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to the ground ambulance organization's selected data collection period.

(c) *Representative sample.* (1) *Random sample.* For purposes of the data collection described in paragraph (b) of this section, and for a year, CMS will select a random sample of 25 percent of eligible ground ambulance organizations that is stratified based on:

(i) Provider versus supplier status and ownership (for-profit, non-profit, and government);

(ii) Service area population density (transports originating in primarily urban, rural, and super rural zip codes); and

(iii) Medicare-billed transport volume categories.

(2) *Selection eligibility.* A ground ambulance organization is eligible to be selected for data reporting under this section for a year if it is enrolled in Medicare and has submitted to CMS at least one Medicare ambulance transport claim during the year prior to the selection under paragraph (b)(1) of this section.

(3) *Notification of selection for a year.* CMS will notify an eligible ground ambulance organization that it has been selected to report data under this section for a year at least 30 days prior to the beginning of the calendar year in which the ground ambulance organization must begin to collect data by posting a list of selected organizations on the CMS web page and providing written notification to each selected ground ambulance organization via email or U.S. mail.

(4) *Limitation.* CMS will not select the same ground ambulance organization under this paragraph (c) in 2 consecutive years, to the extent practicable.

(d) *Hardship exemption.* A ground ambulance organization selected under paragraph (c) of this section may request and CMS may grant an exception to the reporting requirements under paragraph (b) of this section in the event of a significant hardship, such as a natural disaster, bankruptcy, or similar situation that the Secretary determines interfered with the ability of the ground ambulance organization to submit such information in a timely manner for the data collection period selected by the ground ambulance organization.

(1) To request a hardship exemption, the ground ambulance organization must submit a request to CMS, in the form and manner specified by CMS, within 90 calendar days of the date that CMS notified the ground ambulance organization that it would receive a 10 percent payment reduction as a result of not submitting sufficient information under the data collection system. The request form must include all of the following:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Ground ambulance organization address.

(iv) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable).

(v) Reason for requesting a hardship exemption.

(vi) Evidence of the impact of the hardship (such as photographs, newspaper or other media articles, financial data, bankruptcy filing, etc.).

(vii) Date when the ground ambulance organization would be able to begin collecting data under paragraph (b) of this section.

(viii) Date and signature of the chief executive officer or other designated personnel of the ground ambulance organization.

(2) CMS will provide a written response to the hardship exemption request within 30 days of its receipt of the hardship exemption form.

(e) *Notification of non-compliance and informal review.* (1) *Notification of noncompliance.* A ground ambulance organization selected under paragraph (c) of this section for a year that does not sufficiently report data under paragraph (b) of this section, will receive written notification from CMS that it will receive a payment reduction under §414.610(c)(9).

(2) *Informal review.* A ground ambulance organization that receives a written notification under paragraph (e)(1) of a payment reduction under §414.610(c)(9) may submit a request for an informal review within 90 days of the date it received the notificationby submitting a request to CMS, in the form and manner specified by CMS, that includes all of the following information:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address with the street location of the ground ambulance organization.

(iv) Ground ambulance organization's selected data collection period and data reporting period.

(v) A statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.

(f) *Public availability of data.* Beginning in 2024, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

(g) *Limitations on review.* There is no administrative or judicial review under section 1869 or section 1878 of the Act, or otherwise of the data required for submission under paragraph (b) of this section or the selection of ground ambulance organizations under paragraph (c) of this section.

[84 FR 63193, Nov. 15, 2019, as amended at 86 FR 65669, Nov. 19, 2021; 87 FR 70226, Nov. 18, 2022]

Subpart I—Payment for Drugs and Biologicals

SOURCE: 69 FR 1116, Jan. 7, 2004, unless otherwise noted.

§ 414.701 Purpose.

This subpart implements section 1842(o) of the Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Part B of Title XVIII of the Act (hereafter in this subpart referred to as the ''program'') that are not paid on a cost or prospective payment system basis. Examples of drugs that are subject to the rules contained in this subpart are: Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal, hepatitis, and COVID–19 vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anticancer drugs.

[85 FR 71197, Nov. 6, 2020]

§ 414.704 Definitions.

As used in this subpart, the following definition applies. *Drug* refers to both drugs and biologicals.

§ 414.707 Basis of payment.

(a) *Method of payment.* (1) Payment for a drug in calendar year 2004 is based on the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) 85 percent of the average wholesale price determined as of April 1, 2003, subject to the exceptions as specified in paragraphs (a)(2) through (a)(8) of this section.

(2) The payment limits for the following drugs are calculated using 95 percent of the average wholesale price:

(i) Blood clotting factors.

(ii) A drug or biological furnished during 2004 that was not available for Medicare payment as of April 1, 2003.

(iii) Pneumococcal, influenza, and COVID–19 vaccines as well as hepatitis B vaccine that is furnished to individuals at high or intermediate risk of contracting hepatitis B (as defined in §410.63(a) of this subchapter).

(iv) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(3) The payment limits for infusion drugs furnished through a covered item of durable medical equipment are calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(4) The payments limits for drugs contained in the following table are calculated based on the percentages of the average wholesale price determined as of April 1, 2003 that are specified in the table.

Drug	Percentage used to calculate 2004 payment limit
EPOETIN ALFA	87
LEUPROLIDE ACETATE	81
GOSERELIN ACETATE	80
RITUXIMAB	81
PACLITAXEL	81
DOCETAXEL	80
CARBOPLATIN	81
IRINOTECAN	80
GEMCITABINE HCL	80
PAMIDRONATE DISODIUM	85

Drug	Percentage used to calculate 2004 payment limit
DOLASETRON MESYLATE	80
FILGRASTIM	81
HYLAN G-F 20	82
MYCOPHENOLATE MOFETIL	86
GRANISETRON HCL	80
ONDANSETRON	87
VINORELBINE TARTATE	81
SARGRAMOSTIM	80
TOPOTECAN	84
IPRATROPIUM BROMIDE	80
ALBUTEROL SULFATE	80
IMMUNE GLOBULIN	80
LEUCOVORIN CALCIUM	80
DOXORUBICIN HCL	80
DEXAMETHOSONE SODIUM PHOSPHATE	86
HEPARIN SODIUM LOCK-FLUSH	80
CROMOLYN SODIUM	80
ACETYLCYSTEINE	80

(5) The payment limits for imiglucerase and alglucerase are calculated using 94 percent of the average wholesale price determined as of April 1, 2003.

(6) Exception. The payment limit for a drug otherwise subject to paragraph (a)(1)(ii) or paragraph (a)(4) of this section may be calculated using the percentage of the average wholesale price as the Secretary deems appropriate based on data and information submitted by the drug manufacturer.

(i) The manufacturer must submit data after October 15, 2003 and before January 1, 2004.

(ii) The percentage only applies for drugs furnished on or after April 1, 2004.

(7) In the case of blood and blood products (other than blood clotting factors), the payment limits shall be determined in the same manner as such payment limit was determined on October 1, 2003.

(b) *Mandatory assignment.* Effective with services furnished on or after February 1, 2001, payment for any drug covered under Part B of Medicare may be made on an assignment-related basis only. All billers must accept the program allowed charge as payment in full and may not bill nor collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts, if applicable. Violations of this requirement may subject the supplier to sanctions, as provided by the statute (See §402 of this chapter).

(c) *Mandatory reporting of anemia quality indicators.* The following provisions are effective January 1, 2008:

(1) Each request for payment for anti-anemia drugs furnished to treat anemia resulting from the treatment of cancer must report the beneficiary's most recent hemoglobin or hematocrit level;

(2) Each request for payment for use of erythropoiesis stimulating agents must report the beneficiary's most recent hemoglobin or hematocrit level.

[69 FR 1116, Jan. 7, 2004, as amended at 72 FR 66402, Nov. 27, 2007; 85 FR 71197, Nov. 6, 2020; 87 FR 70226, Nov. 18, 2022]

Subpart J—Submission of Manufacturer's Average Sales Price Data

SOURCE: 69 FR 17938, Apr. 6, 2004, unless otherwise noted.

§414.800 Purpose.

This subpart implements section 1847A of the Act by specifying the requirements for submission of a manufacturer's average sales price data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1842(o)(1)(D), 1847A, and 1881(b)(13)(A)(ii) of the Act.

§414.802 Definitions.

As used in this subpart, unless the context indicates otherwise—

Bona fide service fees means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Drug means a drug or a biological, and for purposes of applying section 1847A(f) of the Act, includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

Manufacturer means any entity that is engaged in the following (This term

does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

(1) Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Unit means the product represented by the 11-digit National Drug Code, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by a National Drug Code varies. The method of counting units excludes units of CAP drugs (as defined in § 414.902 of this part) sold to an approved CAP vendor (as defined in § 414.902 of this part) for use under the CAP (as defined in § 414.902 of this part).

[69 FR 17938, Apr. 6, 2004, as amended at 71 FR 48143, Aug. 18, 2006; 71 FR 69787, Dec. 1, 2006; 74 FR 62012, Nov. 25, 2009; 76 FR 73473, Nov. 28, 2011; 86 FR 65669, Nov. 19, 2021]

§ 414.804 Basis of payment.

(a) *Calculation of manufacturer's average sales price.* (1) The manufacturer's average sales price for a quarter for a drug represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after excluding sales as specified in paragraph (a)(4) of this section and then deducting price concessions as specified in paragraphs (a)(2) and (a)(3) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales as specified in paragraph (a)(4) of this section).

(2) *Price concessions.* (i) In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions. Price concessions include the following types of transactions and items:

(A) Volume discounts.

(B) Prompt pay discounts.

(C) Cash discounts.

(D) Free goods that are contingent on any purchase requirement.

(E) Chargebacks and rebates (other than rebates under the Medicaid program).

(ii) For the purposes of paragraph (a)(2)(i), bona fide services fees are not considered price concessions.

(3) To the extent that data on price concessions, as described in paragraph (a)(2) of this section, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in this paragraph.

(i)(A) For each National Drug Code with at least 12 months of sales (including products for which the manufacturer has redesignated the National Drug Code for the specific product and package size and has 12 months of sales across the prior and current National Drug Codes), after adjusting for exempted sales, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period available associated with sales subject to the average sales price reporting requirement divided by the total in dollars for the sales subject to the average sales price reporting requirement for the same 12-month period.

(B) For each National Drug Code with less than 12 months of sales, the calculation described in paragraph (i)(A) of this section is performed for the time period equaling the total number of months of sales.

(ii) The manufacturer multiplies the applicable percentage described in paragraph (a)(3)(i)(A) or (a)(3)(i)(B) of this section by the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted. (The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the net total sales amount for the quarter to the nearest whole dollar.) The result of this multiplication is then subtracted from the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted.

(iii) The manufacturer uses the result of the calculation described in paragraph (a)(3)(ii) of this section as the numerator and the number of units sold in the quarter (after adjusting for exempted sales) as the denominator to calculate the manufacturer's average sales price for the National Drug Code for the quarter being submitted.

(iv) *Example.* After adjusting for exempted sales, the total lagged price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for National Drug Code 12345–6789–01 subject to the ASP reporting requirement equal $200,000, and the total in dollars for the sales subject to the average sales price reporting requirement for the same period equals $600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = 0.33333. The total in dollars for the sales subject to the average sales price reporting requirement for the quarter being reported, equals $50,000 for 10,000 units sold. The manufacturer's average sales price calculation for this National Drug Code for this quarter is: $50,000 − (0.33333 × $50,000) = $33,334 (net total sales amount); $33,334/10,000 = $3.33 (average sales price).

(4) *Exempted sales.* (i) In calculating the manufacturer's average sales price, a manufacturer must exclude sales that are exempt from inclusion in the determination of the best price under section 1927(c)(1)(C)(i) of the Act and sales that are merely nominal in amount as applied for purposes of section 1927(c)(1)(C)(ii)(III) of the Act, as limited by section 1927(c)(1)(D) of the Act.

(ii) In determining nominal sales exempted under section 1927(c)(1)(C)(ii)(III) of the Act, the manufacturer calculates the average manufacturer price as defined in section 1927(k) of the Act and then identifies sales that are eligible to be considered a nominal sale under section 1927(c)(1)(D) of the Act and are at less than 10 percent of the average manufacturer price. To identify nominal sales, the manufacturer must use the average manufacturer price for the calendar quarter that is the same calendar quarter as the average sales price reporting period.

(5) The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) The manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA approved label as defined by section 201(k) of the Food, Drug, and Cosmetic Act.

(7) Each report must be certified by one of the following:

(i) The manufacturer's Chief Executive Officer (CEO).

(ii) The manufacturer's Chief Financial Officer (CFO).

(iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

(b) [Reserved]

[69 FR 17938, Apr. 6, 2004, as amended at 69 FR 55764, Sept. 16, 2004; 70 FR 70332, Nov. 21, 2005; 71 FR 69787, Dec. 1, 2006; 72 FR 18914, Apr. 16, 2007; 75 FR 73626, Nov. 29, 2010]

§ 414.806 Penalties associated with misrepresentation and the failure to submit timely and accurate ASP data.

(a) *Misrepresentation.* Section 1847A(d)(4)(A) of the Act specifies the penalties associated with misrepresentations in the reporting of the manufacturer's average sales price for a drug as defined at § 414.802.

(b) *Failure to provide timely information or the submission of false information.* (1) For a manufacturer that has entered into and has in effect a rebate agreement under section 1927 of the Act, section 1927(b)(3)(C) of the Act specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

(2) For a manufacturer that has not entered into and does not have in effect a rebate agreement under section 1927 of the Act, sections 1847A(d)(4)(B) and (C) of the Act specify the penalties associated with a manufacturer's failure

to submit timely information or the submission of false information.

[86 FR 65669, Nov. 19, 2021]

Subpart K—Payment for Drugs and Biologicals Under Part B

SOURCE: 69 FR 66424, Nov. 15, 2004, unless otherwise noted.

§ 414.900 Basis and scope.

(a) This subpart implements sections 1842(o), 1847A, and 1847B of the Act and outlines two payment methodologies applicable to drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) Examples of drugs that are subject to the requirements specified in this subpart are:

(1) Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs.

(2) Separately billable drugs at independent dialysis facilities not under the ESRD composite rate.

(3) Statutorily covered drugs, for example—

(i) Influenza.

(ii) Pneumococcal, Hepatitis B, and COVID–19 vaccines.

(iii) Antigens.

(iv) Hemophilia blood clotting factor.

(v) Immunosuppressive drugs.

(vi) Certain oral anti-cancer drugs.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005; 85 FR 71197, Nov. 6, 2020]

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Approved CAP vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program under 1847B of the Act.

Bid means an offer to furnish a CAP drug within a category of CAP drugs in a competitive acquisition area for a particular price and time period.

Biosimilar biological product means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA) as defined at section 1847A(c)(6)(H) of the Act.

CAP drug means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Competitive acquisition area means a geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

Drug means both drugs and biologicals.

Emergency delivery means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Emergency situation means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of § 414.906(e) are met.

Local carrier means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

Manufacturer's average sales price means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

Multiple source drug means a drug described by section 1847A(c)(6)(C) of the Act.

Pacific Territories means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

Participating CAP physician means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims.

Participating CAP physician election agreement means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

Prescription order means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

Reference biological product means the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product as defined at section 1847A(c)(6)(I) of the Act.

Refundable single-dose container or single-use package drug means a single source drug or biological or a biosimilar biological product for which payment is made under this part and that is furnished from a single-dose container or single-use package based on FDA-approved labeling or product information. The term ''refundable single-dose container or single-use package drug'' excludes—

(1) A drug that is a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA-approved labeling.

(2) A drug for which the FDA-approved labeling for any National Drug Code assigned to a billing and payment code of such drug requires filtration during the drug preparation process, prior to dilution and administration and that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

(3) A drug approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first National Drug Code assigned to the billing and payment code of such drug.

Routine delivery means delivery of a drug within 2 business days in appropriate shipping and packaging in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. In each case, this timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Single source drug means a drug described by section 1847A(c)(6)(D) of the Act.

Timely delivery means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

Unit is defined as in part 414, subpart J of this chapter.

Wholesale acquisition cost (WAC) means the price described by section 1847A(c)(6)(B) of the Act.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005; 75 FR 73626, Nov. 29, 2010; 87 FR 70226, Nov. 18, 2022]

§ 414.904 Average sales price as the basis for payment.

(a) *Method of payment.* Payment for a drug furnished on or after January 1, 2005 is based on the lesser of—

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(3) For purposes of this paragraph—

(i) CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label.

(ii) Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit.

(iii) No payment is made for amounts of product in excess of that reflected on the FDA-approved label.

(b) *Multiple source drugs*—(1) *Average sales prices.* The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(iii) For purposes of this subsection and subsection (c), the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(c) *Single source drugs*—(1) *Average sales price.* The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(d) *Limitations on the average sales price*—(1) *Wholesale acquisition cost for a single source drug.* The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) *Payment limit for a drug furnished to an end-stage renal disease patient.* (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the

percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(iii) Effective for drugs and biologicals furnished in CY 2006 and subsequent calendar years, the payment for such drugs and biologicals furnished in connection with renal dialysis services and separately billed by freestanding and hospital-based renal dialysis facilities not paid on a cost basis is the amount determined under section 1847A of the Act.

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by the applicable threshold percentage specified in paragraph (d)(3)(iii) or (iv) of this section, the Inspector General is responsible for informing the Secretary (at such times as specified by the Secretary) and the payment amount for the drug or biological will be substituted subject to the following adjustments:

(i) The payment amount substitution will be applied at the next average sales price payment amount calculation period after the Inspector General informs the Secretary (at such times specified by the Secretary) about billing codes for which the average sales price has exceeded the average manufacturer price by the applicable threshold percentage, and will remain in effect for 1 quarter after publication.

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when all of the following criteria are met:

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met.

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(C) Beginning in 2013, the drug and dosage form described by the HCPCS code is not identified by the FDA to be in short supply at the time that ASP calculations are finalized.

(iii) The applicable percentage threshold for average manufacturer price comparisons is 5 percent and is reached when—

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons is 5 percent.

(4) *Payment adjustment for certain drugs for which there is a self-administered version*—(i) *In general.* Except as provided in paragraphs (d)(4)(ii) and (iii) of this section, if the Inspector General identifies a drug or biological product in a study described in section 1847A(g)(1) of the Act, the Secretary must apply the payment limit for the applicable billing and payment code as specified in paragraph (d)(4)(iv) of this section, beginning with the first day of the second quarter after such study is publicly available. The methodology described in this paragraph will be recalculated each quarter thereafter, except when conditions described in paragraph (d)(4)(ii) are met.

(ii) *Exception.* The adjustment described in paragraph (d)(4)(i) of this section does not apply to the payment limit for a billing and payment code for a quarter if, at the time that ASP calculations are finalized for such quarter, the drug in the dosage form described by the billing and payment code is included by the FDA on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act.

(iii) *Special rule for certain billing and payment codes.* Effective July 1, 2021, for a billing and payment code described under section 1847A(g)(3) of the Act, the payment limit for the applicable billing and payment code must be determined as described in paragraph

(d)(4)(iv) of this section, and the exception specified at paragraph (d)(4)(ii) of this section does not apply.

(iv) *Lesser-of methodology.* For purposes of this section, the payment limit is the lesser of:

(A) The payment limit determined under section 1847A of the Act for such billing and payment code if each National Drug Code for such product so identified under section 1847A(g)(1) of the Act were excluded from such determination; and

(B) The payment limit otherwise determined under section 1847A of the Act for such billing and payment code without application of section 1847A(g) of the Act.

(v) *NDC changes.* For an Inspector General-identified National Drug Code, as described under section 1847A(g)(1) or (3) of the Act, for which the manufacturer has redesignated the National Drug Code (without changes to the dosage form), the application of the lesser-of methodology described in this paragraph must use manufacturer-reported ASP data associated with the redesignated National Drug Code in the same manner as the one originally identified by the Inspector General.

(e) *Exceptions to the average sales price*—(1) *Vaccines.* The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as defined in § 410.63(a) of this subchapter), pneumococcal vaccine, influenza vaccine, and COVID–19 vaccine are calculated using 95 percent of the average wholesale price.

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished before January 1, 2017, through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(3) *Blood and blood products.* In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) *Payment limit in a case where the average sales price during the first quarter of sales is unavailable.* In the case of a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on the wholesale acquisition cost or the Medicare Part B drug payment methodology in effect on November 1, 2003.

(5) *Treatment of certain drugs.* Beginning with April 1, 2008, the payment amount for—

(i) Each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii) is the lower of—

(A) The payment amount that would be determined for such drug or biological applying section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(ii) A multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii)) is the lower of—

(A) The payment amount that would be determined for such drug or biological taking into account the application of section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

(i) If manufacturer ASP data is not available prior to the publication deadline for quarterly payment limits and the unavailability of manufacturer ASP data significantly changes the quarterly payment limit for the billing code when compared to the prior quarter's billing code payment limit, the payment limit is calculated by carrying over the most recent available

manufacturer ASP price from a previous quarter for an NDC in the billing code, adjusted by the weighted average of the change in the manufacturer ASPs for the NDCs that were reported for both the most recently available previous quarter and the current quarter.

(j) *Biosimilar biological products.* Effective January 1, 2016, the payment amount for a biosimilar biological drug product (as defined in §414.902) for all NDCs assigned to such product is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference drug product (as defined in §414.902).

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 70332, Nov. 21, 2005; 71 FR 69788, Dec. 1, 2006; 72 FR 66402, Nov. 27, 2007; 73 FR 69937, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 74 FR 62012, Nov. 25, 2009; 75 FR 73626, Nov. 29, 2010; 76 FR 73473, Nov. 28, 2011; 77 FR 69368, Nov. 16, 2012; 80 FR 71382, Nov. 16, 2015; 82 FR 53363, Nov. 15, 2017; 83 FR 60074, Nov. 23, 2018; 85 FR 71197, Nov. 6, 2020; 86 FR 65669, Nov. 19, 2021; 87 FR 70226, Nov. 18, 2022]

§414.906 Competitive acquisition program as the basis for payment.

(a) *Program payment.* Beginning in 2006, as an alternative to payment under §414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in §414.908(b).

(2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.

(3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary.

(4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.

(5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

(b) *Exceptions to competitive acquisition.* Specific CAP drugs, including a category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs.

(c) *Computation of payment amount.* Except as specified in paragraph (c)(2) of this section, payment for CAP drugs is based on bids submitted as a result of the bidding process as described in §414.910 of this subpart.

(1) *Single payment amount.* (i) A single payment amount for each CAP drug in the competitive acquisition area is determined on the basis of the bids submitted and accepted and updated from the bidding period to the beginning of the payment year.

(ii) The single payment amount is then updated quarterly based on the approved CAP vendor's reasonable net acquisition costs for that category as determined by CMS, and limited by the weighted payment amount established under section 1847A of the Act across all drugs for which a composite bid is required in the category.

(iii) The payment amount for each other drug for which the approved CAP vendor submits a bid in accordance with §414.910 of this subpart and each other drug that is approved by CMS for the approved CAP vendor to furnish under the CAP is also updated quarterly based on the approved CAP vendor's reasonable net acquisition costs for each HCPCS code and limited by

the payment amount established under section 1847A of the Act.

(2) *Updates to payment amount.* (i) The first update is effective on the first day of claims processing for the first quarter of an approved CAP vendor's contract. The first quarterly contract update is based on the reasonable net acquisition cost (RNAC) data reported to CMS or its designee for any purchases of drug before the beginning of CAP claims processing for the contract period and reported to CMS no later than 30 days before the beginning of CAP claims processing.

(ii) For subsequent quarters, each approved CAP vendor must report to CMS or its designee RNAC data for a quarter of CAP drug purchases within 30 days of the close of that quarter.

(iii) For all quarters, only RNAC data from approved CAP vendors that are supplying CAP drugs under their CAP contract at the time updates are being calculated must be used to calculate updated CAP payment amounts.

(iv) CMS excludes such RNAC data submitted by an approved CAP vendor if, during the time calculations are being done, CMS knows that the approved CAP vendor will not be under contract for the applicable quarterly update.

(v) The payment amount weights must be calculated based on the more recent of the following:

(A) Contract bidding weights.

(B) CAP claims data.

(vi) The payment limit must be determined using the most recent payment limits available to CMS under section 1847A of the Act.

(vii) The following payment amount update calculation must be applied for the group of all drugs for which a composite bid is required.

(A) The most recent previous composite payment amount for the group is updated by—

(*1*) Calculating the percent change in reasonable net acquisition costs for each approved CAP vendor;

(*2*) Calculating the median of all participating approved CAP vendors' adjusted CAP payment amounts; and

(*3*) Limiting the payment as described in paragraph (c)(1) of this section.

(B) The median percent change, subject to the limit described in paragraph (c)(1) of this section, must be the update percentage for that quarter.

(C) The single update percentage must be applied to the payment amount for each drug in the group of drugs for which a composite bid is required in the category.

(viii) The following payment amount update calculation must be applied for each of the following items: Each HCPCS code not included in the composite bid list; Each HCPCS code added to the drug list during the contract period; and each drug that has not yet been assigned a HCPCS code, but for which a HCPCS code will be established.

(A) The most recent previous payment amount for each drug must be updated by calculating the percent change in reasonable net acquisition costs for each approved CAP vendor, then calculating the median of all participating approved CAP vendors' adjusted CAP payment amounts.

(B) The median percent change calculated for each drug, subject to the limit described in paragraph (c)(1) of this section, must be applied to the payment amount for each drug.

(3) *Alternative payment amount.* The alternative payment amount established under section 1847A of the Act may be used to establish payment for a CAP drug if—

(i) The drug is properly assigned to a category established under the CAP; and

(ii) It is a drug for which a HCPCS code must be established.

(d) *Adjustments.* There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

(e) *Resupply of participating CAP physician drug inventory.* A participating CAP physician may acquire drugs under the CAP to resupply his or her private inventory if all of the following requirements are met:

(1) The drugs were required immediately.

(2) The participating CAP physician could not have anticipated the need for the drugs.

(3) The approved CAP vendor could not have delivered the drugs in a timely manner. For purposes of this section, timely manner means delivery within the emergency delivery timeframe, as defined in §414.902.

(4) The participating CAP physician administered the drugs in an emergency situation, as defined in §414.902.

(f) *Substitution or addition of drugs on an approved CAP vendor's CAP drug list*—(1) *Short-term substitution of a CAP drug*. On an occasional basis (for a period of time less than 2 weeks), an approved CAP vendor may agree to furnish a substitute NDC within a HCPCS code on the approved CAP vendor's CAP drug list if the approved CAP vendor—

(i) Is willing to accept the payment amount that was established for the HCPCS code under this section; and

(ii) Obtains the participating CAP physician's prior approval.

(2) *Long-term substitution or addition of a CAP drug*. An approved CAP vendor may submit a request, as specified in paragraph (f)(3) of this section, for approval to substitute an NDC supplied by the approved CAP vendor for another NDC within the same HCPCS code or to add an NDC to the approved CAP vendor's drug list, if at least one of the following criteria is met:

(i) Proposed substitution of an NDC for a period of 2 weeks or longer.

(ii) Proposed addition of one or more NDCs within a HCPCS code included in the CAP drug category specified by CMS or on the approved CAP vendor's approved CAP drug list.

(iii) Proposed addition of—

(A) One or more newly issued HCPCS codes; or

(B) One of the following single indication orphan drug J codes or their updates: J0205, J0256, J9300, J1785, J2355, J3240, J7513, J9010, J9015, J9017, J9160, J9216.

(iv) Beginning January 1, 2007, the proposed addition of a drug(s) that has not yet been assigned a HCPCS code, but for which a HCPCS code must be established.

(v) On or after January 1, 2010, the proposed addition of drugs with similar therapeutic uses to drugs already supplied under the CAP by the approved CAP vendor(s).

(3) *Requesting the addition or substitution of CAP drug*. An approved CAP vendor that meets the one of the criteria specified in paragraph (f)(2) must submit a written request to CMS or its designee. The request must—

(i) Specify the NDC(s) and the respective HCPCS code that is to be added or substituted.

(ii) Address the rationale for the substitution or addition of the NDC(s) or the addition of the HCPCS code(s) as applicable; and

(iii) Address the impact of the substitution of the NDC(s) or the addition of the NDC(s) or HCPCS code(s), or both on—

(A) Patient and drug safety;

(B) Drug waste; and

(C) The potential for cost savings.

(iv) In the case of additions requested under paragraph (f)(2)(v) of this section, address and document the need for such an expansion based on demand for the product(s).

(4) *Approval of a request(s)*. CMS or its designee notifies the approved CAP vendor of its decision.

(i) Except as specified in paragraph (f)(4)(ii) of this section, an approved request is effective at the beginning of the next calendar quarter.

(ii) Approved substitutions for request based on a drug shortage or other exigent circumstance may become effective immediately provided that—

(A) CMS approves the immediate substitution; and

(B) The approved CAP vendor's notifies its CAP participating physicians of the substitution immediately following CMS approval.

(5) *Payment for an approved drug change(s)*. The payment for—

(i) Substituted or added CAP drugs that are within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is the single payment for that HCPCS code, as determined and updated in accordance with paragraph (c)(1) of this section; or

(ii) Added CAP drugs that are not within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is specified under paragraph (c)(2) of this section.

(g) *Deletion of drugs on an approved CAP vendor's CAP drug list*. Deletion of

drugs on an approved CAP vendor's CAP drug list due to unavailability requires a written request and approval as described in paragraphs (f)(3)(i) through (iii) and (f)(4) of this section.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 71 FR 9460, Feb. 24, 2006; 74 FR 62012, Nov. 25, 2009]

§ 414.908 Competitive acquisition program.

(a) Participating CAP *physician selection of an approved CAP vendor*. (1) CMS provides the participating CAP physician with a process for the selection of an approved CAP vendor on an annual basis, with exceptions as specified in § 414.908(a)(2). Participating CAP physicians will also receive information about the CAP in the enrollment process for Medicare participation set forth in section 1842(h) of the Act.

(2) A participating CAP physician may select an approved CAP vendor outside the annual selection process or opt out of the CAP for the remainder of the annual selection period when—

(i) The selected approved CAP vendor ceases participation in the CAP;

(ii) The physician leaves a group practice participating in CAP;

(iii) The participating CAP physician relocates to another competitive acquisition area; or

(iv) The approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(i) have been met (if this subparagraph (a)(2)(iv) applies, the physician can withdraw from the CAP category for the remainder of the year immediately upon notice to CMS and the approved CAP vendor); or

(v) Other exigent circumstances defined by CMS are present, including—

(A) If, up to and including 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a written request to the designated carrier to terminate the CAP election agreement because CAP participation imposes a burden on the physician's practice. The written request must document the burden. The designated carrier will process the participating CAP physician's request and CMS will approve or deny the request under the dispute resolution process as specified under § 414.917 of this subpart.

(B) If, more than 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a written request to the designated carrier to terminate the CAP election agreement because, based on a change in circumstances of which the participating CAP physician was not previously aware, CAP participation imposes a burden on the physician's practice. The written request must document the burden. The designated carrier will process the participating CAP physician's request and CMS will approve or deny the request under the dispute resolution process as specified under § 414.917 of this subpart.

(3) The physician participating in the CAP—

(i) Elects to use an approved CAP vendor for the drug category and area as set forth in § 414.908(b);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written prescription order to the approved CAP vendor with complete patient information for patients new to the approved CAP vendor or when information changes. Abbreviated information may be sent on all subsequent orders for a patient for which the approved CAP vendor has previously received complete information and that has no changes to the original information. Prescription orders may be initiated by telephone, with a follow-up written order provided within 8 hours for routine deliveries and immediately for emergency deliveries;

(iv) Does not receive payment for the CAP drug;

(v) Except where applicable State pharmacy law prohibits it, provides the following information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3):

(A) Date of order.

(B) Beneficiary name, address, and phone number.

(C) Physician identifying information:

Name, practice location/shipping address, group practice information (if applicable), PIN, and UPIN.

(D) Drug name.

(E) Strength.

(F) Quantity ordered.

(G) Dose.

(H) Frequency/instructions.

(I) Anticipated date of administration.

(J) Beneficiary Medicare information/Health insurance (HIC) number.

(K) Supplementary insurance information (if applicable).

(L) Medicaid information (if applicable).

(M) Additional patient information: date of birth, allergies, height/weight, ICD–9–CM (if necessary).

(vi) Agrees to accept the particular National Drug Codes (NDCs) supplied by the approved CAP vendor for the duration of the participating CAP physician's enrollment with the approved CAP vendor, subject to paragraphs (a)(3)(vii) and (a)(3)(xiv) of this section. By electing to participate with an approved CAP vendor, the participating CAP physician also agrees to accept the changes to the approved CAP vendor's CAP drug list that have been approved in accordance with §414.906(f).

(vii) Agrees to place routine orders for CAP drugs at the HCPCs level, except when medical necessity requires a particular formulation on the approved CAP vendor's CAP drug list. Medical necessity must be documented. When the conditions of this paragraph are met, the participating CAP physician may submit a prescription order to the approved CAP vendor that specifies the NDC.

(viii) Notifies the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered. The participating CAP physician and the approved CAP vendor agree on how to handle the unused CAP drug. If it is agreed that the participating CAP physician will maintain the CAP drug in his inventory for administration at a later date, the participating CAP physician submits a new prescription order at that time. This prescription order specifies that the CAP drug is being obtained from the participating CAP physician's CAP inventory and shipment should not occur;

(ix) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(x) Agrees to file the Medicare claim within 30 calendar days of the date of drug administration.

(xi) Agrees to submit documentation such as medical records or certification, as necessary, to support payment for a CAP drug;

(xii) Agrees not to transport CAP drugs from one practice location or place of service to another location except in accordance with a written agreement between the participating CAP physician and the approved CAP vendor that requires that drugs are not subjected to conditions that will jeopardize their integrity, stability, and/or sterility while being transported.

(xiii) Agrees to provide the CMS-developed CAP fact sheet to beneficiaries; and

(xiv) May receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(4) Physician group practices. If a physician group practice using a group billing number(s) elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group's billing number(s).

(b) *Program requirements.* (1) CMS selects approved CAP vendors through a competition among entities based on the following:

(i) Submission of the bid prices using the OMB-approved Vendor Application and Bid Form for CAP drugs within the category and competitive acquisition area that—

(A) Places the vendor among the qualified bidders with the lowest five composite bids; and

(B) Does not exceed the weighted payment amount established under section 1847A of the Act across all drugs in that category.

(ii) Ability to ensure product integrity.

(iii) Customer service/Grievance process.

(iv) At least 3 years experience in furnishing Part B injectable drugs.

(v) Financial performance and solvency.

(vi) Record of integrity and the implementation of internal integrity measures.

(vii) Internal financial controls.

(viii) Acquisition of all CAP drugs directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Maintenance of appropriate licensure to supply CAP drugs in States in which they are supplying CAP drugs.

(x) Cost-sharing assistance as described in § 414.914(g).

(xi) Other factors as determined by CMS.

(2) Approved CAP vendors must also meet the contract requirements under § 414.914.

(c) *Additional considerations.* CMS may refuse to award a contract or terminate an approved CAP vendor contract based upon the following:

(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in § 414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66402, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§ 414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

[70 FR 39095, July 6, 2005]

§ 414.912 Conflicts of interest.

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

[70 FR 39094, July 6, 2005]

§414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in §414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at §414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in §414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in §414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Respond within 2 business days to any inquiry, or sooner if the inquiry is related to drug quality;

(6) Staff a toll-free telephone line from 8:30 a.m. or earlier and until 5 p.m. or later for all time zones served in the continental United States by the CAP vendor on business days (Monday through Friday excluding Federal holidays) to provide customer assistance, and establish reasonable hours of operation for Hawaii, Alaska, Puerto Rico, and the other U.S. territories;

(7) Staff an emergency toll-free telephone line for weekend and evening access when the call center is closed, and determine what hours on Saturday and Sunday the call center is staffed and which hours a toll-free emergency line is activated; and

(8) Include assistance for the disabled, the hearing impaired, and Spanish-speaking inquirers in all customer service operations.

(9) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(10) Be enrolled in Medicare as a participating supplier;

(11) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(12) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of paragraph (h) of this section or §414.916(b) of this subpart are met;

(13) Provide direct notification to participating CAP physicians enrolled with them of updates to the approved CAP vendor's CAP drug list on a quarterly basis. Changes must be disseminated at least 30 days before the approved changes are due to take effect, unless immediate notification as described in §414.906(f)(4) is required. The approved CAP vendor's entire CAP drug list must be disseminated at least once yearly; and approved CAP vendors must make a complete list that incorporates the most recent updates available to physicians on an ongoing basis. CMS posts on its web site the updated CAP drug lists for each approved CAP vendor.

(14) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor, the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(15) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(16) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in §1003.101 of this title. The availability of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors must inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries receive cost-sharing waivers.

(h) The approved CAP vendor must verify drug administration prior to collection of any applicable cost sharing amount.

(1) The approved CAP vendor documents, in writing, the following information necessary to verify drug administration:

(i) Beneficiary name.

(ii) Health insurance number.

(iii) Expected date of administration.

(iv) Actual date of administration.

(v) Identity of the participating CAP physician.

(vi) Prescription order number.

(vii) Identity of the individuals who supply and receive the information.

(viii) Dosage supplied.

(ix) Dosage administered.

(2) If the information is obtained verbally, the approved CAP vendor must also maintain the following information:

(i) The identities of individuals who exchanged the information.

(ii) The date and time that the information was obtained.

(3) The approved CAP vendor must provide this information to CMS or the beneficiary upon request.

(i) The approved CAP vendor must comply with the following procedures before it may refuse to make further shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of payment by Medicare, or the verification of drug administration by the participating CAP physician, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) An approved CAP vendor that has received payment from the designated carrier for CAP drugs that have not been administered must promptly refund payment for such drugs to the designated carrier and must refund any coinsurance and deductible collected from the beneficiary and his or her supplemental insurer.

(3) At the time of billing the beneficiary, or the participating CAP physician's presentation of the bill on behalf of the approved CAP vendor, the approved CAP vendor must inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and §414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) For purposes of paragraph (i) of this section delivery means postmark date, or the date the coinsurance bill or notice was presented to the beneficiary by the participating CAP physician on behalf of the approved CAP vendor.

(i) Except as specified in paragraph (i)(5)(ii) of this section, if after 45 days from delivery of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost-sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary.

(ii) If the beneficiary has requested cost-sharing assistance within 45 days of receiving delivery of the approved CAP vendor's bill, provisions of paragraphs (i)(6), (i)(7), or (i)(8) of this section, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in §414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the delivery of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and §414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with §414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the date of delivery of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

[70 FR 39096, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§414.916 Dispute resolution for vendors and beneficiaries.

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems

persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in §414.908(a)(3). The recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and gather relevant additional information from the participating CAP physician before deciding whether to suspend the participating CAP physician's CAP election agreement. A suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year.

(4) Upon notification from CMS of a participating CAP physician's suspension from the program, the approved CAP vendor must cease delivery of CAP drugs to the suspended participating CAP physician until the suspension has been lifted.

(5) The participating CAP physician may appeal that suspension by requesting a reconsideration of CMS' decision. The reconsideration will address whether the participating CAP physician's denied claims and appeals were the result of the participating CAP physician's failure to participate in accordance with the requirements of §414.908(a)(3).

(c) *Reconsideration*—(1) *Right to a reconsideration.* A participating CAP physician dissatisfied with a determination that his or her CAP election agreement has been suspended by CMS or a determination under §414.917(d) denying the participating CAP physician's request to terminate participation in the CAP under §414.908(a)(v) is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS reconsiders any determination to suspend a participating CAP physician's election agreement if the participating CAP physician files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* A participating CAP physician who is dissatisfied with a CMS decision to suspend his or her CAP election agreement may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the participating CAP physician of CMS' decision to suspend his or her CAP election agreement. From the date of receipt of the decision letter until the day the reconsideration determination is final, the ASP payment methodology under section 1847A of the Act applies to the physician.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the participating CAP physician disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the participating CAP physician's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from approved CAP vendors, local carriers, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* A participating CAP physician may withdraw his or her request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the participating CAP physician the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the participating CAP physician the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate a participating CAP physician's CAP election agreement.

(7) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the participating CAP physician 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);

(*3*) Representatives from the local carrier;

(*4*) Representatives from the approved CAP vendor; and

(*5*) Legal counsel.

(B) The hearing is conducted by the hearing officer who receives relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in paragraph (c)(7)(ii)(A) of this section; and

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

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician within 10 days of receipt of the hearing request, and the findings and recommendations are due to the participating CAP physician within 30 days of the hearing's conclusion.

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

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the director of the CMS Center for Medicare Management or his or her designee chooses to review that decision within 30 days. If the decision is favorable to the participating CAP physician, then the participating CAP physician may resume his or her participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official issues a final reconsideration determination to the participating CAP physician on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final. If the final decision is unfavorable to the participating CAP physician, then the participating CAP physician's CAP election agreement is terminated.

(d) The approved CAP vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved CAP vendor in full, unless a properly executed advance beneficiary notice is in place. When a beneficiary receives an inappropriate coinsurance bill, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. This is in addition to, rather than in place of, any other beneficiary appeal rights. The designated carrier will

first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file.

[70 FR 39097, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§ 414.917 Dispute resolution and process for suspension or termination of approved CAP contract and termination of physician participation under exigent circumstances.

(a) *General rule.* If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug supplied by the approved CAP vendor to be unsatisfactory, then the physician may address the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. If CMS suspends an approved CAP vendor's CAP contract for noncompliance or terminates the CAP contract in accordance with §414.914(a), the approved CAP vendor may request a reconsideration in accordance with paragraph (c) of this section.

(b) *Dispute resolution.* (1) When a participating CAP physician is dissatisfied with an approved CAP vendor's service or the quality of a CAP drug supplied by the approved CAP vendor, then the participating CAP physician may use the approved CAP vendor's grievance process. If the service or quality issues are not resolved through the grievance process to the physician's satisfaction, then the participating CAP physician may ask the designated carrier to—

(i) Review the approved CAP vendor's performance; and

(ii) Potentially recommend termination of the approved CAP vendor's CAP contract.

(2) *Responsibility of the designated carrier.* The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. This recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and, gather relevant additional information from the approved CAP vendor, the participating CAP physician, the local carrier, and the beneficiary before deciding whether to terminate the approved CAP vendor's CAP contract.

(4) The approved CAP vendor may appeal that termination by requesting a reconsideration. A determination must be made as to whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. The approved CAP vendor's contract will remain suspended during the reconsideration process.

(c) *Reconsideration*—(1) *Right to reconsideration.* An approved CAP vendor dissatisfied with a determination that its CAP contract has been suspended or terminated by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS will reconsider any determination to suspend or terminate an approved CAP vendor's contract if the approved CAP vendor files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* An approved CAP vendor that is dissatisfied with a CMS decision to suspend or terminate its CAP contract may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the approved CAP vendor of the suspension or termination of its CAP contract.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the approved CAP vendor disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the approved CAP vendor's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from participating CAP physicians, the local carrier, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* An approved CAP vendor may

withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the approved CAP vendor the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the Director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the approved CAP vendor the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate the approved CAP vendor's CAP contract.

(7) *Informal hearing procedures.* (i) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the approved CAP vendor 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);

(*3*) Representatives from the local carriers and the designated carrier;

(*4*) The participating CAP physician who requested the suspension, if any; and

(*5*) Legal counsel.

(B) The hearing will be conducted by the hearing officer, who will receive relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in the paragraph (c)(7)(ii)(A) of this section; and

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

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer will present the findings and recommendations to the approved CAP vendor that requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the hearing officer will send a hearing notice to the approved CAP vendor within 10 days of receipt of the hearing request, and the findings and recommendations are due to the approved CAP vendor within 30 days from of the hearing's conclusion.

(ii) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the Director of the CMS Center for Medicare Management or his or her designee (CMS official) chooses to review that decision within 30 days. If the decision is favorable to the approved CAP vendor, then the approved CAP vendor may resume participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the approved CAP vendor.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official will issue a final reconsideration determination to the approved CAP vendor on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final.

(d) *CAP participating physicians' exigent circumstances provision.* The following process must be completed for participating CAP physicians' requests to terminate their participation in the program under exigent circumstances provisions described in §414.908(a)(2)(v):

(1) The designated carrier must—

(i) Determine whether a request to terminate CAP participation was related to approved CAP vendor service, and if so, forward the issue to the approved CAP vendor's grievance process within 1 business day of the receipt of the request; or

(ii) Continue to investigate, consistent with § 414.916(b)(2) of this chapter, and within 2 business days of receipt, do any of the following:

(A) Request a single, 2-business day extension. No later than the end of any 2-business day extension, the designated carrier must make findings and a recommendation as provided in subparagraph (B) or (C).

(B) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician be permitted to terminate his or her participation in the CAP.

(C) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician not be permitted to terminate his or her participation in the CAP.

(ii) In the case of a request made under § 414.908(a)(2)(v)(B), the designated carrier also shall include in its recommendation its finding with respect to whether the request is based on a change in circumstances of which the participating CAP physician was previously unaware.

(2) CMS will consider the carrier's findings and recommendation and may also make its own findings. As a result, CMS will—

(i) Approve or deny the request to terminate participation in the CAP within 2 business days of receipt of the recommendation.

(ii) Communicate the decision to the appropriate Medicare contractors and the participating CAP physician.

(3) A denial of the participating CAP physician's request to terminate participation in the CAP must include written notification of the right to request reconsideration under § 414.916(c).

(4) Upon termination of participation in the CAP a physician must—

(i) Continue to submit claims for drugs supplied and administered under the CAP prior to the effective date of the physician's termination from the CAP consistent with § 414.908(a) until all such claims are timely submitted.

(ii) Return any unused CAP drugs that had not been administered to the beneficiary prior to the effective date of the physician's termination from the CAP to the approved CAP vendor consistent with applicable law and regulation and any agreement with the approved CAP vendor.

(iii) Cooperate in any post-payment review activities on claims submitted under the CAP, as required under section 1847B(a)(3) of the Act.

(5) An approved CAP vendor that has billed and been paid for CAP drugs that have not been administered must refund any payments made by CMS or the beneficiary and his or her supplemental insurer in accordance with § 414.914(h)(3)(i)(2) of this chapter.

[70 FR 39098, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§ 414.918 Assignment.

Payment for a CAP drug may be made only on an assignment-related basis.

[70 FR 39099, July 6, 2005]

§ 414.920 Judicial review.

The following areas under the CAP are not subject to administrative or judicial review:

(a) The establishment of payment amounts.

(b) The awarding of vendor contracts.

(c) The establishment of competitive acquisition areas.

(d) The selection of CAP drugs.

(e) The bidding structure.

(f) The number of vendors selected.

[70 FR 39099, July 6, 2005]

§ 414.930 Compendia for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

(a) *Definitions.* For the purposes of this section:

Compendium means a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example a compendium of anti-cancer treatment. A compendium—

(i) Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases.

(ii) Is indexed by drug or biological.

(iii) Has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

Publicly transparent process for evaluating therapies means that the process provides that the following information from an internal or external request for inclusion of a therapy in a compendium are available to the public for a period of not less than 5 years, which includes availability on the compendium's Web site for a period of not less than 3 years, coincident with the compendium's publication of the related recommendation:

(i) The internal or external request for listing of a therapy recommendation including criteria used to evaluate the request.

(ii) A listing of all the evidentiary materials reviewed or considered by the compendium pursuant to the request.

(iii) A listing of all individuals who have substantively participated in the review or disposition of the request.

(iv) Minutes and voting records of meetings for the review and disposition of the request.

Publicly transparent process for identifying potential conflicts of interests means that process provides that the following information is identified and made timely available in response to a public request for a period of not less than 5 years, coincident with the compendium's publication of the related recommendation:

(i) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium. This may include, for example, compensation arrangements such as salary, grant, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the review and disposition of the request and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(ii) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(b) *Process for listing compendia for determining medically-accepted uses of drugs and biologicals in anti-cancer treatment.* (1) The CMS process—

(i) Receives formal written requests for changes to the list of compendia during a 30 day window beginning January 15 each year.

(ii) Publishes a listing of the timely, complete requests by March 15th and solicits public comment on the requests for 30 days. The listing identifies the requestor and the requested action.

(iii) Considers a compendium's attainment of the MedCAC (Medicare Evidence Development and Coverage Advisory Committee, previously known as the MCAC—Medicare Coverage Advisory Committee) recommended desirable characteristics of compendia (including explicit listing and recommendations) in reviewing requests. CMS may consider additional reasonable factors.

(iv) Considers a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence.

(v) Considers whether the publication that is the subject of the request meets the definition of a compendium in this section.

(vi) Publishes its decision no later than 90 days after the close of the public comment period.

(2) *Exception.* In addition to the annual process outlined in paragraph (b)(1) of this section, CMS may internally generate a request for changes to the list of compendia at any time.

(c) *Written request for review.* (1) CMS will review a complete, written request that is submitted in writing, electronically or via hard copy (no duplicate submissions) and includes the following:

(i) The full name and contact information of the requestor.

(ii) The full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

(iii) A complete written copy of the compendium that is the subject of the request.

(iv) The specific action that is requested of CMS.

(v) Materials that the requestor must submit for CMS review in support of the requested action.

(vi) A single compendium as its subject.

(d) CMS may at its discretion combine and consider multiple requests that refer to the same compendium.

(e) For the purposes of this section, publication by CMS may be accomplished by posting on the CMS Web site.

[72 FR 66404, Nov. 27, 2007, as amended at 74 FR 62013, Nov. 25, 2009]

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) *Provision of information to manufacturers*—(1) *In general.* For each calendar quarter beginning on or after January 1, 2023, CMS reports to each manufacturer (as defined in § 414.802) of a refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Information on the total number of billing units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined by the JW modifier (or any successor modifier that includes the same data).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (a)(3) of this section.

(iii) For purposes of this section, the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(2) *Exclusion of units of packaged drugs.* The total number of billing units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of paragraph (a)(1) of this section, and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (c)(2) of this section, shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(3) *Reports.* Reports are sent once annually.

(b) *Manufacturer requirement.* For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, pay a refund that is equal to the amount determined in accordance with paragraph (c) of this section for such drug for such quarter.

(1) Refund amounts that the manufacturer is liable for pursuant to this paragraph are paid in 12-month intervals, in a manner specified by CMS.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than 30 days following the resolution of the dispute.

(3) Amounts paid as refunds pursuant to this paragraph shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act.

(c) *Refund amount.* The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which—

(1) The product of:

(i) The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

(ii) The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(2) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the quarter.

(3) For purposes of paragraph (c)(1)(ii) of this section, the term ''applicable percentage'' means 10 percent except where an increased applicable percentage is applied in paragraph (d) of this section.

(d) *Treatment of drugs that have unique circumstances.* For purposes of paragraph (c)(1)(ii) of this section, the term ''applicable percentage'' means

(1) 35 percent for drugs that are reconstituted with a hydrogel and have variable dosing based on patient-specific characteristics

(2) [Reserved]

(e) *Dispute resolution.* Each manufacturer has an opportunity to dispute information in the report described in paragraph (a) of this section by submitting an error report as described in this paragraph.

(1) *Error report information.* To assert that there have been one or more errors in the report, a manufacturer must submit a dispute with each asserted error and provide the following information—

(i) Manufacturer name and address;

(ii) The name, telephone number, and email address of one or more employees or representatives of the manufacturer.

(iii) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation;

(iv) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of why the manufacturer believes that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

(2) *Form, manner, and timing of submission.* Each manufacturer asserting an error must submit its error report(s), in the form and manner specified by CMS, within 30-days after the issuance of the report.

(f) *Enforcement.* (1) *Manufacturer audits.* Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this section shall be subject to periodic audit with respect to such drug and such refunds.

(2) *Civil money penalty.* The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (b) of this section for such drug for a calendar quarter in an amount equal to the sum of—

(i) The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

(ii) 25 percent of such amount.

[87 FR 70226, Nov. 18, 2022, as amended at 88 FR 15920, Mar. 15, 2023]

Subpart L—Supplying and Dispensing Fees

§ 414.1000 Purpose.

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

[69 FR 66425, Nov. 15, 2004]

§ 414.1001 Basis of payment.

(a) *Supplying fees.* Beginning in CY 2006—

(1) A supplying fee of $24 is paid to a pharmacy for the first prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(2) A supplying fee of $16 is paid to a pharmacy for each prescription following the first prescription (as specified in paragraph (a)(1) of this section) of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(3) A separate supplying fee is paid to a pharmacy for each prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) *Supplying fees following transplant.* Beginning CY 2006—(1) A supplying fee of $50 is paid to pharmacy for the initial supplied prescription of drugs and

biologicals described in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a patient during the first 30-day period following a transplant.

(2) A supplying fee of $16 is paid to a pharmacy for each prescription following an initial prescription after a transplant (as specified in paragraph (b)(1) of this section) of drugs and biologicals describe in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(c) *30-day dispensing fees.* Beginning CY 2006—(1) A dispensing fee of $57 is paid to a supplier to the extent that the prescription is for the initial dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(2) Except for supplied inhalation drugs that meet criteria described in paragraph (c)(1) of this section, a dispensing fee of $33 is paid for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(d) *90-day dispensing fee.* Beginning CY 2006, a dispensing fee of $66 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 90-day supply.

[70 FR 70334, Nov. 21, 2005]

Subpart M—Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services

SOURCE: 72 FR 66404, Nov. 27, 2007, unless otherwise noted.

§ 414.1100 Basis and scope.

This subpart implements sections 1834(k)(1) and (k)(3) of the Act by specifying the payment methodology for comprehensive outpatient rehabilitation facility services covered under Part B of Title XVIII of the Act that are described at section 1861(cc)(1) of the Act.

§ 414.1105 Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) services.

(a) *Payment under the physician fee schedule.* Except as otherwise specified under paragraphs (b), (c), (d), and (e) of this section payment for CORF services, as defined under § 410.100 of this chapter, is paid the lesser of 80 percent of the following:

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

(2) The nonfacility amount determined under the physician fee schedule established under section 1848(b) of the Act for the item or service.

(b) *Payment for physician services.* No separate payment for physician services that are CORF services under § 410.100(a) of this chapter will be made.

(c) *Payment for supplies and durable medical equipment, prosthetic and orthotic devices, and drugs and biologicals.* Supplies and durable medical equipment that are CORF services under § 410.100(l) of this chapter, prosthetic device services that are CORF services under § 410.100(f), orthotic devices that are CORF services under § 410.100(g) of this chapter and drugs and biologicals that are CORF services under § 410.100(k) of this chapter are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d); or

(2) The amount determined under the DMEPOS fee schedule established under part 414 subparts D and F for the item or the single payment amount established under the DMEPOS competitive bidding program provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d).

(d) *Payment for drugs and biologicals.* Drugs and biologicals that are CORF services under § 410.100(j) of this chapter, are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (c); or

(2) The amount determined using the same methodology for drugs (as defined in § 414.704 of this chapter) described in section 1842(o)(1) of the Act provided that payment for such *drug* is not included in the payment amount for other CORF services paid under paragraphs (a) or (c).

(e) *Payment for CORF services when no fee schedule amount for the service.* If there is no fee schedule amount established for a CORF service, payment for the item or service will be the lesser of 80 percent of:

(i) The actual charge for the service provided that payment for such item or service is not included in the payment amount for other CORF services paid under paragraphs (a), (c), or (d) of this section.

(ii) The amount determined under the fee schedule established for a comparable service as specified by the Secretary provided that payment for such item or service is not included in the payment amount for other CORF services paid under paragraphs (a), (c), or (d) of this section.

Subpart N—Value-Based Payment Modifier Under the Physician Fee Schedule

SOURCE: 77 FR 69368, Nov. 16, 2012, unless otherwise noted.

§ 414.1200 Basis and scope.

(a) *Basis.* This subpart implements section 1848(p) of the Act by establishing a payment modifier that provides for differential payment starting in 2015 to a group of physicians and starting in 2017 to a group and a solo practitioner under the Medicare Physician Fee Schedule based on the quality of care furnished compared to cost during a performance period.

(b) *Scope.* This subpart sets forth the following:

(1) The application of the value-based payment modifier.

(2) Performance and payment adjustment periods.

(3) Reporting mechanisms for the value-based payment modifier.

(4) Alignment of PQRS quality of care measures with the quality measures for the value-based payment modifier.

(5) Additional measures for groups and solo practitioners.

(6) Cost measures.

(7) Attribution for quality of care and cost measures.

(8) Scoring methods for the value-based payment modifier.

(9) Benchmarks for quality of care measures.

(10) Benchmarks for cost measures.

(11) Composite scores.

(12) Reliability of measures.

(13) Payment adjustments.

(14) Value-based payment modifier quality-tiering scoring methodology.

(15) Limitation of review.

(16) Inquiry process.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68005, Nov. 13, 2014]

§ 414.1205 Definitions.

As used in this subpart, unless otherwise indicated—

Accountable care organization (ACO) has the same meaning given this term under § 425.20 of this chapter.

Certified registered nurse anesthetist (CRNA) has the same meaning given this term under section 1861(bb)(2) of the Act.

Critical access hospital has the same meaning given this term under § 400.202 of this chapter.

Electronic health record (EHR) has the same meaning given this term under § 414.92 of this chapter.

Eligible professional has the same meaning given this term under section 1848(k)(3)(B) of the Act.

Federally Qualified Health Center has the same meaning given this term under § 405.2401(b) of this chapter.

Group of physicians (Group) means a single Taxpayer Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN.

Performance period means the calendar year that will be used to assess the quality of care furnished compared to cost.

Performance rate mean the calculated rate for each quality or cost measure such as the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure.

Physician has the same meaning given this term under section 1861(r) of the Act.

Physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) have the same meanings given these terms under section 1861(aa)(5) of the Act.

Physician Fee Schedule has the same meaning given this term under part 410 of this chapter.

Physician Quality Reporting System means the system established under section 1848(k) of the Act.

Risk score means the beneficiary risk score derived from the CMS Hierarchical Condition Categories (HCC) model.

Solo practitioner means a single Taxpayer Identification Number (TIN) with one eligible professional who is identified by an individual National Provider Identifier (NPI) billing under the TIN.

Taxpayer Identification Number (TIN) has the same meaning given this term under § 425.20 of this chapter.

Value-based payment modifier means the percentage as determined under § 414.1270 by which amounts paid to a group or solo practitioner under the Medicare Physician Fee Schedule established under section 1848 of the Act are adjusted based upon a comparison of the quality of care furnished to cost as determined by this subpart.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68005, Nov. 13, 2014; 80 FR 71382, Nov. 16, 2015]

§ 414.1210 Application of the value-based payment modifier.

(a) The value-based payment modifier is applicable:

(1) For the CY 2015 payment adjustment period, to physicians in groups with 100 or more eligible professionals based on the performance period described at § 414.1215(a).

(2) For the CY 2016 payment adjustment period, to physicians in groups with 10 or more eligible professionals based on the performance period described at § 414.1215(b).

(3) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(4) For the CY 2018 payment adjustment period, to nonphysician eligible professionals who are physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with 2 or more eligible professionals and to physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(b) *Exceptions.* (1) Groups of physicians that are participating in the Medicare Shared Savings Program, the testing of the Pioneer ACO model, or other similar Innovation Center or CMS initiatives shall not be subject to any adjustments under the value-based payment modifier for CY 2015 and CY 2016.

(2) *Application of the value-based payment modifier to participants in the Shared Savings Program.*

(i) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners that participate in an ACO under the Shared Savings Program during the performance period for the payment adjustment period as described at § 414.1215. The value-based payment modifier for a group or solo practitioner that participates in an ACO under the Shared Savings Program during the performance period is determined based on paragraphs (b)(2)(i)(A) through (D) of this section.

(A) The cost composite is classified as ''average'' under §414.1275(b).

(B) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under §425.504 of this chapter, the quality composite score is calculated under §414.1260(a) using quality data reported by the ACO for the performance period through the ACO GPRO Web interface as required under §425.504(a)(1) of this chapter or another mechanism specified by CMS and the ACO all-cause readmission measure. Groups and solo practitioners that participate in two or more ACOs during the applicable performance period receive the quality composite score of the ACO that has the highest numerical quality composite score. For the CY 2018 payment adjustment period, the CAHPS for ACOs survey also will be included in the quality composite score. For the CY 2017 and 2018 payment adjustment periods, for groups and solo practitioners who participate in a Shared Savings Program ACO that does not successfully report quality data as required by the Shared Savings Program under §425.504 and who meet the requirements to avoid the PQRS payment adjustment for CY 2018 by reporting to the PQRS outside the ACO, the quality composite is classified as ''average'' under §414.1275(b).

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to –4% for groups of physicians with 10 or more eligible professionals and equal to –2% for groups of physicians with two to nine eligible professionals and for physician solo practitioners. If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group of physician or physician solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group has 10 or more eligible professionals or +2 × (rather than +1 ×) for a solo practitioner or the group has two to nine eligible professionals.

(D) For the CY 2018 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to the downward payment adjustment amounts described at §414.1270(d)(1). If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group or solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2018 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group of physicians has 10 or more eligible professionals, +2 × (rather than +1 ×) for a physician solo practitioner or if the group of physicians has two to nine eligible professionals, or +2 × (rather than +1 ×) for a solo practitioner who is a nonphysician eligible professional or if the group consists of nonphysician eligible professionals.

(E) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier for groups and solo practitioners that participate in an ACO under the Shared Savings Program during the applicable performance period is determined as described under paragraph (b)(2) of this section, regardless of whether any eligible professionals in the group or the solo practitioner also participate in an

Innovation Center model during the performance period.

(F) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under § 425.504 of this chapter, the same value-based payment modifier adjustment will be applied in the payment adjustment period to all groups based on size as specified under § 414.1275 and solo practitioners that participated in the ACO during the performance period.

(ii) For the CY 2018 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to nonphysician eligible professionals in groups with 2 or more eligible professionals and to nonphysician eligible professionals who are solo practitioners that participate in an ACO under the Shared Savings Program during the performance period for the payment adjustment period as described at § 414.1215. The value-based payment modifier for nonphysician eligible professionals is determined in the same manner as for physicians as described under paragraphs (b)(2)(i)(A) through (D) of this section.

(3) *Application of the value-based payment modifier to participants in the Pioneer ACO Model and the Comprehensive Primary Care Initiative.* (i) For the CY 2017 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians in groups with 2 or more eligible professionals and for physicians who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215.

(ii) For the CY 2018 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and for physicians and nonphysician eligible professionals who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215.

(iii) For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in the Pioneer ACO Model or CPC Initiative if at least one eligible professional billing under the TIN in the performance period for the payment adjustment period as described at § 414.1215 is participating in the Pioneer ACO Model or CPC Initiative in the performance period.

(4) *Application of the value-based payment modifier to participants in other similar Innovation Center models.* (i) For the CY 2017 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians in groups with 2 or more eligible professionals and for physicians who are solo practitioners that participate in other similar Innovation Center models during the performance period for the payment adjustment period as described at § 414.1215.

(ii) For the CY 2018 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and for physicians and nonphysician eligible professionals who are solo practitioners that participate in other similar Innovation Center models during the performance period for the payment adjustment period as described at § 414.1215.

(iii) For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in a similar Innovation Center model if at least one eligible professional billing under the TIN in the performance period for the payment adjustment period as described at § 414.1215 is participating in the similar model in the performance period.

(c) *Group size and composition determination.* (1) The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups and solo practitioners subject to the value-

based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the Physician Quality Reporting System group registration process during the applicable performance period described at § 414.1215. Groups are removed from the PECOS-generated list if, based on a claims analysis, the group did not have the required number of eligible professionals, as defined in paragraph (a) of this section, that submitted claims during the performance period for the applicable calendar year payment adjustment period. Solo practitioners are removed from the PECOS-generated list if, based on a claims analysis, the solo practitioner did not submit claims during the performance period for the applicable calendar year payment adjustment period.

(2) Beginning with the CY 2016 payment adjustment period, the size of a group during the applicable performance period will be determined by the lower number of eligible professionals as indicated by the PECOS-generated list or claims analysis.

(3) For the CY 2018 payment adjustment period, the composition of a group during the applicable performance period will be determined based on whether the group includes physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and/or other types of nonphysician eligible professionals as indicated by the PECOS-generated list or claims analysis.

[77 FR 69368, Nov. 16, 2012, as amended at 78 FR 74820, Dec. 10, 2013; 79 FR 68005, Nov. 13, 2014; 80 FR 71382, Nov. 16, 2015; 81 FR 80555, Nov. 15, 2016]

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

(a) The performance period is calendar year 2013 for value-based payment modifier adjustments made in the calendar year 2015 payment adjustment period.

(b) The performance period is calendar year 2014 for value-based payment modifier adjustments made in the calendar year 2016 payment adjustment period.

(c) The performance period is calendar year 2015 for value-based payment modifier adjustments made in the calendar year 2017 payment adjustment period.

(d) The performance period is calendar year 2016 for value-based payment modifier adjustments made in the calendar year 2018 payment adjustment period.

[77 FR 69368, Nov. 16, 2012, as amended at 78 FR 74820, Dec. 10, 2013; 80 FR 71383, Nov. 16, 2015]

§ 414.1220 Reporting mechanisms for the value-based payment modifier.

Solo practitioners and groups subject to the value-based payment modifier (or individual eligible professionals within such groups) may submit data on quality measures as specified under the Physician Quality Reporting System using the reporting mechanisms for which they are eligible.

[78 FR 74820, Dec. 10, 2013, as amended at 79 FR 68006, Nov. 13, 2014]

§ 414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which solo practitioners and groups (or individual eligible professionals within such groups) are eligible to report under the Physician Quality Reporting System in a given calendar year are used to calculate the value-based payment modifier for the applicable payment adjustment period, as defined in § 414.1215, to the extent a solo practitioner or a group (or individual eligible professionals within such group) submit data on such measures.

[79 FR 68006, Dec. 13, 2014]

§ 414.1230 Additional measures for groups and solo practitioners.

The value-based payment modifier includes the following additional quality measures (outcome measures) as applicable for all groups and solo practitioners subject to the value-based payment modifier:

(a) A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes. The

rate of potentially preventable hospital admissions for diabetes is a composite measure of uncontrolled diabetes, short term diabetes complications, long term diabetes complications and lower extremity amputation for diabetes.

(b) A composite of rates of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia.

(c) Rates of an all-cause hospital readmissions measure, except for groups with between two to nine eligible professionals and solo practitioners starting with the CY 2017 payment adjustment period.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71383, Nov. 16, 2015]

§ 414.1235 Cost measures.

(a) *Included measures.* Beginning with the CY 2016 payment adjustment period, costs for groups and solo practitioners subject to the value-based payment modifier are assessed based on a cost composite comprised of the following 6 cost measures (only the measures identified in paragraphs (a)(1) through (5) of this section are included for the value-based payment modifier for the CY 2015 payment adjustment period):

(1) Total per capita costs for all attributed beneficiaries.

(2) Total per capita costs for all attributed beneficiaries with diabetes.

(3) Total per capita costs for all attributed beneficiaries with coronary artery disease.

(4) Total per capita costs for all attributed beneficiaries with chronic obstructive pulmonary disease.

(5) Total per capita costs for all attributed beneficiaries with heart failure.

(6) Medicare Spending per Beneficiary associated with an acute inpatient hospitalization.

(b) *Included payments.* Cost measures enumerated in paragraph (a) of this section include all fee-for-service payments made under Medicare Part A and Part B.

(c) *Cost measure adjustments.* (1) Payments under Medicare Part A and Part B will be adjusted using CMS' payment standardization methodology to ensure fair comparisons across geographic areas.

(2) The CMS–HCC model (and adjustments for ESRD status) is used to adjust standardized payments for the measures listed at paragraphs (a)(1) through (5) of this section.

(3) The beneficiary's age and severity of illness are used to adjust the Medicare Spending per Beneficiary measure as specified in paragraph (a)(6) of this section.

(4) Beginning with the CY 2016 payment adjustment period, the cost measures of a group and solo practitioner subject to the value-based payment modifier are adjusted to account for the group's and solo practitioner's specialty mix, by computing the weighted average of the national specialty specific expected costs and comparing this to the group's actual risk adjusted costs. Each national specialty-specific expected cost is weighted by the proportion of Part B payments incurred by each specialty within the group.

(5) The national specialty-specific expected costs referenced in paragraph (c)(4) of this section are derived by calculating, for each specialty, the weighted average of the risk-adjusted costs computed across all groups, where the weight for each group is equal to the number of beneficiaries attributed to the group, times the number of eligible professionals in the group with the relevant specialty, times the proportion of eligible professionals in the group with the relevant specialty.

[78 FR 74821, Dec. 10, 2013, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71383, Nov. 16, 2015]

§ 414.1240 Attribution for quality of care and cost measures.

(a) Beneficiaries are attributed to groups and solo practitioners subject to the value-based payment modifier using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter, for measures other than the Medicare Spending per Beneficiary measure.

(b) For the Medicare Spending per Beneficiary (MSPB) measure, an MSPB episode is attributed to the group or the solo practitioner subject to the

value-based payment modifier whose eligible professionals submitted the plurality of claims (as measured by allowable charges) under the group's or solo practitioner's TIN for Medicare Part B services, rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at § 414.1215.

[79 FR 68007, Nov. 13, 2014]

§ 414.1245 Scoring methods for the value-based payment modifier using the quality-tiering approach.

For each quality of care and cost measure, a standardized score is calculated for each group and solo practitioner subject to the value-based payment modifier by dividing—

(a) The difference between their performance rate and the benchmark, by

(b) The measure's standard deviation.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68007, Nov. 13, 2014]

§ 414.1250 Benchmarks for quality of care measures.

(a) The benchmark for quality of care measures reported through the PQRS using the claims, registries, QCDR, or web interface is the national mean for that measure's performance rate (regardless of the reporting mechanism) during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate. Beginning with the CY 2016 performance period, eCQMs reported via EHRs are excluded from the overall benchmark for quality of care measures and separate eCQM benchmarks will be developed. The eCQM benchmark is the national mean for the measure's performance rate during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate.

(b) The benchmark for each outcome measure under § 414.1230, is the national mean for that measure's performance rate during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate.

[79 FR 68007, Nov. 13, 2014, as amended at 80 FR 71384, Nov. 16, 2015]

§ 414.1255 Benchmarks for cost measures.

(a) For the CY 2015 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups of physicians for which beneficiaries are attributed to the group of physicians that are subject to the value-based payment modifier. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of beneficiaries used to calculate the group of physician's performance rate.

(b) Beginning with the CY 2016 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups and solo practitioners that meet the minimum number of cases for that measure under § 414.1265(a). In calculating the national benchmark, groups and solo practitioners' performance rates are weighted by the number of beneficiaries used to calculate the group or solo practitioner's performance rate.

[78 FR 74821, Dec. 10, 2013, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71384, Nov. 16, 2015]

§ 414.1260 Composite scores.

(a)(1) The standardized score for each quality of care measure is classified into one of the following equally weighted domains to determine the quality composite:

(i) Patient safety.

(ii) Patient experience.
(iii) Care coordination.
(iv) Clinical care.
(v) Population/community health.
(vi) Efficiency.

(2) If a domain includes no measure or does not reach the minimum case size in § 414.1265, the remaining domains are equally weighted to form the quality of care composite.

(b)(1) The standardized score for each cost measure is grouped into two separate and equally weighted domains to determine the cost composite:

(i) Total per capita costs for all attributed beneficiaries: Total per capita costs measure and Medicare Spending per Beneficiary measure; and

(ii) Total per capita costs for all attributed beneficiaries with specific conditions: Diabetes, coronary artery disease, chronic obstructive pulmonary disease, or heart failure (four measures).

(2) Measures within each domain are equally weighted.

[77 FR 69368, Nov. 16, 2012, as amended at 78 FR 74821, Dec. 10, 2013]

§ 414.1265 Reliability of measures.

To calculate a composite score for a quality measure or a cost measure, a group or solo practitioner subject to the value-based payment modifier must have 20 or more cases for that measure.

(a) In a performance period, if a group or solo practitioner has fewer than 20 cases for a measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(1) Starting with the CY 2017 payment adjustment period, the exception to this paragraph (a) is the all-cause hospital readmissions measure described at § 414.1230(c). In a performance period, if a group has fewer than 200 cases for this all-cause hospital readmissions measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(2) Starting with the CY 2017 payment adjustment period, the Medicare Spending Per Beneficiary measure described at § 414.1235(a)(6) is an exception to this paragraph (a). In a performance period, if a group or a solo practitioner has fewer than 125 episodes for this MSPB measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(b)(1) For the CY 2015 payment adjustment period, if a reliable quality of care composite or cost composite cannot be calculated, payments will not be adjusted under the value-based payment modifier.

(2) Beginning with the CY 2016 payment adjustment period, a group and a solo practitioner subject to the value-based payment modifier will receive a quality composite score that is classified as ''average'' under § 414.1275(b)(1) if such group and solo practitioner do not have at least one quality measure that meets the minimum number of cases under paragraph (a) of this section.

(3) Beginning with the CY 2016 payment adjustment period, a group and a solo practitioner subject to the value-based payment modifier will receive a cost composite score that is classified as ''average'' under § 414.1275(b)(2) if such group and solo practitioner do not have at least one cost measure that meets the minimum number of cases under paragraph (a) of this section.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71384, Nov. 16, 2015]

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

(a) For the CY 2015 payment adjustment period:

(1) *Downward payment adjustments.* A downward payment adjustment will be applied to a group of physicians subject to the value-based payment modifier if—

(i) Such group neither self-nominates for the PQRS GPRO and reports at least one measure, nor elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(A) Such adjustment will be −1.0 percent.

(B) [Reserved]

(ii) Such group elects that its value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance

(low quality and high costs; low quality and average costs; or average quality and high costs).

(A) Such adjustment will not exceed −1.0 percent as specified in §414.1275(c)(1).

(B) [Reserved]

(2) *No payment adjustments.* There will be no value-based payment modifier adjustment applied to a group of physicians subject to the value-based payment modifier if such group either:

(i) Self-nominates for the PQRS GPRO and reports at least one measure; or

(ii) Elects the PQRS administrative claims option for CY 2013 as defined in §414.90(h).

(3) *Upward payment adjustments.* If a group of physicians subject to the value-based payment modifier elects that the value-based payment modifier be calculated using a quality-tiering approach, upward payment adjustments are determined based on the projected aggregate amount of downward payment adjustments determined under paragraph (a)(1) of this section and applied as specified in §414.1275(c)(1).

(b) For the CY 2016 payment adjustment period:

(1) A downward payment adjustment of −2.0 percent will be applied to a group of physicians subject to the value-based payment modifier if, during the applicable performance period as defined in §414.1215, the following apply:

(i) Such group does not self-nominate for the PQRS GPRO and meet the criteria as a group to avoid the PQRS payment adjustment for CY 2016 as specified by CMS; and

(ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS.

(2) For a group of physicians comprised of 100 or more eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(2).

(3) For a group of physicians comprised of between 10 and 99 eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(2), except that such adjustment will be 0.0 percent if the group of physicians is determined to be low quality/high cost, low quality/average cost, or average quality/high cost.

(4) If at least fifty percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as ''average'' under §414.1275(b)(1).

(c) For the CY 2017 payment adjustment period:

(1) A downward payment adjustment of −2.0 percent will be applied to a group with two to nine eligible professionals and a solo practitioner and a downward payment adjustment of −4.0 percent will be applied to a group with 10 or more eligible professionals subject to the value-based payment modifier if, during the applicable performance period as defined in §414.1215, the following apply:

(i) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2017 as specified by CMS; and

(ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2017 as specified by CMS; or

(iii) Such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2017 as specified by CMS.

(2) For a group comprised of 10 or more eligible professionals that is not included in paragraph (c)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(3)(i).

(3) For a group comprised of between two to nine eligible professionals and a solo practitioner that are not included in paragraph (c)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(3)(ii).

(4) If at least fifty percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2017 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

(d) For the CY 2018 payment adjustment period:

(1) A downward payment adjustment of −1.0 percent will be applied to a solo practitioner, a group with two to nine eligible professionals, and a group consisting only of nonphysician eligible professionals subject to the value-based payment modifier and no physicians; and a downward payment adjustment of −2.0 percent will be applied to a group with 10 or more eligible professionals and at least one physician if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) For groups:

(A) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; and

(B) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

(ii) For solo practitioners, such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

(2) For a group composed of 10 or more eligible professionals that is not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(i).

(3) For a group composed of between two to nine eligible professionals and a solo practitioner that are not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(ii).

(4) For a group and a solo practitioner consisting of nonphysician eligible professionals that are not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(iii).

(5) If at least 50 percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

[78 FR 74821, Dec. 10, 2013, as amended at 79 FR 68007, Nov. 13, 2014; 80 FR 71384, Nov. 16, 2015; 82 FR 53363, Nov. 15, 2017]

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(a) The value-based payment modifier amount for a group and a solo practitioner subject to the value-based payment modifier is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

(b) Quality composite and cost composite are classified into high, average, and low categories based on whether the composites are statistically above, not different from, or below the mean composite scores.

(1) Quality composites that are one or more standard deviations above the mean are classified into the high category. Quality composites that are one or more standard deviations below the mean are classified into the low category.

(2) Cost composites that are one or more standard deviations below the mean are classified into the low category. Cost composites that are one or more standard deviations above the mean are classified into the high category.

(c)(1) The following value-based payment modifier percentages apply to the CY 2015 payment adjustment period:

CY 2015 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+ 2.0x*	+ 1.0x*	+ 0.0
Average quality	+ 1.0x*	+ 0.0%	–0.5
Low quality	+ 0.0%	–0.5%	–1.0

*Groups of physicians eligible for an additional + 1.0x if (1) reporting Physician Quality Reporting System quality measures through the GPRO web-interface or CMS-qualified registry, and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(2) The following value-based payment modifier percentages apply to the CY 2016 payment adjustment period:

CY 2016 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+ 2.0x*	+ 1.0x*	+ 0.0
Average quality	+ 1.0x*	+ 0.0%	–1.0
Low quality	+ 0.0%	–1.0%	–2.0

*Groups of physicians eligible for an additional + 1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(3) The following value-based payment modifier percentages apply to the CY 2017 payment adjustment period:

(i) For groups with 10 or more eligible professionals:

CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR GROUPS WITH 10 OR MORE ELIGIBLE PROFESSIONALS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+ 0.0%	*+ 2.0x	*+ 4.0x
Average Cost	− 2.0%	+ 0.0%	*+ 2.0x
High Cost	− 4.0%	− 2.0%	+ 0.0%

*Groups eligible for an additional + 1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(ii) For groups with two to nine eligible professionals and solo practitioners:

CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR GROUPS WITH TWO TO NINE ELIGIBLE PROFESSIONALS AND SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+ 0.0%	*+ 1.0x	*+ 2.0x
Average Cost	+ 0.0%	+ 0.0%	*+ 1.0x
High Cost	+ 0.0%	+ 0.0%	+ 0.0%

*Groups and solo practitioners eligible for an additional + 1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(4) The following value-based payment modifier percentages apply to the CY 2018 payment adjustment period, for physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners or who are in groups of any size:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	*+1.0x	*+2.0x

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS—Continued

Cost/quality	Low quality	Average quality	High quality
Average Cost	+0.0%	+0.0%	*+1.0x
High Cost	+0.0%	+0.0%	+0.0%

*Eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(d)(1) Groups of physicians subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2015 payment adjustment period elect the quality-tiering approach or for the CY 2016 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of + 3x (rather than + 2x); and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of + 2x (rather than + 1x).

(2) Groups and solo practitioners subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2017 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of + 5x (rather than + 4x) if the group has 10 or more eligible professionals or + 3x (rather than + 2x) if a solo practitioner or the group has two to nine eligible professionals; and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of + 3x (rather than + 2x) if the group has 10 or more eligible professionals or + 2x (rather than + 1x) if a solo practitioner or the group has two to nine eligible professionals.

(3) Groups and solo practitioners subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2018 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of +3x (rather than +2x); and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +2x (rather than +1x).

[77 FR 69368, Nov. 16, 2012, as amended at 78 FR 74822, Dec. 10, 2013; 79 FR 68008, Nov. 13, 2014; 80 FR 71385, Nov. 16, 2015; 82 FR 53363, Nov. 15, 2017]

§ 414.1280 Limitation on review.

(a) There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of all of the following:

(1) The establishment of the value-based payment modifier.

(2) The evaluation of the quality of care composite, including the establishment of appropriate measure of the quality of care.

(3) The evaluation of costs composite, including establishment of appropriate measures of costs.

(4) The dates of implementation of the value-based payment modifier.

(5) The specification of the initial performance period and any other performance period.

(6) The application of the value-based payment modifier.

(7) The determination of costs.

(b) [Reserved]

§ 414.1285 Informal inquiry process.

After the dissemination of the annual Physician Feedback reports, a group and a solo practitioner may contact CMS to inquire about its report and

the calculation of the value-based payment modifier.

[77 FR 69368, Nov. 16, 2012, as amended at 79 FR 68008, Nov. 13, 2014]

Subpart O—Merit-Based Incentive Payment System and Alternative Payment Model Incentive

SOURCE: 81 FR 77537, Nov. 4, 2016, unless otherwise noted.

§ 414.1300 Basis and scope.

(a) *Basis.* This subpart implements the following provisions of the Act:

(1) Section 1833(z)—Incentive Payments for Participation in Eligible Alternative Payment Models.

(2) Section 1848(k)—Quality Reporting System.

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

(4) Section 1848(q)—Merit-based Incentive Payment System.

(b) *Scope.* This subpart part sets forth the following:

(1) The circumstances under which eligible clinicians are not considered MIPS eligible clinicians with respect to a year.

(2) How individual MIPS eligible clinicians can have their performance assessed as a group.

(3) The data submission methods and data submission criteria for each of the MIPS performance categories.

(4) Methods for calculating a performance category score for each of the MIPS performance categories.

(5) Methods for calculating a MIPS final score and applying the MIPS payment adjustment to MIPS eligible clinicians.

(6) Requirements for an APM to be designated an ''Advanced APM.''

(7) Methods for eligible clinicians and entities participating in Advanced APMs to meet the participation thresholds to become Qualifying APM Participants (QPs) and Partial QPs.

(8) Methods and processes for counting participation in Other Payer Advanced APMs in making QP and Partial QP determinations.

(9) Methods for calculating and paying the APM Incentive Payment to QPs.

(10) Criteria for Physician-Focused Payment Models (PFPMs).

[81 FR 77537, Nov. 4, 2016, as amended at 86 FR 65669, Nov. 19, 2021]

§ 414.1305 Definitions.

As used in this section, unless otherwise indicated—

Additional performance threshold means the numerical threshold for a MIPS payment year against which the final scores of MIPS eligible clinicians are compared to determine the additional MIPS payment adjustment factors for exceptional performance.

Advanced Alternative Payment Model (Advanced APM) means an APM that CMS determines meets the criteria set forth in § 414.1415.

Affiliated practitioner means an eligible clinician identified by a unique APM participant identifier on a CMS-maintained list who has a contractual relationship with the APM Entity for the purposes of supporting the APM Entity's quality or cost goals under the Advanced APM.

Affiliated practitioner list means the list of Affiliated Practitioners of an APM Entity that is compiled from a CMS-maintained list.

Aligned Other Payer Medical Home Model means an aligned other payer payment arrangement (not including a Medicaid payment arrangement) operated by a payer formally partnering in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU) with CMS, and is determined by CMS to have the following characteristics:

(1) The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38

Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity of care.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Alternative Payment Model (APM) means any of the following:

(1) A model under section 1115A of the Act (other than a health care innovation award).

(2) The shared savings program under section 1899 of the Act.

(3) A demonstration under section 1866C of the Act.

(4) A demonstration required by Federal law.

Ambulatory Surgical Center (ASC)-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for a period prior to the performance period as specified by CMS; and

(2) Beginning with the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for the MIPS determination period.

APM Entity means an entity that participates in an APM or other payer arrangement through a direct agreement with CMS or an other payer or through Federal or State law or regulation.

APM Entity group means the group of eligible clinicians participating in an APM Entity, as identified by a combination of the APM identifier, APM Entity identifier, Taxpayer Identification Number (TIN), and National Provider Identifier (NPI) for each participating eligible clinician.

APM Incentive Payment means the lump sum incentive payment for a year paid to an eligible clinician who is a QP for the year from 2019 through 2024.

Attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician or group may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS.

Attributed beneficiary means a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination.

Attribution-eligible beneficiary means a beneficiary who during the QP Performance Period:

(1) Is not enrolled in Medicare Advantage or a Medicare cost plan;

(2) Does not have Medicare as a secondary payer;

(3) Is enrolled in both Medicare Parts A and B;

(4) Is at least 18 years of age;

(5) Is a United States resident; and

(6) Has a minimum of one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on evaluation and management services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of evaluation and management and/or other services.

Certified Electronic Health Record Technology (CEHRT) means the following:

(1) For any calendar year before 2019, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets one of the following:

(i) The 2014 Edition Base EHR definition (as defined at 45 CFR 170.102) and that has been certified to the certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS advancing care information performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

(ii) Certification to—

(A) The following certification criteria:

(*1*) CPOE at—

(*i*) 45 CFR 170.314(a)(1), (18), (19) or (20); or

(*ii*) 45 CFR 170.315(a)(1), (2) or (3).

(*2*)(*i*) Record demographics at 45 CFR 170.314(a)(3); or

(*ii*) 45 CFR 170.315(a)(5).

(*3*)(*i*) Problem list at 45 CFR 170.314(a)(5); or

(*ii*) 45 CFR 170.315(a)(6).

(*4*)(*i*) Medication list at 45 CFR 170.314(a)(6); or

(*ii*) 45 CFR 170.315(a)(7).

(*5*)(*i*) Medication allergy list 45 CFR 170.314(a)(7); or

(*ii*) 45 CFR 170.315(a)(8).

(*6*)(*i*) Clinical decision support at 45 CFR 170.314(a)(8); or

(*ii*) 45 CFR 170.315(a)(9).

(*7*) Health information exchange at transitions of care at one of the following:

(*i*) 45 CFR 170.314(b)(1) and (2).

(*ii*) 45 CFR 170.314(b)(1), (b)(2), and (h)(1).

(*iii*) 45 CFR 170.314(b)(1), (b)(2), and (b)(8).

(*iv*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and (h)(1).

(*v*) 45 CFR 170.314(b)(8) and (h)(1).

(*vi*) 45 CFR 170.314(b)(1), (b)(2), and 170.315(h)(2).

(*vii*) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(h)(2).

(*viii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(h)(2).

(*ix*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(h)(2).

(*x*) 45 CFR 170.314(b)(8), (h)(1), and 170.315(h)(2).

(*xi*) 45 CFR 170.314(b)(1), (b)(2), and 170.315(b)(1).

(*xii*) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(b)(1).

(*xiii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(b)(1).

(*xiv*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(b)(1).

(*xv*) 45 CFR 170.314(b)(8), (h)(1), and 170.315(b)(1).

(*xvi*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(1).

(*xvii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(2).

(*xviii*) 45 CFR 170.314(h)(1) and 170.315(b)(1).

(*xix*) 45 CFR 170.315(b)(1) and (h)(1).

(*xx*) 45 CFR 170.315(b)(1) and (h)(2).

(*xxi*) 45 CFR 170.315(b)(1), (h)(1), and (h)(2); and

(B) Clinical quality measures at—

(*1*) 45 CFR 170.314(c)(1) or 170.315(c)(1);

(*2*) 45 CFR 170.314(c)(2) or 170.315(c)(2);

(*3*) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (3) and optionally (4); or 45 CFR 170.315(c)(3)(i) and (ii) and optionally (c)(4); and can be electronically accepted by CMS if the data is submitted electronically.

(C) Privacy and security at—

(*1*) 45 CFR 170.314(d)(1) or 170.315(d)(1);

(*2*) 45 CFR 170.314(d)(2) or 170.315(d)(2);

(*3*) 45 CFR 170.314(d)(3) or 170.315(d)(3);

(*4*) 45 CFR 170.314(d)(4) or 170.315(d)(4);

(*5*) 45 CFR 170.314(d)(5) or 170.315(d)(5);

(*6*) 45 CFR 170.314(d)(6) or 170.315(d)(6);

(*7*) 45 CFR 170.314(d)(7) or 170.315(d)(7);

(*8*) 45 CFR 170.314(d)(8) or 170.315(d)(8); and

(D) The certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

(iii) The definition for 2019 and subsequent years specified in paragraph (2) of this definition.

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria—

(i) At 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category including the following:

(A) The applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) and optionally (c)(4), and can be electronically accepted by CMS.

CMS-approved survey vendor means a survey vendor that is approved by CMS for a particular performance period to administer the CAHPS for MIPS survey and to transmit survey measures data to CMS.

CMS Multi-Payer Model means an Advanced APM that CMS determines, per the terms of the Advanced APM, has at least one other payer arrangement that is designed to align with the terms of that Advanced APM.

CMS Web Interface means a web product developed by CMS that is used by groups that have elected to utilize the CMS Web Interface to submit data on the MIPS measures and activities.

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey; and administrative claims measures.

(1) For the CY 2021 through CY 2024 performance periods/2023 through 2026 MIPS payment years, collection types include CMS Web Interface measures for APM Entities reporting through the APM Performance Pathway in accordance with § 414.1367.

(2) [Reserved]

Covered professional services has the meaning given by section 1848(k)(3)(A) of the Act.

Eligible clinician means ''eligible professional'' as defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination and, includes any of the following:

(1) A physician.

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

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

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

Episode payment model means an APM or other payer arrangement designed to improve the efficiency and quality of care for an episode of care by bundling payment for services furnished to an individual over a defined period of time for a specific clinical condition or conditions.

Estimated aggregate payment amounts means the total payments to a QP for Medicare Part B covered professional services for the incentive payment base period, estimated by CMS as described in § 414.1450(b).

Facility-based group means a group that CMS determines meets the criteria specified in § 414.1380(e)(2)(ii).

Facility-based MIPS eligible clinician means an individual MIPS eligible clinician who CMS determines meets the criteria specified in § 414.1380(e)(2)(i).

Final score means a composite assessment (using a scoring scale of 0 to 100) for each MIPS eligible clinician for a performance period determined using the methodology for assessing the total

performance of a MIPS eligible clinician according to performance standards for applicable measures and activities for each performance category.

Group means a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN.

Health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

Health Professional Shortage Areas (HPSA) means areas as designated under section 332(a)(1)(A) of the Public Health Service Act.

High priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure.

Hospital-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS; and

(2) For the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period; and

(3) Beginning with the 2022 MIPS payment year, an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period.

Improvement activities means an activity that relevant MIPS eligible clinician, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

Improvement scoring means an assessment measuring improvement for each MIPS eligible clinician or group for a performance period using a methodology that compares improvement from one performance period to another performance period.

Incentive payment base period means the calendar year prior to the year in which CMS disburses the APM Incentive Payment.

Low-volume threshold means:

(1) For the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Medicare Part B-enrolled individuals.

(2) For the 2020 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has allowed charges for covered professional services less than or equal to $90,000 or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals.

(3) For the 2021 and 2022 MIPS payment years, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered

professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

(4) For the 2019 and 2020 MIPS payment years, the low-volume threshold determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding to the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

(5) Beginning with the 2023 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

Meaningful EHR user for MIPS means a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT.

Measure benchmark means the level of performance that the MIPS eligible clinician is assessed on for a specific performance period at the measures and activities level.

Medicaid APM means a payment arrangement authorized by a State Medicaid program that meets the Other Payer Advanced APM criteria set forth in § 414.1420.

Medical Home Model means an APM under section 1115A of the Act that is determined by CMS to have the following characteristics:

(1) The APM has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity of care.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Medicaid Medical Home Model means a payment arrangement under title XIX that CMS determines to have the following characteristics:

(1) The payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Merit-based Incentive Payment System (MIPS) means the program required by section 1848(q) of the Act.

MIPS APM means:

(1) For the 2019 through 2022 MIPS payment years, an APM that meets the criteria specified under §414.1370(b).

(2) Beginning with the 2023 MIPS payment year, an APM that meets the criteria as set forth in §414.1367(b).

MIPS determination period means:

(1) Beginning with the 2021 MIPS payment year, a 24-month assessment period consisting of:

(i) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out; and

(ii) A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs.

(2) Subject to §414.1310(b)(1)(iii), an individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold or as having special status, as applicable, during the first segment of the MIPS determination period will be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician, group, or APM Entity group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of such segment.

MIPS eligible clinician as identified by a unique billing TIN and NPI combination used to assess performance, means any of the following (except as excluded under §414.1310(b)):

(1) For the 2019 and 2020 MIPS payment years:

(i) A physician (as defined in section 1861(r) of the Act);

(ii) A physician assistant, a nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act);

(iii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); and

(iv) A group that includes such clinicians.

(2) For the 2021 through 2023 MIPS payment years:

(i) A clinician described in paragraph (1) of this definition;

(ii) A physical therapist or occupational therapist;

(iii) A qualified speech-language pathologist;

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

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act);

(vi) A registered dietician or nutrition professional; and

(vii) A group that includes such clinicians.

(3) For the 2024 MIPS payment year and future years:

(i) A clinician described in paragraph (2) of this definition;

(ii) A clinical social worker (as defined in section 1861(hh)(1) of the Act);

(iii) A certified nurse midwife (as defined in section 1861(gg)(2) of the Act); and

(iv) A group that includes such clinicians.

MIPS payment year means a calendar year in which the MIPS payment adjustment factor, and if applicable the additional MIPS payment adjustment factor, are applied to Medicare Part B payments.

MIPS Value Pathway means a subset of measures and activities established through rulemaking.

Multispecialty group means a group as defined at § 414.1305 that consists of two or more specialty types as determined by CMS using Medicare Part B claims.

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

New Medicare-Enrolled MIPS eligible clinician means an eligible clinician who first becomes a Medicare-enrolled eligible clinician within the Provider Enrollment, Chain and Ownership System (PECOS) during the performance period for a year and had not previously submitted claims under Medicare as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier.

Non-patient facing MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the non-patient facing determination period described in paragraph (4) of this definition, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(2) Beginning with the 2021 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(3) For purposes of this definition, a patient-facing encounter is an instance in which the individual MIPS eligible clinician or group bills for items and services furnished such as general office visits, outpatient visits, and procedure codes under the PFS, as specified by CMS.

(4) For the 2019 and 2020 MIPS payment year, the non-patient facing determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible MIPS clinician, group, or virtual group that is identified as non-patient facing during the initial 12-month segment will continue to be considered non-patient facing for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the non-patient facing determination period includes a 60-day claims run out. For the 2020 MIPS payment year and future years, each segment of the non-

patient facing determination period includes a 30-day claims run out.

Other MIPS APM means a MIPS APM that does not require reporting through the CMS Web Interface.

Other Payer Advanced APM means an other payer arrangement that meets the Other Payer Advanced APM criteria set forth in §414.1420.

Other payer arrangement means a payment arrangement with any payer that is not an APM.

Partial Qualifying APM Participant (Partial QP) means an eligible clinician determined by CMS to have met the relevant Partial QP threshold under §414.1430(a)(2) and (4) and (b)(2) and (4) for a year.

Partial QP patient count threshold means the minimum threshold score specified in §414.1430(a)(4) and (b)(4) that an eligible clinician must attain through a patient count methodology described in §§414.1435(b) and 414.1440(c) to become a Partial QP for a year.

Partial QP payment amount threshold means the minimum threshold score specified in §414.1430(a)(2) and (b)(2) that an eligible clinician must attain through a payment amount methodology described §§414.1435(a) and 414.1440(b) to become a Partial QP for a year.

Participation List means the list of participants in an APM Entity that is compiled from a CMS-maintained list.

Performance category score means the assessment of each MIPS eligible clinician's performance on the applicable measures and activities for a performance category for a performance period based on the performance standards for those measures and activities.

Performance standards means the level of performance and methodology that the MIPS eligible clinician is assessed on for a MIPS performance period at the measures and activities level for all MIPS performance categories.

Performance threshold means the numerical threshold for a MIPS payment year against which the final scores of MIPS eligible clinicians are compared to determine the MIPS payment adjustment factors.

Physician Compare means the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

Population health measure means a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services.

Primary care services for purposes of CMS Web Interface and CAHPS for MIPS survey beneficiary assignment means the set of services identified by the following:

(1) CPT codes:

(i) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and

(ii) Beginning with the 2023 MIPS payment year, 99421, 99422, and 99423 (codes for online digital evaluation and management services (e-visit)); 99441, 99442, and 99443 (codes for telephone evaluation and management services); and 96160 and 96161 (codes for administration of health risk assessment).

(2) HCPCS codes:

(i) G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

(ii) Beginning with the 2023 MIPS payment year, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

QCDR measure means a quality measure that is submitted by a QCDR and approved by CMS under §414.1400. QCDR measures consist of:

(1) Measures that are not included in the MIPS final list of quality measures described in §414.1330(a)(1) for the applicable MIPS payment year; and

(2) Measures that are included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year, but have undergone substantive changes, as determined by CMS.

QP patient count threshold means the minimum threshold score specified in § 414.1430(a)(3) and (b)(3) that an eligible clinician must attain through a patient count methodology described in §§ 414.1435(b) and 414.1440(c) to become a QP for a year.

QP payment amount threshold means the minimum threshold score specified in § 414.1430(a)(1) and (b)(1) that an eligible clinician must attain through the payment amount methodology described in §§ 414.1435(a) and 414.1440(b) to become a QP for a year.

QP Performance Period means the time period that CMS will use to assess the level of participation by an eligible clinician in Advanced APMs and Other Payer Advanced APMs for purposes of making a QP determination for the eligible clinician for the year as specified in § 414.1425. The QP Performance Period begins on January 1 and ends on August 31 of the calendar year that is 2 years prior to the payment year.

Qualified clinical data registry (QCDR) means:

(1) For the 2019, 2020 and 2021 MIPS payment year, a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

(2) Beginning with the 2022 MIPS payment year, an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

Qualified registry means a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. The registry must have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS.

Qualifying APM participant (QP) means an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold under § 414.1430(a)(1), (a)(3), (b)(1), or (b)(3) for a year based on participation in an APM Entity that is also participating in an Advanced APM.

Rural area means a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

Single specialty group means a group as defined at § 414.1305 that consists of one specialty type as determined by CMS using Medicare Part B claims.

Small practice means:

(1) For the 2019 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians.

(2) For the 2020 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during a 12-month assessment period that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period and includes a 30-day claims run out.

(3) Beginning with the 2021 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period.

Solo practitioner means a practice consisting of 1 eligible clinician (who is also a MIPS eligible clinician).

Special status means that a MIPS eligible clinician:

(1) Meets the definition of an ASC-based MIPS eligible clinician, facility-based MIPS eligible clinician, hospital-based MIPS eligible clinician, non-patient facing MIPS eligible clinician, or is in a small practice; or

(2) Is located in an HPSA or rural area.

Subgroup means a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI.

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to:

(1) Direct;

(2) Log in and upload;

(3) Log in and attest;

(4) Medicare Part B claims; and

(5) CMS Web Interface (except as provided in paragraph (5)(i) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years).

(i) For the CY 2021 through CY 2024 performance periods/2023 through 2026 MIPS payment years, submission types include the CMS Web Interface for APM Entities reporting through the APM Performance Pathway in accordance with §414.1367.

(ii) [Reserved]

Submitter type means the MIPS eligible clinician, group, Virtual Group, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, or APM Entity, as applicable, that submits data on measures and activities under MIPS.

Third party intermediary means an entity that CMS has approved under §414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories.

Threshold Score means the percentage value that CMS determines for an eligible clinician based on the calculations described in §414.1435 or §414.1440.

Topped out non-process measure means a measure where the Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors.

Topped out process measure means a measure with a median performance rate of 95 percent or higher.

Virtual group means a combination of two or more TINs assigned to one or more solo practitioners or to one or more groups consisting of 10 or fewer eligible clinicians, or both, that elect to form a virtual group for a performance period for a year.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53950, Nov. 16, 2017; 83 FR 60075, Nov. 23, 2018; 84 FR 63194, Nov. 15, 2019; 85 FR 54872, Sept. 2, 2020; 85 FR 85029, Dec. 28, 2020; 86 FR 65670, Nov. 19, 2021; 86 FR 73159, Dec. 27, 2021; 87 FR 70227, Nov. 18, 2022]

§414.1310 Applicability.

(a) *Program implementation.* Except as specified in paragraph (b) of this section, MIPS applies to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

(b) *Exclusions.* (1) For a year, a MIPS eligible clinician does not include an eligible clinician who:

(i) Is a Qualifying APM Participant (as defined at §414.1305);

(ii) Is a Partial Qualifying APM Participant and does not elect to participate in MIPS as a MIPS eligible clinician; or

(iii) Does not exceed the low volume threshold.

(A) Beginning with the 2021 MIPS payment year, if an individual eligible clinician or group exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the individual eligible clinician or group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under §414.1315 constitutes an election under this paragraph (b)(1)(iii)(A) and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year.

(B) For the 2021 and 2022 MIPS payment years, if an APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated

as MIPS eligible clinicians for the applicable MIPS payment year.

(2) Eligible clinicians, as defined at § 414.1305, who are not MIPS eligible clinicians, as defined at § 414.1305, have the option to voluntarily report measures and activities for MIPS.

(c) *Treatment of new Medicare-enrolled eligible clinicians.* New Medicare-enrolled eligible clinician, as defined at § 414.1305, will not be treated as a MIPS eligible clinician until the subsequent year and the performance period for such subsequent year.

(d) *Clarification.* In no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for items and services furnished during a year by a eligible clinician, including an eligible clinician described in paragraph (b) or (c) of this section, who is not a MIPS eligible clinician, including an eligible clinician who voluntarily reports on applicable measures and activities under MIPS.

(e) *Requirements for groups.* (1) Except as provided under §§ 414.1315(a)(2), 414.1317(b), 414.1318(b), and 414.1370(f)(2) each MIPS eligible clinician in the group receives a final score based on the group's combined performance assessment.

(2) For individual MIPS eligible clinicians to participate in MIPS as a group, all of the following requirements must be met:

(i) Groups must meet the definition of a group at all times during the applicable performance period.

(ii) Individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.

(iii) Individual eligible clinicians that elect to participate in MIPS as a group will have their performance assessed at the group level across all four MIPS performance categories.

(iv) Groups must adhere to an election process established by CMS, as applicable.

[81 FR 77537, Nov. 4, 2016, as amended at 83 FR 60076, Nov. 23, 2018; 84 FR 63195, Nov. 15, 2019; 85 FR 85030, Dec. 28, 2020; 86 FR 65670, Nov. 19, 2021]

§ 414.1315 Virtual groups.

(a) *Eligibility.* (1) For a MIPS payment year, a solo practitioner or a group of 10 or fewer eligible clinicians may elect to participate in MIPS as a virtual group with at least one other such solo practitioner or group. The election must be made prior to the start of the applicable performance period and cannot be changed during the performance period. A solo practitioner or group may elect to be in no more than one virtual group for a performance period, and, in the case of a group, the election applies to all MIPS eligible clinicians in the group.

(2) Except as provided under § 414.1370(f)(2), each MIPS eligible clinician in the virtual group receives a MIPS payment adjustment factor and, if applicable, an additional MIPS payment adjustment factor based on the virtual group's combined performance assessment.

(b) *Election deadline.* The election deadline is December 31 of the calendar year preceding the applicable performance period.

(c) *Election process.* For the 2020 MIPS payment year and future years, the virtual group election process is as follows:

(1) *Stage 1: Virtual group eligibility determination.* (i) For the 2020 MIPS payment year, the virtual group eligibility determination period is an assessment period of up to 5 months beginning on July 1 and ending as late as November 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out.

(ii) Beginning with the 2021 MIPS payment year, the virtual group eligibility determination period is the first segment of the MIPS determination period.

(2) *Stage 2: Virtual group formation.* (i) Solo practitioners and groups that elect to participate in MIPS as a virtual group must establish a formal

written agreement that satisfies paragraph (c)(3) of this section prior to the election.

(ii) A designated virtual group representative must submit an election, on behalf of the solo practitioners and groups that compose a virtual group, to participate in MIPS as a virtual group for a performance period in a form and manner specified by CMS by the election deadline specified in paragraph (b) of this section. The virtual group election must include each TIN and NPI associated with the virtual group and contact information for the virtual group representative.

(iii) After an election is made, the virtual group representative must contact their designated CMS contact to update any election information that changed during a performance period at least one time prior to the start of data submission.

(3) *Virtual group agreement.* The virtual group arrangement must be set forth in a formal written agreement among the parties, consisting of each solo practitioner and group that composes a virtual group. The agreement must comply with the following requirements:

(i) Identifies each party by name, TIN, and each NPI under the TIN, and includes as parties only the solo practitioners and groups that compose the virtual group.

(ii) Is for a term of at least one performance period.

(iii) Requires each party to notify each NPI under the party's TIN regarding their participation in the MIPS as a virtual group.

(iv) Sets forth each NPI's rights and obligations in, and representation by, the virtual group, including, but not limited to, the reporting requirements and how participation in the MIPS as a virtual group affects the NPI's ability to participate in the MIPS outside of the virtual group.

(v) Describes how the opportunity to receive payment adjustments will encourage each member of the virtual group (and each NPI under each TIN in the virtual group) to adhere to quality assurance and improvement.

(vi) Requires each party to update its Medicare enrollment information, including the addition or removal of NPIs billing under its TIN, on a timely basis in accordance with Medicare program requirements and to notify the other parties of any such changes within 30 days of the change.

(vii) Requires completion of a close-out process upon termination or expiration of the agreement that requires each party to furnish all data necessary for the parties to aggregate their data across the virtual group's TINs.

(viii) Expressly requires each party to participate in the MIPS as a virtual group and comply with the requirements of the MIPS and all other applicable laws (including, but not limited to, Federal criminal law, the Federal False Claims Act, the Federal anti-kickback statute, the Federal civil monetary penalties law, the Federal physician self-referral law, and the Health Insurance Portability and Accountability Act of 1996).

(ix) Is executed on behalf of each party by an individual who is authorized to bind the party.

(d) *Virtual group reporting requirements.* For solo practitioners and groups of 10 or fewer eligible clinicians to participate in MIPS as a virtual group, all of the following requirements must be met:

(1) Virtual groups must meet the definition of a virtual group at all times during the applicable performance period.

(2) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

(3) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group will have their performance assessed at the virtual group level across all four MIPS performance categories.

(4) Virtual groups must adhere to the election process described in paragraph (c) of this section.

[83 FR 60077, Nov. 23, 2018, as amended at 84 FR 63195, Nov. 15, 2019]

§ 414.1317 APM Entity groups.

(a) *APM entity group determination.* The APM Entity group will be determined according to the requirements set forth in § 414.1425(b)(1).

(1) In addition to the dates set forth in § 414.1425(b)(1), for purposes of MIPS, the APM Entity group includes an eligible clinician who is on a Participation List on December 31 of the MIPS performance period.

(2) For purposes of MIPS scoring, the APM Entity group will be comprised only of those eligible clinicians within the APM Entity group who are determined to be MIPS eligible at the individual or group level.

(3) For purposes of calculating the APM Entity group score, MIPS scores submitted by virtual groups will not be included.

(b) *APM Entity group scoring.* The MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(1) *Determination of performance category score for each MIPS eligible clinician in an APM Entity.* For APM Entities, where a performance category is not reported by the APM Entity, CMS uses one score for each MIPS eligible clinician in an APM Entity group to derive a single average APM Entity score for the performance category. The applicable score for each MIPS eligible clinician is the higher of either:

(i) A group score based on the measure data for the performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups.

(ii) An individual score based on the measure data for the performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician in an APM Entity receives an exception from the reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's performance category score.

(2) *Performance category weights.* The cost performance category weight is zero percent of the final score for an APM Entity. The performance category reweighting scenarios under § 414.1380(c)(2) apply to an APM Entity.

(3) *Improvement scoring for APM Entity groups.* For an APM Entity for which CMS calculated a total performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS calculates an improvement score for each performance category for which a previous year's total performance category score is available as specified in § 414.1380(b).

(4) *Extreme and uncontrollable circumstances.* Beginning with the 2022 MIPS payment year, an APM Entity may submit to CMS an application described at § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(2) requesting reweighting of all four MIPS performance categories and for all MIPS eligible clinicians in the APM Entity group, based on extreme and uncontrollable circumstances.

(i) An APM Entity must demonstrate in its application to CMS that greater than 75 percent of its participant MIPS eligible clinicians would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

(ii) If CMS approves the request for reweighting based on an APM Entity's application, and if MIPS data are submitted for the APM Entity for the applicable performance period, all four of the MIPS performance categories will be reweighted for the APM Entity group notwithstanding the data submission.

[85 FR 85030, Dec. 28, 2020, as amended at 86 FR 65671, Nov. 19, 2021]

§ 414.1318 Subgroups.

(a) *Eligibility and special status*—(1) *General.* Except as provided under paragraph (a)(2) of this section and subject to paragraph (a)(4) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for a subgroup is determined at the group level in accordance with §§ 414.1305 and 414.1310.

(2) *Exclusions.* An individual eligible clinician or group that elects to participate in MIPS as a MIPS eligible clinician in accordance with §414.1310(b)(1)(iii)(A) or (b)(2) is not eligible to participate in a subgroup.

(3) *Single subgroup per eligible clinician.* An individual eligible clinician (as represented by a TIN–NPI combination) may register for no more than one subgroup within a group's TIN.

(4) *Subgroup determination period.* CMS will apply the low-volume threshold criteria for a subgroup as described under paragraph (a)(1) of this section using information from the initial 12-month segment of the applicable MIPS determination period.

(b) *Final score.* Except as provided under §414.1317(b) and paragraph (b)(1) of this section, each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance.

(1) CMS will not assign a final score for a subgroup that registers and does not submit data as a subgroup for the applicable performance period.

(2) [Reserved]

(c) *Subgroup reporting requirements.* For individual eligible clinicians to participate in MIPS as a subgroup, all of the following requirements must be met:

(1) Individual eligible clinicians that elect to participate in MIPS as a subgroup must aggregate their quality and improvement activities performance data across the subgroup's identifier.

(2) Individual eligible clinicians that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all the MIPS performance categories based on an MVP in accordance with §414.1365. Subgroups that are MVP Participants must adhere to an election process described in §414.1365(b).

[86 FR 65671, Nov. 19, 2021; as amended at 87 FR 70227, Nov. 18, 2022]

§414.1320 MIPS performance period.

(a) For purposes of the 2019 MIPS payment year, the performance period for all performance categories and submission mechanisms except for the cost performance category and data for the quality performance category reported through the CMS Web Interface, for the CAHPS for MIPS survey, and for the all-cause hospital readmission measure, is a minimum of a continuous 90-day period within CY 2017, up to and including the full CY 2017 (January 1, 2017 through December 31, 2017). For purposes of the 2019 MIPS payment year, for data reported through the CMS Web Interface or the CAHPS for MIPS survey and administrative claims-based cost and quality measures, the performance period under MIPS is CY 2017 (January 1, 2017 through December 31, 2017).

(b) For purposes of the 2020 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is CY 2018 (January 1, 2018 through December 31, 2018).

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2018, up to and including the full CY 2018 (January 1, 2018 through December 31, 2018).

(c) For purposes of the 2021 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is CY 2019 (January 1, 2019 through December 31, 2019).

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

(d) For purposes of the CY 2020 performance period/2022 MIPS payment year, the performance period for:

(1) The quality and cost performance categories are the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.

(2) The improvement activities performance categories are a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(e) Beginning with the 2023 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that

occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1).

(2) The improvement activities performance categories is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(f) For purposes of the 2022 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

(g) For purposes of the 2023 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

(h) For purposes of the 2024 MIPS payment year and each subsequent MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 60078, Nov. 23, 2018; 84 FR 63195, Nov. 15, 2019; 85 FR 85030, Dec. 28, 2020; 86 FR 65671, Nov. 19, 2021]

§ 414.1325 Data submission requirements.

(a) *Applicable performance categories.* (1) Except as provided in paragraph (a)(2) of this section or under § 414.1370, as applicable, individual MIPS eligible clinicians and groups must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with this section. Except for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician or group by a third party intermediary described at § 414.1400.

(2) There are no data submission requirements for:

(i) The cost performance category or administrative claims-based quality measures. Performance in the cost performance category and on such measures is calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

(ii) The quality and cost performance categories, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in § 414.1380(e).

(b) *Data submission types for individual MIPS eligible clinicians.* An individual MIPS eligible clinician may submit their MIPS data using:

(1) For the quality performance category, the direct, login and upload, and Medicare Part B claims (beginning with the 2021 MIPS payment year for small practices only) submission types.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(c) *Data submission types for groups.* Groups may submit their MIPS data using:

(1) For the quality performance category, the direct; login and upload; Medicare Part B claims (beginning with the CY 2019 MIPS performance period/2021 MIPS payment year, for small practices only); and CMS Web Interface (for groups consisting of 25 or more eligible clinicians, a third party intermediary submitting on behalf of a group) submission type.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and

upload, or login and attest submission types.

(d) *Use of multiple data submission types.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians, groups, and virtual groups may submit their MIPS data using multiple data submission types for any performance category described in paragraph (a)(1) of this section, as applicable; provided, however, that the MIPS eligible clinician, group, or virtual group uses the same identifier for all performance categories and all data submissions.

(e) *Data submission deadlines.* The data submission deadlines are as follows:

(1) For the direct, login and upload, login and attest, and CMS Web Interface submission types, March 31 following the close of the applicable performance period or a later date as specified by CMS.

(2) For the Medicare Part B claims submission type, data must be submitted on claims with dates of service during the applicable performance period that must be processed no later than 60 days following the close of the applicable performance period.

[83 FR 60078, Nov. 23, 2018, as amended at 85 FR 85031, Dec. 28, 2020; 86 FR 65671, Nov. 19, 2021]

§ 414.1330 Quality performance category.

(a) For a MIPS payment year, CMS uses the following quality measures, as applicable, to assess performance in the quality performance category:

(1) Measures included in the MIPS final list of quality measures established by CMS through rulemaking;

(2) QCDR measures approved by CMS under § 414.1400;

(3) Facility-based measures described in § 414.1380; and

(4) MIPS APM measures described in § 414.1370.

(b) Unless a different scoring weight is assigned by CMS, performance in the quality performance category comprises:

(1) 60 percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 50 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 45 percent of a MIPS eligible clinician's final score for MIPS payment years 2021 and 2022.

(4) 40 percent of a MIPS eligible clinician's final score for the MIPS payment year 2023.

(5) 30 percent of a MIPS eligible clinician's final score for the MIPS payment year 2024 and future years.

[83 FR 60078, Nov. 23, 2018, as amended at 84 FR 63195, Nov. 15, 2019; 85 FR 85031, Dec. 28, 2020]

§ 414.1335 Data submission criteria for the quality performance category.

(a) *Criteria.* A MIPS eligible clinician or group must submit data on MIPS quality measures in one of the following manners, as applicable:

(1) *For Medicare Part B claims measures, MIPS CQMs, eCQMs, or QCDR measures.* (i) Except as provided in paragraph (a)(1)(ii) of this section, submit data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(ii) MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(2) *For CMS Web Interface measures.* (i) Report on all measures included in the CMS Web Interface. The group is required to report on at least one measure for which there is Medicare patient data.

(ii) [Reserved]

(3) *For the CAHPS for MIPS survey.* (i) For the 12-month performance period, a group that participates in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the

applicable performance period to transmit survey measures data to CMS.

(ii) [Reserved]

(b) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 60079, Nov. 23, 2018; 84 FR 63195, Nov. 15, 2019]

§ 414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on:

(1) At least 50 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2019.

(2) At least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2020 and 2021.

(3) At least 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2022, 2023, 2024, and 2025.

(4) At least 75 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026 and 2027.

(b) MIPS eligible clinicians and groups submitting quality measure data on Medicare Part B claims measures must submit data on:

(1) At least 50 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2019.

(2) At least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2020 and 2021.

(3) At least 70 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2022, 2023, 2024, and 2025.

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026 and 2027.

(c) Groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey must submit data on the sample of the Medicare Part B patients CMS provides, as applicable.

(1) *For CMS Web Interface measures.* (i) The group must report on the first 248 consecutively ranked beneficiaries in the sample for each measure or module. If the sample of eligible assigned beneficiaries is less than 248, then the group must report on 100 percent of assigned beneficiaries.

(ii) [Reserved]

(2) [Reserved]

(d) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 60079, Nov. 23, 2018; 84 FR 63195, Nov. 15, 2019; 86 FR 65671, Nov. 19, 2021; 87 FR 70227, Nov. 18, 2022]

§ 414.1350 Cost performance category.

(a) *Specification of cost measures.* For purposes of assessing performance of MIPS eligible clinicians on the cost performance category, CMS specifies cost measures for a performance period.

(b) *Attribution.* (1) Cost measures are attributed at the TIN/NPI level for the 2017 thorough 2019 performance periods.

(2) For the total per capita cost measure specified for the 2017 through 2019 performance periods, beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

(3) For the Medicare Spending per Beneficiary clinician (MSPB clinician) measure specified for the 2017 through 2019 performance periods, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB clinician measure during the applicable performance period.

(4) For the acute condition episode-based measures specified for the 2017

performance period, an episode is attributed to each MIPS eligible clinician who bills at least 30 percent of inpatient evaluation and management (E/M) visits during the trigger event for the episode.

(5) For the procedural episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills a Medicare Part B claim with a trigger code during the trigger event for the episode.

(6) For the acute inpatient medical condition episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who bills inpatient E/M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E/M claim lines in that hospitalization.

(7) For the procedural episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(8) Beginning with the 2020 performance period, each cost measure is attributed according to the measure specifications for the applicable performance period.

(c) *Case minimums.* (1) For the total per capita cost measure, the case minimum is 20.

(2) For the Medicare spending per beneficiary clinician measure, the case minimum is 35.

(3) For the episode-based measures specified for the 2017 performance period, the case minimum is 20.

(4) For the procedural episode-based measures specified beginning with the CY 2019 performance period/2021 MIPS payment year, the case minimum is 10, unless otherwise specified for individual measures. Beginning with the CY 2022 performance period/2024 MIPS payment year, the case minimum for Colon and Rectal Resection procedural episode-based measure is 20 episodes.

(5) For the acute inpatient medical condition episode-based measures specified beginning with the 2019 performance period, the case minimum is 20.

(6) For the chronic condition episode-based measures specified beginning with the CY 2022 performance period/2024 MIPS payment year, the case minimum is 20.

(d) *Scoring weight.* Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the cost performance category comprises:

(1) Zero percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 10 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 15 percent of a MIPS eligible clinician's final score for MIPS payment years 2021 and 2022.

(4) 20 percent of the MIPS final score for MIPS payment year 2023.

(5) 30 percent of the MIPS final score for MIPS payment year 2024 and each subsequent MIPS payment year.

[83 FR 60079, Nov. 23, 2018, as amended at 84 FR 63195, Nov. 15, 2019, 85 FR 85031, Dec. 28, 2020; 86 FR 65671, Nov. 19, 2021]

§ 414.1355 Improvement activities performance category.

(a) For a MIPS payment year, CMS uses improvement activities included in the MIPS final inventory of improvement activities established by CMS through rulemaking to assess performance in the improvement activities performance category.

(b) Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises:

(1) 15 percent of a MIPS eligible clinician's final score for MIPS payment year 2019 and for each MIPS payment year thereafter.

(2) [Reserved]

(c) The following are the list of subcategories, of which, with the exception of Participation in an APM, include activities for selection by a MIPS eligible clinician or group:

(1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

(2) Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR.

(3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other clinicians, and use of remote monitoring or telehealth.

(4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision making mechanisms.

(5) Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.

(6) Participation in an APM.

(7) Achieving health equity, such as for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.

(8) Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty uniformed services MIPS eligible clinician activities, and measuring MIPS eligible clinician volunteer participation in domestic or international humanitarian medical relief work.

(9) Integrated behavioral and mental health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; cross training of MIPS eligible clinicians, and integrating behavioral health with primary care to address substance use disorders or other behavioral health conditions, as well as integrating mental health with primary care.

[81 FR 77537, Nov. 4, 2016, as amended at 83 FR 60079, Nov. 23, 2018]

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) For purposes of the transition year of MIPS and future years, MIPS eligible clinicians or groups must submit data on MIPS improvement activities in one of the following manners:

(1) *Via direct, login and upload, and login and attest.* For the applicable performance period, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

(i) Submit a yes response for activities within the improvement activities inventory.

(ii) [Reserved]

(2) *Groups and virtual groups.* Beginning with the 2022 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

(b) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 60080, Nov. 23, 2018; 84 FR 63196, Nov. 15, 2019; 86 FR 65671, Nov. 19, 2021]

§ 414.1365 MIPS Value Pathways.

(a) *General.* (1) Beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, CMS uses MVPs included in the MIPS final inventory of MVPs established by CMS through rulemaking to assess performance for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

(2) [Reserved]

(b) *MVP/Subgroup registration.* (1) To report an MVP, an MVP Participant must register for the MVP, and if applicable, as a subgroup during a period that begins on April 1 and ends on November 30 of the applicable CY performance period or a later date specified by CMS. To report the CAHPS for MIPS survey associated with an MVP, a group, subgroup or APM Entity must complete their registration by June 30 of such performance period or a later date specified by CMS.

(2) At the time of registration, the MVP Participant must submit the following information, as applicable:

(i) Each MVP Participant must select an MVP, 1 population health measure included in the MVP, and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored.

(ii) Each subgroup must submit a list of each TIN/NPI associated with the subgroup and a plain language name for the subgroup.

(iii) TINs must provide a description of each subgroup that is registered.

(c) *MVP reporting requirements*—(1) Quality. Except as provided in paragraph (c)(1)(i) of this section, an MVP Participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure), included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

(i) Paragraph (c)(1) introductory text of this section does not apply to a small practice that reports on an MVP that includes fewer than 4 Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable.

(ii) [Reserved]

(2) *Cost.* An MVP Participant is scored on the cost measures included in the MVP that they select and report.

(3) *Improvement activities.* An MVP Participant who reports an MVP, must report one of the following:

(i) Two medium-weighted improvement activities;

(ii) One high-weighted improvement activity;

(iii) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at §414.1380(b)(3)(ii).

(4) *Foundational layer*—(i) Promoting interoperability. An MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described at §414.1375(b).

(A) For the CY 2023 and 2024 performance periods/2025 and 2026 MIPS payment years, an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category.

(B) [Reserved]

(ii) *Population health measures.* Each MVP Participant is scored on 1 population health measure in accordance with paragraph (d)(1) of this section.

(d) *MVP scoring*—(1) General. An MVP Participant that is not an APM Entity is scored on measures and activities included in the MVP in accordance with paragraphs (d)(1) through (3) of this section. An MVP Participant that is an APM Entity is scored on measures and activities included in the MVP in accordance with §414.1317(b).

(2) *Performance standards.* Unless otherwise indicated in this paragraph (d), the performance standards described at §414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP.

(3) *Performance categories.* An MVP Participant is scored under MIPS in four performance categories.

(i) *Quality performance category.* Except as provided in paragraphs (d)(3)(i)(A)(1) and (d)(3)(i)(B) of this section, the quality performance category score for MVP Participants is calculated in accordance with §414.1380(b)(1) based on measures included in the MVP.

(A) *Population health measures.* Except as provided in paragraph (d)(3)(i)(A)(*1*) of this section, each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP participant's total measure achievement points and total available measure achievement points.

(*1*) A subgroup is scored on each selected population health measure based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

(*2*) [Reserved]

(B) *Outcomes-based administrative claims measures.* MVP Participants receive zero measure achievement points for each selected outcomes-based administrative claims measure that does

not have a benchmark or meet the case minimum requirement.

(*1*) A subgroup is scored on each selected outcomes-based administrative claims measure based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure will receive zero measure achievement points.

(*2*) [Reserved]

(ii) *Cost performance category*. The cost performance category score is calculated for an MVP Participant using the methodology at §414.1380(b)(2)(i) through (v) and the cost measures included in the MVP that they select and report.

(A) A subgroup is scored on each cost measure included in the MVP that it selects and reports based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under §414.1380(b)(2)(i) through (v).

(B) [Reserved]

(iii) *Improvement activities performance category*. The improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants will receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under §414.1360 on which data is submitted in accordance with §414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at §414.1380(b)(3)(ii).

(iv) *Promoting interoperability performance category*. The Promoting Interoperability performance category score is calculated for an MVP Participant using the methodology at §414.1380(b)(4), except as provided in paragraph (d)(3)(iv)(A) of this section.

(A) If a subgroup does not submit its affiliated group's data for the Promoting Interoperability performance category, the subgroup will receive a score of zero for the Promoting Interoperability performance category.

(B) [Reserved]

(e) *Final score calculation*. The final score is calculated for an MVP Participant using the methodology at §414.1380(c), unless otherwise indicated in this paragraph (e).

(1) *MVP performance category weights*. For an MVP Participant that is not an APM Entity, the final score is calculated using the performance category weights described at §414.1380(c)(1). For an MVP Participant that is an APM Entity, the final score is calculated using the performance category weights described at §414.1317(b).

(2) *Reweighting MVP performance categories*—(i) General reweighting. For an MVP Participant that is not an APM Entity, in accordance with paragraph (e)(2)(iii) of this section, a scoring weight different from the weights described at §414.1380(c)(1) will be assigned to a performance category, and its weight as described at §414.1380(c)(1) will be redistributed to another performance category or categories, in the circumstances described at §414.1380(c)(2)(i)(A)(2) through (9) and §414.1380(c)(2)(i)(C). For an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with §414.1317(b).

(ii) *Subgroups*. For an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the following circumstances independent of the affiliated group:

(A) A subgroup may submit an application to CMS demonstrating that it was subject to extreme and uncontrollable circumstances and receive reweighting in accordance with §414.1380(c)(2)(i)(A)(6) and (c)(2)(i)(C)(2). In the event that a subgroup submits data for a performance category, the scoring weight described at §414.1380(c)(1) would be applied and its weight would not be redistributed.

(B) A subgroup will receive reweighting if CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for the

subgroup are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the subgroup and its agents, in accordance with §414.1380(c)(2)(i)(A)(9) and (c)(2)(i)(C)(10).

(iii) *Reweighting scenarios.* For an MVP Participant that is not an APM Entity, a scoring weight different from the weights described at §414.1380(c)(1) will be assigned to a performance category, and its weight as described at §414.1380(c)(1) will be redistributed to another performance category or categories, in accordance with §414.1380(c)(2)(ii). For an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with §414.1317(b).

(3) *Facility-based scoring.* If an MVP Participant, that is not an APM Entity, is eligible for facility-based scoring, a facility-based score also will be calculated in accordance with §414.1380(e).

(4) *Complex patient bonus.* A complex patient bonus will be added to the final score for an MVP Participant in accordance with §414.1380(c)(3).

[86 FR 65671, Nov. 19, 2021, as amended at 87 FR 70227, Nov. 18, 2022]

§414.1367 APM performance pathway.

(a) *General.* Beginning with the 2023 MIPS payment year, the APM Performance Pathway is a MIPS scoring methodology available to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM.

(b) *Criteria for MIPS APMs.* MIPS APMs are those in which:

(1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation; and

(2) The APM bases payment on quality measures and cost/utilization.

(c) *MIPS performance category scoring in the APM Performance Pathway*—(1) *Quality.* Except as provided in paragraphs (c)(1)(i) and (ii) of this section, the quality performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with §414.1380(b)(1) based on the APM Performance Pathway quality measure set established by CMS through rulemaking for a MIPS payment year.

(i) Each submitted measure that does not have a benchmark or meet the case minimum requirement is excluded from the MIPS eligible clinician, group, or APM Entity group's total measure achievement points and total available measure achievement points.

(ii) Any measure that is identified as topped out is not subject to the scoring cap described at §414.1380(b)(1)(iv).

(2) *Cost.* The cost performance category weight is zero percent for MIPS eligible clinicians who are scored through the APM Performance Pathway.

(3) *Improvement activities.* The improvement activities performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with §414.1380(b)(3) based on the activities required by the MIPS APM that are included in the MIPS final inventory of improvement activities described in §414.1355(a) (excluding any such activities that the MIPS eligible clinician, group, or APM Entity group does not perform). MIPS eligible clinicians, groups, or APM Entities may report additional improvement activities in accordance with §414.1360.

(4) *Promoting interoperability.* The promoting interoperability performance category will be scored for the MIPS eligible clinician, group, or APM Entity as described in §414.1375.

(d) *APM Performance Pathway performance category weights*—(1) *Performance category weights.* Subject to paragraph (d)(2) of this section, the performance category weights used to calculate the final score for a MIPS eligible clinician, group, or APM Entity reporting through the APM performance Pathway are:

(i) Quality: 50 percent.

(ii) Cost: 0 percent.

(iii) Improvement Activities: 20 percent.

(iv) Promoting Interoperability: 30 percent.

(2) *Reweighting MIPS performance categories.* If CMS determines, in accordance with §414.1380(c)(2), that a different scoring weight should be assigned to the quality or promoting interoperability performance category,

CMS will redistribute the performance category weights as follows:

(i) If CMS reweights the quality performance category to 0 percent: Promoting Interoperability performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to 0 percent: Quality performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(e) *Final score.* The final score is calculated for a MIPS eligible clinician, group, or APM Entity in accordance with § 414.1380(c).

[85 FR 85031, Dec. 28, 2020]

§ 414.1370 APM scoring standard under MIPS.

(a) *General.* For the 2019 through 2022 MIPS payment years, the APM scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified on the Participation List for the performance period of an APM Entity participating in a MIPS APM.

(b) *Criteria for MIPS APMs.* MIPS APMs are those in which:

(1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation;

(2) The APM is designed such that APM Entities participating in the APM include at least one MIPS eligible clinician on a Participation List;

(3) The APM bases payment on quality measures and cost/utilization; and

(4) The APM is not either of the following:

(i) *New APMs.* An APM for which the first performance year begins after the first day of the MIPS performance period for the year.

(ii) *APM in final year of operation for which the APM scoring standard is impracticable.* An APM in the final year of operation for which CMS determines, within 60 days after the beginning of the MIPS performance period for the year, that it is impracticable for APM Entity groups to report to MIPS using the APM scoring standard.

(c) *APM scoring standard performance period.* The MIPS performance period under § 414.1320 applies for the APM scoring standard.

(d) *APM participant identifier.* The APM participant identifier for an eligible clinician is the combination of four identifiers:

(1) APM identifier (established for the APM by CMS);

(2) APM Entity identifier (established for the APM Entity by CMS);

(3) Medicare-enrolled billing TIN; and

(4) Eligible clinician NPI.

(e) *APM Entity group determination.* For the APM scoring standard, the APM Entity group is determined in the manner prescribed in § 414.1425(b)(1).

(1) *Full TIN APM.* In addition to the dates set forth in § 414.1425(b)(1), the APM Entity group includes an eligible clinician who is on a Participation List in a Full TIN APM on December 31 of the MIPS performance period.

(2) For purposes of calculating the APM Entity group score under the APM scoring standard, MIPS scores submitted by virtual groups will not be included.

(f) *APM Entity group scoring under the APM scoring standard.* The MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(1) If a Shared Savings Program ACO does not report data on quality measures as required by the Shared Savings Program under § 425.508 of this chapter, each ACO participant TIN will be treated as a unique APM Entity for purposes of the APM scoring standard and the ACO participant TINs may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements.

(2) MIPS eligible clinicians who participate in a group or have elected to participate in a virtual group and who are also on a MIPS APM Participation List will be included in the assessment under MIPS for purposes of producing a group or virtual group score and under the APM scoring standard for purposes of producing an APM Entity score. The MIPS payment adjustment for these eligible clinicians is based solely on their

APM Entity score; if the APM Entity group is exempt from MIPS all eligible clinicians within that APM Entity group are also exempt from MIPS.

(g) *MIPS performance category scoring under the APM scoring standard*—(1) *Quality*. Beginning in the 2020 Performance year—

(i) *MIPS APMs that require APM Entities to submit quality data through a MIPS submission mechanism*. The MIPS quality performance category score for a performance period will be calculated for the APM Entity using the data submitted for the APM Entity through a MIPS submission mechanism in accordance with §414.1335.

(ii) *MIPS APMs that do not require APM Entities to submit quality data through a MIPS submission mechanism*. The APM Entity will be assigned an APM Quality Reporting Credit worth 50 percent of the total quality performance category score. The APM Quality Reporting Credit will be added to the MIPS quality performance category score to generate an APM Entity quality performance category score, which in no case shall exceed 100. The MIPS quality performance category score for a performance period will be calculated for the APM Entity using the data submitted for the APM Entity through a MIPS submission mechanism in accordance with §414.1335.

(iii) *Determination of score for each MIPS eligible clinician in an APM entity*. Regardless of whether a MIPS APM requires APM Entities to submit quality data through a MIPS submission mechanism, if data are not submitted for an APM Entity through a MIPS submission mechanism in accordance with §414.1335, the score for each MIPS eligible clinician in such APM Entity is the higher of either:

(A) A TIN level score based on the measure data for the quality performance category reported by a TIN for the MIPS eligible clinician in accordance with §414.1335; or

(B) An individual level score based on the measure data for the quality performance category reported by the MIPS eligible clinician in accordance with §414.1335.

(iv) *Quality improvement score*. For an APM Entity for which CMS calculated a total quality performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS calculates a quality improvement score for the APM Entity group as specified in §414.1380(b)(1)(xvi).

(2) *Cost*. The cost performance category weight is zero percent for APM Entities in MIPS APMs.

(3) *Improvement activities*. (i) CMS assigns an improvement activities score for each MIPS APM for a MIPS performance period based on the requirements of the MIPS APM. The assigned improvement activities score applies to each APM Entity group for the MIPS performance period. In the event that the assigned score does not represent the maximum improvement activities score, an APM Entity may report additional activities.

(ii) [Reserved]

(4) *Promoting Interoperability*. (i) For the 2019 and 2020 MIPS payment years, each Shared Savings Program ACO participant TIN must report data on the Promoting Interoperability performance category separately from the ACO, as specified in §414.1375(b)(2). The ACO participant TIN scores are weighted according to the number of MIPS eligible clinicians in each TIN as a proportion of the total number of MIPS eligible clinicians in the APM Entity group, and then aggregated to determine an APM Entity score for the ACI performance category.

(ii) For the 2019 and 2020 MIPS payment years, for APM Entities in MIPS APMs other than the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. Beginning with the 2021 MIPS payment year, for APM Entities in MIPS APMs including the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. The score for each MIPS eligible clinician is the higher of either:

(A) A group score based on the measure data for the Promoting Interoperability performance category reported

by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups; or

(B) An individual score based on the measure data for the Promoting Interoperability performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician participating in a MIPS APM receives an exception from the Promoting Interoperability performance category reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's Promoting Interoperability performance category score under the APM scoring standard.

(A) If all MIPS eligible clinicians in an APM Entity have been excepted from reporting the Promoting Interoperability performance category, the performance category weight will be reweighted to zero for the APM Entity for that MIPS performance period.

(B) [Reserved]

(h) *APM scoring standard performance category weights.* The performance category weights used to calculate the MIPS final score for an APM Entity group for the APM scoring standard performance period are:

(1) *Quality.* (i) For MIPS APMs that require use of the CMS Web Interface: 50 percent.

(ii) For Other MIPS APMs, 0 percent for 2017, 50 percent beginning in 2018.

(2) *Cost.* 0 percent.

(3) *Improvement activities.* (i) For MIPS APMs that require use of the CMS Web Interface: 20 percent.

(ii) For Other MIPS APMs, 25 percent for 2017, 20 percent beginning in 2018.

(4) *Promoting Interoperability.* (i) For MIPS APMs that require use of the CMS Web Interface: 30 percent.

(ii) For Other MIPS APMs, 25 percent for 2017, 30 percent beginning in 2018.

(5) *Reweighting the MIPS Performance categories for the APM scoring standard.* If CMS determines there are not sufficient measures or activities applicable and available to MIPS eligible clinicians, CMS will assign weights as follows:

(i) If CMS reweights the quality performance category to 0 percent:

(A) In 2017, the improvement activities performance category is reweighted to 25 percent and the Promoting Interoperability performance category is reweighted to 75 percent; and

(B) Beginning in 2018, the Promoting Interoperability performance category is reweighted to 75 percent and the improvement activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to zero percent:

(A) In 2017, the quality performance category is reweighted to 75 percent and the improvement activities performance category will remain at 25 percent.

(B) Beginning in 2018, the quality performance category is reweighted to 80 percent and the improvement activities performance category will remain at 20 percent.

(i) *Total APM Entity Score.* CMS scores each performance category and then multiplies each performance category score by the applicable performance category weight. CMS then calculates the sum of each weighted performance category score and then applies all applicable adjustments. APM Entities will receive MIPS bonuses applied to the final score as set forth in § 414.1380(b).

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53953, Nov. 16, 2017; 83 FR 23610, May 22, 2018; 83 FR 60080, Nov. 23, 2018; 84 FR 63196, Nov. 15, 2019; 85 FR 85031, Dec. 28, 2020]

§ 414.1375 Promoting Interoperability (PI) performance category.

(a) *Final score.* Unless a different scoring weight is assigned by CMS under sections 1848(o)(2)(D), 1848(q)(5)(E)(ii), or 1848(q)(5)(F) of the Act, performance in the Promoting Interoperability performance category comprises 25 percent of a MIPS eligible clinician's final score for each MIPS payment year.

(b) *Reporting for the Promoting Interoperability performance category.* To earn a performance category score for the Promoting Interoperability performance category for inclusion in the final score, a MIPS eligible clinician must:

(1) *CEHRT.* Use CEHRT as defined at § 414.1305 for the performance period;

(2) *Report MIPS—Promoting Interoperability objectives and measures.* Report on the objectives and associated measures as specified by CMS for the Promoting Interoperability performance category for the performance period as follows:

(i) For the 2019 and 2020 MIPS payment years: For each base score measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or claim an exclusion for each measure that includes an option for an exclusion; and

(ii) Beginning with the 2021 MIPS payment year:

(A) Report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs;

(B) For each required measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or an exclusion for each measure that includes an option for an exclusion; and

(C) Beginning with the 2024 MIPS payment year, report that the MIPS eligible clinician completed the actions included in the SAFER Guides measure during the year in which the performance period occurs.

(3) *Engaging in activities related to supporting providers with the performance of CEHRT; support for health information exchange and the prevention of information blocking; actions to limit or restrict the compatibility or interoperability of CEHRT.* (i) Supporting providers with the performance of CEHRT (SPPC). To engage in activities related to supporting providers with the performance of CEHRT, the MIPS eligible clinician—

(A) Must attest that he or she:

(*1*) Acknowledges the requirement to cooperate in good faith with ONC direct review of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and

(*2*) If requested, cooperated in good faith with ONC direct review of his or her health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the MIPS eligible clinician in the field.

(B) Optionally, may also attest that he or she:

(*1*) Acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received; and

(*2*) If requested, cooperated in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the MIPS eligible clinician in the field.

(ii) *Support for health information exchange and the prevention of information blocking.* For the 2019, 2020, 2021, 2022, and 2023 MIPS payment years, the MIPS eligible clinician must attest to CMS that he or she—

(A) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(B) Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times—

(*1*) Connected in accordance with applicable law;

(*2*) Compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170;

(*3*) Implemented in a manner that allowed for timely access by patients to their electronic health information; and

(*4*) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.

(C) Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

(iii) *Actions to limit or restrict the compatibility or interoperability of CEHRT.* Beginning with the 2024 MIPS payment year, the MIPS eligible clinician must attest to CMS that he or she—

(A) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(B) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53955, Nov. 16, 2017; 83 FR 60080, Nov. 23, 2018; 86 FR 65673, Nov. 19, 2021]

§ 414.1380 Scoring.

(a) *General.* MIPS eligible clinicians are scored under MIPS based on their performance on measures and activities in four performance categories. MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, composed of their performance category scores, and calculated according to the final score methodology.

(1) *Performance standards.* (i) For the quality performance category, measures are scored between zero and 10 measure achievement points. Performance is measured against benchmarks. Measure bonus points are available for submitting high-priority measures, submitting measures using end-to-end electronic reporting, and in small practices that submit data on at least 1 quality measure. Beginning with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Starting with the 2024 MIPS payment year, improvement scoring is available in the cost performance category.

(iii) For the improvement activities performance category, each improvement activity is assigned a certain number of points. The points for all submitted activities are summed and scored against a total potential performance category score of 40 points.

(iv) For the Promoting Interoperability performance category, each measure is scored against a maximum number of points. The points for all submitted measures are summed and scored against a total potential performance category score of 100 points.

(2) [Reserved]

(b) *Performance categories.* MIPS eligible clinicians are scored under MIPS in four performance categories. (1) *Quality performance category*—(i) *Measure achievement points.* For the CY 2017 through 2022 performance periods/2019 through 2024 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 and for each administrative claims-based measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section. Except as provided under paragraph (b)(1)(i)(C) of this section, beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive between 1 and 10 measure achievement points (including partial points) for each such measure. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure

required under §414.1335 on which no data is submitted in accordance with §414.1325. MIPS eligible clinicians that submit data in accordance with §414.1325 on a greater number of measures than required under §414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the CY 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with §414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(A) *Lack of benchmark or case minimum.*

(*1*) Except as provided in paragraphs (b)(1)(i)(A)(*2*) and (*3*) of this section, for the CY 2017 through 2022 performance periods/2019 through 2024 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement. Beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians other than small practices receive 0 measure achievement points for each such measure, and small practices receive 3 measure achievement points for each such measure.

(*2*) The following measures are excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points:

(*i*) Each submitted CMS Web Interface-based measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement, or is redesignated as pay-for-reporting for all Shared Savings Program accountable care organizations by the Shared Savings Program; and

(*ii*) Each administrative claims-based measure that does not have a benchmark or meet the case minimum requirement.

(*3*) Beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians receive 7 measure achievement points for each submitted measure in its first year in MIPS and 5 measure achievement points for each submitted measure in its second year in MIPS that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

(B) *Lack of complete data.* (*1*) Except as provided in paragraph (b)(1)(i)(B)(*2*) of this section, for each submitted measure that does not meet the data completeness requirement:

(*i*) For the 2019 MIPS payment year, MIPS eligible clinicians receive 3 measure achievement points;

(*ii*) For the 2020 and 2021 MIPS payment years, MIPS eligible clinicians other than small practices receive 1 measure achievement point, and small practices receive 3 measure achievement points; and

(*iii*) Beginning with the 2022 MIPS payment year, MIPS eligible clinicians other than small practices receive zero measure achievement points, and small practices receive 3 measure achievement points.

(*2*) MIPS eligible clinicians receive zero measure achievement points for each submitted CMS Web Interface-based measure that does not meet the data completeness requirement.

(C) *New measures.* Beginning with the CY 2022 performance period/2024 MIPS payment year, for each measure required under §414.1335 on which data is submitted in accordance with §414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at §414.1340, a MIPS eligible clinician receives between 7 and 10 measure achievement points (including partial points) for each such measure in its first year in MIPS and between 5 and 10 measure achievement points for each such measure in its second year in MIPS.

(ii) *Benchmarks.* Except as provided in paragraphs (b)(1)(ii)(B) and (C) of this section, benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(A) Each benchmark must have a minimum of 20 individual clinicians or groups who reported the measure meeting the case minimum requirement at paragraph (b)(1)(iii) of this section and the data completeness requirement at § 414.1340 and having a performance rate that is greater than zero.

(B) CMS Web Interface collection type uses benchmarks from the corresponding reporting year of the Shared Savings Program.

(C) Beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines may have the potential to result in inappropriate treatment, CMS will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at paragraph (b)(1)(ii) of this section.

(D) Beginning with the CY 2023 performance period/2025 MIPS payment year, CMS will calculate a benchmark for an administrative claims quality measure using the performance on the measures during the current performance period.

(iii) *Minimum case requirements.* Except as otherwise specified in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

(iv) *Topped out measures.* CMS will identify topped out measures in the benchmarks published for each Quality Payment Program year.

(A) For the 2020 MIPS payment year, each topped out measure specified by CMS through rulemaking receives no more than 7 measure achievement points, provided that the benchmark for the applicable collection type is identified as topped out in the benchmarks published for the 2018 MIPS performance period.

(B) Beginning with the 2021 MIPS payment year, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(v) *Measure bonus points.* MIPS eligible clinicians receive measure bonus points for the following measures, except as otherwise required under § 414.1335, regardless of whether the measure is included in the MIPS eligible clinician's total measure achievement points.

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures.

(*1*) *Limitations.* (*i*) Each high priority measure must meet the case minimum requirement at paragraph (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

(*ii*) For the 2019 through 2023 MIPS payments years, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

(*iii*) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that collect data in accordance with § 414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(B) *End-to-end electronic reporting.* Subject to paragraph (b)(1)(v)(B)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary.

(*1*) *Limitations.* (*i*) For the 2019 through 2023 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

(*ii*) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians

that collect data in accordance with §414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(*iii*) Beginning in the 2024 MIPS payment year, MIPS eligible clinicians will no longer receive measure bonus for submitting using end-to-end electronic reporting.

(C) *Small practices.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians in small practices receive 6 measure bonus points if they submit data to MIPS on at least 1 quality measure.

(vi) *Improvement scoring.* Improvement scoring is available to MIPS eligible clinicians that demonstrate improvement in performance in the current MIPS performance period compared to performance in the performance period immediately prior to the current MIPS performance period based on measure achievement points.

(A) Improvement scoring is available when the data sufficiency standard is met, which means when data are available and a MIPS eligible clinician has a quality performance category achievement percent score for the previous performance period and the current performance period.

(*1*) Data must be comparable to meet the requirement of data sufficiency which means that the quality performance category achievement percent score is available for the current performance period and the previous performance period and quality performance category achievement percent scores can be compared.

(*2*) Quality performance category achievement percent scores are comparable when submissions are received from the same identifier for two consecutive performance periods.

(*3*) If the identifier is not the same for 2 consecutive performance periods, then for individual submissions, the comparable quality performance category achievement percent score is the highest available quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for the individual. For group, virtual group, and APM Entity submissions, the comparable quality performance category achievement percent score is the average of the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for each of the individuals in the group.

(*4*) Improvement scoring is not available for clinicians who were scored under facility-based measurement in the performance period immediately prior to the current MIPS performance period.

(B) The improvement percent score may not total more than 10 percentage points.

(C) The improvement percent score is assessed at the performance category level for the quality performance category and included in the calculation of the quality performance category score as described in paragraph (b)(1)(vii) of this section.

(*1*) The improvement percent score is awarded based on the rate of increase in the quality performance category achievement percent score of MIPS eligible clinicians from the previous performance period to the current performance period.

(*2*) An improvement percent score is calculated by dividing the increase in the quality performance category achievement percent score from the prior performance period to the current performance period by the prior performance period quality performance category achievement percent score multiplied by 10 percent.

(*3*) An improvement percent score cannot be lower than zero percentage points.

(*4*) Beginning with the CY 2018 performance period/2020 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

(*5*) The improvement percent score is zero if the MIPS eligible clinician did not fully participate in the quality performance category for the current performance period.

(D) For the purpose of improvement scoring methodology, the term ''quality performance category achievement percent score'' means the total measure achievement points divided by the

total available measure achievement points, without consideration of measure bonus points or improvement percent score.

(E) For the purpose of improvement scoring methodology, the term ''improvement percent score'' means the score that represents improvement for the purposes of calculating the quality performance category score as described in paragraph (b)(1)(vii) of this section.

(F) For the purpose of improvement scoring methodology, the term ''fully participate'' means the MIPS eligible clinician met all requirements in §§ 414.1335 and 414.1340.

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category score cannot exceed 100 percentage points.

(A) For each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 414.1325(e), performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes or errors'' means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes or inclusion of inactive or inaccurate codes, or changes to clinical guidelines or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the data submission deadline at § 414.1325(e)(1).

(B) Beginning with the 2021 MIPS payment year, for groups that submit 5 or fewer measures and register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements, the total available measure achievement points are reduced by 10 points.

(2) *Cost performance category.* For each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark. Achievement points are awarded based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between. CMS assigns partial points based on the percentile distribution.

(i) Cost measure benchmarks are determined by CMS based on cost measure performance during the performance period. At least 20 MIPS eligible clinicians or groups must meet the minimum case volume specified under § 414.1350(c) for a cost measure in order for a benchmark to be determined for the measure. If a benchmark is not determined for a cost measure, the measure will not be scored.

(ii) A MIPS eligible clinician must meet the minimum case volume specified under § 414.1350(c) to be scored on a cost measure.

(iii) The cost performance category score is the sum of the following, not to exceed 100 percent:

(A) The total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points; and

(B) The cost improvement score, as determined under paragraph (b)(2)(iv) of this section.

(iv) The cost improvement score is determined for a MIPS eligible clinician that demonstrates improvement in performance in the current MIPS performance period compared to their

performance in the immediately preceding MIPS performance period.

(A) The cost improvement score is determined at the measure level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement is available. Sufficient data is available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the same cost measure(s) for 2 consecutive performance periods. If the cost improvement score cannot be calculated because sufficient data is not available, then the cost improvement score is zero.

(C) The cost improvement score is determined by comparing the number of measures with a statistically significant change (improvement or decline) in performance; a change is determined to be significant based on application of a t-test. The number of cost measures with a significant decline is subtracted from the number of cost measures with a significant improvement, with the result divided by the number of cost measures for which the MIPS eligible clinician or group was scored for 2 consecutive performance periods. The resulting fraction is then multiplied by the maximum cost improvement score.

(D) The cost improvement score cannot be lower than zero percentage points.

(E) The maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points. The maximum cost improvement score beginning with the 2024 MIPS payment year is 1 percentage point.

(v) A cost performance category score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

(A) Beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. For purposes of this paragraph (b)(2)(v)(A), ''significant changes'' are changes external to the care provided, and that CMS determines may lead to misleading or inaccurate results. Significant changes include, but are not limited to, rapid or unprecedented changes to service utilization, and will be empirically assessed by CMS to determine the extent to which the changes impact the calculation of a cost measure score that reflects clinician performance.

(B) [Reserved]

(3) *Improvement activities performance category*. Subject to paragraphs (b)(3)(i) and (ii) of this section, the improvement activities performance category score equals the total points for all submitted improvement activities divided by 40 points, multiplied by 100 percent. MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity required under §414.1360 on which data is submitted in accordance with §414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under §414.1360 on which data is submitted in accordance with §414.1325.

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent.

(ii) For MIPS eligible clinicians in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, the improvement activities performance category score is 100 percent. For the 2019

MIPS payment year, at least one practice site within a group's TIN must be certified or recognized as a patient-centered medical home or comparable specialty practice. For the 2020 MIPS payment year and future years, at least 50 percent of the practice sites within a group's TIN must be recognized as a patient-centered medical home or comparable specialty practice. MIPS eligible clinicians that wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. A practice is certified or recognized as a patient-centered medical home if it meets any of the following criteria:

(A) The practice has received accreditation from an accreditation organization that is nationally recognized.

(B) The practice is participating in a Medicaid Medical Home Model or Medical Home Model.

(C) The practice is a comparable specialty practice that has received recognition through a specialty recognition program offered through a nationally recognized accreditation organization; or

(D) The practice has received accreditation from other certifying bodies that have certified a large number of medical organizations and meet national guidelines, as determined by the Secretary. The Secretary must determine that these certifying bodies must have 500 or more certified member practices, and require practices to include the following:

(*1*) Have a personal physician/clinician in a team-based practice.

(*2*) Have a whole-person orientation.

(*3*) Provide coordination or integrated care.

(*4*) Focus on quality and safety.

(*5*) Provide enhanced access.

(4) *Promoting Interoperability performance category.* (i) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the base score, performance score, and any applicable bonus scores, not to exceed 100 percentage points. A MIPS eligible clinician cannot earn a performance score or bonus score unless they have earned a base score.

(A) A MIPS eligible clinician earns a base score by reporting for each base score measure, as applicable: The numerator (of at least one) and denominator, or a yes/no statement, or an exclusion.

(B) A MIPS eligible clinician earns a performance score by reporting on the performance score measures specified by CMS. A MIPS eligible clinician may earn up to 10 or 20 percentage points as specified by CMS for each performance score measure reported.

(C) A MIPS eligible clinician may earn the following bonus scores:

(*1*) A bonus score of 5 percentage points for reporting to one or more additional public health agencies or clinical data registries.

(*2*) A bonus score of 10 percentage points for attesting to completing one or more improvement activities specified by CMS using CEHRT.

(*3*) For the 2020 MIPS payment year, a bonus score of 10 percentage points for submitting data for the measures for the base score and the performance score generated solely from CEHRT as defined in § 414.1305 for 2019 and subsequent years.

(ii) Beginning with the 2019 performance period/2021 MIPS payment year, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the required measures and any applicable bonus scores, not to exceed 100 points.

(A) A MIPS eligible clinician earns a score for each measure by reporting, as applicable: the numerator (of at least one) and denominator, or a yes/no statement. If an exclusion is reported for a measure, the points available for that measure are redistributed to another measure(s).

(B) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each required measure is worth 10, 20, or 40 points, as specified by CMS. For the 2023 performance period/2025 MIPS payment year and subsequent years, each required measure is worth 10, 15, 25 or 30 points, as specified by CMS.

(C) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each optional measure is worth five or ten bonus points, as specified by CMS. For the 2023 performance period/2025 MIPS payment year and subsequent years, each optional measure is worth five bonus points, as specified by CMS.

(c) *Final score calculation.* Each MIPS eligible clinician receives a final score of 0 to 100 points for a performance period for a MIPS payment year calculated as follows. If a MIPS eligible clinician is scored on fewer than 2 performance categories, he or she receives a final score equal to the performance threshold.

TABLE 1 TO PARAGRAPH (c) INTRODUCTORY TEXT

For the 2019 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)], not to exceed 100 points.
For the 2020 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + [the complex patient bonus + the small practice bonus], not to exceed 100 points.
Beginning with the 2021 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + the complex patient bonus, not to exceed 100 points.

(1) *Performance category weights.* The weights of the performance categories in the final score are as follows, unless a different scoring weight is assigned under paragraph (c)(2) of this section:

(i) Quality performance category weight is defined under §414.1330(b).

(ii) Cost performance category weight is defined under §414.1350(d).

(iii) Improvement activities performance category weight is defined under §414.1355(b).

(iv) Promoting Interoperability performance category weight is defined under §414.1375(a).

(2) *Reweighting the performance categories.* (i) In accordance with paragraph (c)(2)(ii) of this section, a scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, in the following circumstances:

(A) CMS determines based on the following circumstances that there are not sufficient measures and activities applicable and available under section 1848(q)(5)(F) of the Act.

(*1*) For the quality performance category, CMS cannot calculate a score for the MIPS eligible clinician because there is not at least one quality measure applicable and available to the clinician.

(*2*) For the cost performance category, CMS cannot reliably calculate a score for the cost measures that adequately captures and reflects the performance of the MIPS eligible clinician.

(*3*) Beginning with the 2021 MIPS payment year, for the quality, cost, improvement activities, and Promoting Interoperability performance categories, the MIPS eligible clinician joins an existing practice during the final 3 months of the performance period year that is not participating in MIPS as a group or joins a practice that is newly formed during the final 3 months of the performance period year.

(*4*) *For the Promoting Interoperability performance category:* (*i*) For the 2021 through 2025 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*ii*) For the 2019 through 2024 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*iii*) For the 2024 through 2025 MIPS payment years, the MIPS eligible clinician is a clinical social worker. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*5*) [Reserved]

(*6*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that prevented the clinician from collecting information that the clinician would submit for a performance category or submitting information that would be used to score a performance category for an extended period of time. Beginning with the 2021 MIPS payment year, in the event that a MIPS eligible clinician submits data for the quality, cost, or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed, unless an exception applies. Exception: for the 2021 MIPS payment year only, if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the Public Health Emergency for the COVID–19 pandemic and also submits data for the quality, cost, or improvement activities performance categories, the preceding sentence will not apply.

(*7*) For the 2019 MIPS payment year, for the quality and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for a performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*8*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for the quality or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*9*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

(B) Under section 1848(q)(5)(E)(ii) of the Act, CMS estimates that the proportion of MIPS eligible clinicians who are physicians as defined in section 1861(r) of the Act and earn a Promoting Interoperability performance category score of at least 75 percent is 75 percent or greater. The estimation is based on data from the performance period that occurs four years before the MIPS payment year and does not include physicians for whom the Promoting Interoperability performance category is weighted at zero percent.

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. Except as provided in paragraphs (c)(2)(i)(C)(*10*) and (*11*) of this section, in the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*1*) The MIPS eligible clinician demonstrates through an application submitted to CMS that they lacked sufficient internet access during the performance period, and insurmountable barriers prevented the clinician from obtaining sufficient internet access.

(*2*) The MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that caused their CEHRT to be unavailable.

(*3*) The MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS.

(*4*) The MIPS eligible clinician demonstrates through an application submitted to CMS that 50 percent or more of their outpatient encounters occurred in practice locations where they had no control over the availability of CEHRT.

(*5*) The MIPS eligible clinician is a non-patient facing MIPS eligible clinician as defined in §414.1305.

(*6*) The MIPS eligible clinician is a hospital-based MIPS eligible clinician as defined in §414.1305.

(*7*) The MIPS eligible clinician is an ASC-based MIPS eligible clinician as defined in §414.1305.

(*8*) Beginning with the 2020 MIPS payment year, the MIPS eligible clinician demonstrates through an application submitted to CMS that their CEHRT was decertified either during the performance period for the MIPS payment year or during the calendar year preceding the performance period for the MIPS payment year, and the MIPS eligible clinician made a good faith effort to adopt and implement another CEHRT in advance of the performance period. In no case may a MIPS eligible clinician be granted this exception for more than 5 years.

(*9*) For the 2020 MIPS payment year through the 2023 MIPS payment year the MIPS eligible clinician demonstrates through an application submitted to CMS that they are in a small practice as defined in §414.1305, and overwhelming barriers prevent them from complying with the requirements for the Promoting Interoperability performance category. Beginning with the 2024 MIPS payment year the MIPS eligible clinician is in a small practice as defined in §414.1305.

(*10*) Beginning with the 2020 MIPS payment year, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

(*11*) For the 2021 MIPS payment year only, the MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the Public Health Emergency for the COVID–19 pandemic.

(ii) A scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, as follows:

(A) For the 2019 MIPS payment year:

TABLE 2 TO PARAGRAPH (c)(2)(ii)(A)

Performance category (%)	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category score (%)	Reweight scenario if no improvement activities performance category score (%)
Quality	60	85	0	75
Cost	0	0	0	0
Improvement Activities	15	15	50	0
Promoting Interoperability	25	0	50	25

(B) For the 2020 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	50	10	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	75	10	15	0
—No Quality	0	10	45	45
—No Improvement Activities	65	10	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	10	90	0
—No Promoting Interoperability and no Improvement Activities	90	10	0	0
—No Quality and no Improvement Activities	0	10	0	90

(C) For the 2021 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	70	15	15	0
—No Quality	0	15	40	45
—No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	15	85	0
—No Promoting Interoperability and no Improvement Activities	85	15	0	0
—No Quality and no Improvement Activities	0	15	0	85

(D) For the 2022 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	70	15	15	0
No Quality	0	15	15	70
No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	85	15	0	0
No Quality and no Improvement Activities	0	15	0	85

(E) For the 2023 MIPS payment year:

TABLE 6 TO PARAGRAPH (c)(2)(ii)(E)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	40	20	15	25
No Cost	55	0	15	30
No Promoting Interoperability	65	20	15	0
No Quality	0	20	15	65
No Improvement Activities	55	20	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	80	20	0	0
No Quality and no Improvement Activities	0	20	0	80

(F) Except as provided in paragraph (c)(2)(ii)(G) of this section, beginning with the 2024 MIPS payment year:

TABLE 7 TO PARAGRAPH (c)(2)(ii)(F)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	55	30	15	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

(G) For small practices beginning with the 2024 MIPS payment year:

TABLE 8 TO PARAGRAPH (c)(2)(ii)(G)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	40	30	30	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	50	0	50	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

(iii) For the Promoting Interoperability performance category to be reweighted in accordance with paragraph (c)(2)(ii) of this section for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting based on the circumstances described in paragraph (c)(2)(i) of this section, or the group or virtual group must meet the definition of a hospital-based MIPS eligible clinician or a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(3) *Complex patient bonus.* For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, provided that a MIPS eligible clinician, group, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as stated in paragraphs (c)(3)(i) through (iv) of this section. For the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section. Beginning with the CY 2023 MIPS performance period/CY 2025 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, or is a facility-based MIPS eligible clinician, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section.

(i) For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, for MIPS eligible clinicians and groups, the complex patient bonus is calculated as follows: [The average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group] + [the dual eligible ratio × 5].

(ii) For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, for APM Entities and virtual groups, the complex patient bonus is calculated as follows: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM Entity or virtual group, respectively] + [the average dual

eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively, × 5].

(iii) For the 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, the complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv) of this section.

(iv) For the 2022 and 2023 MIPS payment years and associated performance periods, the complex patient bonus is calculated pursuant to paragraphs (c)(3)(i) and (ii) of this section, and the resulting numerical value is then multiplied by 2.0. The complex patient bonus cannot exceed 10.0.

(v) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM Entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. To determine the median for the respective risk indicator (HCC and dual proportion), risk indicators associated with the final score assigned to a clinician from the most recent prior performance period, for all those who have submitted data for at least one MIPS performance category or are facility-based, are used.

(vi) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, for MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component = 1.5 + 4 * associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(vii) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, for APM Entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM Entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4 * the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(viii) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

(4) *Small practice bonus.* A small practice bonus of 5 points will be added to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, virtual groups, and APM Entities that meet the definition of a small practice as defined at §414.1305 and participate in MIPS by submitting data on at least one performance category in the 2018 MIPS performance period.

(d) *Scoring for APM Entities.* MIPS eligible clinicians in APM Entities that are subject to the APM scoring standard are scored using the methodology under §414.1370.

(e) *Scoring for facility-based measurement.* For the payment in 2021 MIPS payment year and subsequent years and subject to paragraph (e)(6)(vi) of this section, a MIPS eligible clinician or group will be scored under the quality and cost performance categories using the methodology described in this paragraph (e).

(1) *General.* The facility-based measurement scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified as meeting the requirements in paragraph (e)(2) of this section.

(i) The measures used for facility-based measurement are the measure set finalized for the fiscal year value-based purchasing program for which payment begins during the applicable MIPS performance period.

(ii) Beginning with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period.

(2) *Eligibility for facility-based measurement.* A MIPS eligible clinician is eligible for facility-based measurement for a MIPS payment year if CMS determines the MIPS eligible clinician to be facility-based as an individual clinician or as part of a group, or beginning with the 2023 performance period/2025 MIPS payment year, a virtual group, as follows:

(i) *Facility-based individual determination.* A MIPS eligible clinician is facility-based if the clinician meets all of the following criteria:

(A) Furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the performance period with a 30-day claims run out.

(B) Furnishes at least 1 covered professional service in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, or emergency room setting.

(C) Can be assigned, under the methodology specified in paragraph (e)(5) of this section, to a facility with a value-based purchasing score for the applicable period.

(ii) *Facility-based MIPS eligible group determination.* A facility-based MIPS eligible group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements under paragraph (e)(2)(i) of this section.

(3) [Reserved]

(4) *Data submission for facility-based measurement.* There are no data submission requirements for a MIPS eligible individual clinician to be scored under facility-based measurement. A MIPS eligible group must submit data in the improvement activities or Promoting Interoperability performance categories in order toto be scored as a facility-based MIPS eligible group.

(5) *Determination of applicable facility score.*

(i) A facility-based MIPS eligible clinician is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the clinician provided services to the most Medicare beneficiaries during the period the claims are drawn from in paragraph (e)(2) of this section. If there is an equal number of Medicare beneficiaries treated at more than one facility, the value-based purchasing score for the highest scoring facility is used.

(ii) A facility-based MIPS eligible group is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under paragraph (e)(5)(i) of this section.

(6) *MIPS performance category scoring under the facility-based measurement scoring standard*—(i) *Measures.* The quality and cost measures are those adopted under the value-based purchasing program of the facility for the

year described in paragraph (e)(1)(i) of this section.

(ii) *Benchmarks.* The benchmarks are those adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1) of this section.

(iii) *Performance period.* The performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1) of this section.

(iv) *Quality.* The quality performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category score for those MIPS-eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A MIPS eligible clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality performance category.

(v) *Cost.* The cost performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A MIPS eligible clinician or MIPS eligible group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS cost performance category.

(A) Other cost measures. MIPS eligible clinicians who are scored under facility-based measurement are not scored on cost measures described in paragraph (b)(2) of this section.

(B) [Reserved]

(vi) *Use of score from facility-based measurement.* The MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology described in paragraph (e)(6) of this section unless:

(A) For the CY 2019 MIPS performance period/2021 MIPS payment year, through the CY 2021 MIPS performance period/2023 MIPS payment year, a MIPS eligible clinician or group receives a higher combined MIPS quality and cost performance category score through another MIPS submission.

(B) Beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, a MIPS eligible clinician or group receives a higher MIPS final score through another MIPS submission.

[83 FR 60081, Nov. 23, 2018, as amended at 84 FR 63196, Nov. 15, 2019; 85 FR 19287, Apr. 6, 2020; 85 FR 85031, Dec. 28, 2020; 86 FR 65673, Nov. 19, 2021; 86 FR 73159, Dec. 27, 2021; 87 FR 7747, Feb. 10, 2022; 87 FR 70228, Nov. 18, 2022; 88 FR 15921, Mar. 15, 2023]

§414.1385 Targeted review and review limitations.

(a) *Targeted review.* A MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year. The process for targeted review is as follows:

(1) A MIPS eligible clinician or group (including their designated support staff), or a third party intermediary as defined at §414.1305, may submit a request for a targeted review.

(2) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year. The targeted review request submission period may be extended as specified by CMS.

(3) A request for a targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not submitted

during the targeted review request submission period; or the request is outside of the scope of the targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year. If the targeted review request is denied, there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician or group. If the targeted review request is approved, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician or group.

(4) CMS will respond to each request for a targeted review timely submitted and determine whether a targeted review is warranted.

(5) A request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS' request. Non-responsiveness to CMS' request for additional information may result in a final decision based on the information available, although another non-duplicative request for a targeted review may be submitted before the end of the targeted review request submission period.

(6) If a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to measures, activities, performance categories, and the final score, as well as the MIPS payment adjustment factors.

(7) Decisions based on the targeted review are final, and there is no further review or appeal. CMS will notify the individual or entity that submitted the request for a targeted review of the final decision.

(8) Documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.

(b) *Limitations on review.* Except as specified in paragraph (a)(4) of this section, there is no administrative or judicial review under section 1869 or 1879 of the Act, or otherwise of—

(1) The methodology used to determine the amount of the MIPS payment adjustment factor and the amount of the additional MIPS payment adjustment factor and the determination of such amounts;

(2) The establishment of the performance standards and the performance period;

(3) The identification of measures and activities specified for a MIPS performance category and information made public or posted on the Physician Compare Internet Web site of the CMS; and

(4) The methodology developed that is used to calculate performance scores and the calculation of such scores, including the weighting of measures and activities under such methodology.

[81 FR 77537, Nov. 4, 2016, as amended at 84 FR 63197, Nov. 15, 2019]

§ 414.1390 Data validation and auditing.

(a) *General.* CMS will selectively audit MIPS eligible clinicians and groups on a yearly basis. If a MIPS eligible clinician or group is selected for audit, the MIPS eligible clinician or group will be required to do the following in accordance with applicable law and timelines CMS establishes:

(1) Comply with data sharing requests, providing all data as requested by CMS or our designated entity. All data must be shared with CMS or our designated entity within 45 days of the data sharing request, or an alternate timeframe that is agreed to by CMS and the MIPS eligible clinician or group. Data will be submitted via email, facsimile, or an electronic method via a secure Web site maintained by CMS.

(2) Provide substantive, primary source documents as requested. These documents may include: Copies of claims, medical records for applicable patients, or other resources used in the data calculations for MIPS measures, objectives, and activities. Primary source documentation also may include verification of records for Medicare and non-Medicare beneficiaries where applicable.

(b) *Certification.* All MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS must certify to the best of their knowledge that the data submitted to CMS is true, accurate, and complete. Such certification must accompany the submission and be made at the time of submission.

(c) *Reopening.* CMS may reopen and revise a MIPS payment adjustment in accordance with the rules set forth at §§ 405.980 through 405.986 of this chapter.

(d) *Record retention.* All MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS must retain such data and information for 6 years from the end of the MIPS performance period.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53959, Nov. 16, 2017]

§ 414.1395 Public reporting.

(a) *General.* (1) CMS posts on Physician Compare, in an easily understandable format, the following:

(i) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and

(ii) The names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs.

(2) CMS periodically posts on Physician Compare aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category.

(3) The information made available under this section will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

(b) *Maintain existing public reporting standards.* With the exception of data that must be mandatorily reported on Physician Compare, for each program year, CMS relies on established public reporting standards to guide the information available for inclusion on Physician Compare. The public reporting standards require data included on Physician Compare to be statistically valid, reliable, and accurate; comparable across collection types; and meet the reliability threshold. And, to be included on the public facing profile pages, the data must also resonate with website users, as determined by CMS.

(c) *New measures and activities.* (1) CMS does not publicly report any data on new quality or cost measure for the first 2 years in which it is in the program, after which CMS evaluates the measure to determine whether it is suitable for public reporting under paragraph (b) of this section.

(2) CMS does not publicly report any MVP data on new improvement activity or Promoting Interoperability measure, objective, or activity included in an MVP for the first year in which it is included in the MVP.

(d) *30-day preview period.* For each program year, CMS provides a 30-day preview period for any clinician or group with Quality Payment Program data before the data are publicly reported on Physician Compare.

[82 FR 53959, Nov. 16, 2017, as amended at 83 FR 60087, Nov. 23, 2018; 84 FR 63198, Nov. 15, 2019; 86 FR 65677, Nov. 19, 2021]

§ 414.1400 Third party intermediaries.

(a) *General.* (1) MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity by any of the following third party intermediaries:

(i) QCDR;

(ii) Qualified registry;

(iii) Health IT vendor; or

(iv) CMS-approved survey vendor.

(2) Third party intermediary approval criteria—

(i) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(A) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(B) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(C) All data must be submitted in the form and manner specified by CMS.

(D) If the clinician chooses to opt-in in accordance with §414.1310, the third party intermediary must be able to transmit that decision to CMS.

(E) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(F) Prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan.

(ii) The determination of whether to approve an entity as a third party intermediary for a MIPS payment year may take into account:

(A) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and

(B) Whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician.

(iii) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

(3) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(b) *Additional requirements for QCDRs and qualified registries*—(1) *General.* (i) Beginning with the CY 2021 performance period/2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories:

(A) Quality, except:

(*1*)The CAHPS for MIPS survey; and

(*2*) For qualified registries, QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless the third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at §414.1380(c)(2)(i)(A)(4)(i) through (iii) or (c)(2)(i)(C)(1) through (7) or (c)(2)(i)(C)(9).

(ii) Beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP.

(2) *Self-nomination.* For the CY 2018 and 2019 performance periods/2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR or qualified registry must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the CY 2020 performance period/2022 MIPS payment year and future years, entities seeking to qualify as a QCDR or qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR or qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the CY 2019 performance period/2021 MIPS payment year and future years, existing QCDRs and qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(3) *Conditions for approval.* (i) Beginning with the CY 2020 performance period/2022 MIPS payment year, the QCDR or qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) If an entity seeking to qualify as a QCDR or qualified registry uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

(iii) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR or qualified registry. Exceptions to this requirement may occur if the QCDR or qualified registry submits notification to CMS within the performance period promptly within the month of realization of the impending deficiency and provides sufficient rationale as to why they do not believe they would be able to meet this requirement (for example, if the QCDR does not receive the data from their clinician until the end of the performance period).

(iv) Beginning with the CY 2023 performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination for CMS' approval and may not change the plan once approved without the prior approval of the agency.

(v) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct annual data validation audits in accordance with this paragraph (b)(3)(v).

(A) The QCDR or qualified registry must conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program.

(B) The QCDR or qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The QCDR or qualified registry must conduct data validation on data for each submitter type for which it will submit data, including MIPS eligible clinicians, groups, virtual groups, subgroups, APM entities, voluntary participants, and opt-in participants, if applicable.

(D) The QCDR or qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The QCDR or qualified registry must conduct each data validation audit using a sampling methodology that meets the following requirements:

(*1*) Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR or qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR or qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR or qualified registry may use a sample size of 50 TIN/NPIs.

(*2*) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each QCDR or qualified registry data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, subgroup, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only the MIPS quality measures and QCDR measures, as applicable, that are relevant to the performance period will be used for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the QCDR or qualified registry must report the results of each data validation audit, including the overall data deficiencies

or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or error, and, how and when each deficiency or data error type was corrected.

(*1*) QCDRs and qualified registries must conduct validation on the data they intend to submit for the MIPS performance period and provide the results of the executed data validation plan by May 31st of the year following the performance period.

(*2*) [Reserved]

(vi) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with this paragraph (b)(3)(vi).

(A) If a data validation audit under paragraph (b)(3)(v) of this section identifies one or more deficiency or data error, the QCDR or qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The QCDR or qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The QCDR or qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(3)(iv)(E) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the QCDR or qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected.

(vii) For the CY 2023 performance period/2025 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for any of the 2019 through 2023 MIPS payment years must submit a participation plan for CMS' approval. The participation plan must include the QCDR and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(viii) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(4) *QCDR measures for the quality performance category*—(i) *QCDR measure self-nomination requirements.* For the CY 2018 performance period/2020 MIPS payment year and future years, at the time of self-nomination an entity seeking to become a QCDR must submit the following information for any measure it intends to submit for the payment year.

(A) For MIPS quality measures, the entity must submit specifications including the MIPS measure IDs and specialty-specific measure sets, as applicable.

(B) For a QCDR measure, the entity must submit for CMS approval measure specifications including: Name/title of measure, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

(ii) *QCDR measure submission requirements.* A QCDR must include the CMS-

assigned QCDR measure ID when submitting data on any QCDR measure to CMS.

(iii) *QCDR measure approval criteria.* (A) QCDR measure requirements for approval are:

(*1*) QCDR measures that are beyond the measure concept phase of development.

(*2*) QCDR measures that address significant variation in performance.

(*3*) Beginning with the CY 2022 performance period/2024 MIPS payment year, CMS may approve a QCDR measure only if the QCDR measure meets face validity. Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination.

(*4*) Beginning with the CY 2022 performance period/2023 MIPS payment year, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(*5*) Beginning with the CY 2020 performance period/2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

(B) QCDR measure considerations for approval include, but are not limited to:

(*1*) Measures that are outcome-based rather than clinical process measures.

(*2*) Measures that address patient safety and adverse events.

(*3*) Measures that identify appropriate use of diagnosis and therapeutics.

(*4*) Measures that address the domain of care coordination.

(*5*) Measures that address the domain for patient and caregiver experience.

(*6*) Measures that address efficiency, cost, and resource use.

(*7*) Beginning with the CY 2021 performance period/2023 MIPS payment year -

(*i*) That QCDRs link their QCDR measures as feasible to at least one cost measure, improvement activity, or an MVP at the time of self-nomination.

(*ii*) In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, CMS would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.

(*8*) Beginning with the CY 2020 performance period/2022 MIPS payment year CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(*9*) Greater consideration is given to measures for which QCDRs:

(*i*) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and

(*ii*) Utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint in the CMS Measures Management System to identify measurement gaps prior to measure development.

(*10*) Beginning with the CY 2020 performance period/2022 MIPS payment year, CMS places greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved.

(*i*) Beginning with the CY 2020 performance period/2022 MIPS payment year, in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the

QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

(*ii*) [Reserved]

(C) Beginning with the CY 2021 performance period/2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

(iv) *QCDR measure rejection criteria.* Beginning with the CY 2020 performance period/2022 MIPS payment year, QCDR measure rejection considerations include, but are not limited to:

(A) QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.

(B) QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.

(C) QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.

(D) QCDR measures that meet the topped out definition as described at § 414.1305.

(E) QCDR measures that are process-based, with consideration to whether the removal of the process measure impacts the number of measures available for a specific specialty.

(F) Whether the QCDR measure has potential unintended consequences to a patient's care.

(G) Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.

(H) QCDR measures that split a single clinical practice or action into several QCDR measures.

(I) QCDR measures that are ''checkbox'' with no actionable quality action.

(J) QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years.

(K) QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.

(L) QCDR measures that focus on rare events or ''never events'' in the measurement period.

(M) QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period.

(N) If a QCDR measure owner is not approved or is not in good standing, any associated QCDR measures will not be approved.

(c) *Additional requirements for Health IT vendors.* (1) Beginning with the CY 2021 performance period/2023 MIPS payment year, health IT vendors must be able to submit data for the MIPS performance categories as follows:

(i) Health IT vendors that support MVPs must be able to submit data for all of the MIPS performance categories:

(A) Quality, except:

(*1*) The CAHPS for MIPS survey; and

(*2*) QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

(*1*) The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

(*2*) [Reserved]

(ii) Health IT vendors that do not support MVPs must be able to submit data for at least one of the MIPS performance categories described in paragraphs (c)(1)(i) of this section.

(iii) Beginning with the CY 2023 performance period/2025 MIPS payment year, Health IT vendors must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. Health IT vendors may also support the APP.

(2) [Reserved]

(d) *Additional requirements for CMS-approved survey vendors.* (1) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category.

(2) Entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. The application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. For an entity to be a CMS-approved survey vendor, it must meet the following criteria:

(3) The entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

(i) At least 3 years of experience administering mixed-mode surveys (that is, surveys that employ multiple modes to collect date), including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);

(ii) At least 3 years of experience administering surveys to a Medicare population;

(iii) At least 3 years of experience administering CAHPS surveys within the past 5 years;

(iv) Experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available;

(v) Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

(vi) Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

(4) The entity has certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data.

(5) The entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.

(6) The entity has submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts.

(7) The entity has agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.

(8) The entity has sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(e) *Remedial action and termination of third party intermediaries.* (1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) Require the third party intermediary to submit a corrective action plan (CAP) by a date specified by CMS. The CAP must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the non-compliance.

(B) The impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program, and any QCDRs that were granted licenses to the measures of a QCDR upon which a CAP has been imposed.

(C) The corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future.

(D) The detailed timeline for achieving compliance with the applicable requirements.

(E) The communication plan for communicating the impact to the parties identified in paragraph (e)(1)(i)(B) of this section.

(ii) Publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(2) CMS may immediately or with advance notice terminate a third party intermediary for one or more of the following reasons:

(i) CMS has grounds to impose remedial action;

(ii) CMS has not received a CAP within the specified time-period or the CAP is not accepted by CMS; or

(iii) The third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

(3) A data submission that contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

(4) For purposes of this paragraph (e), CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, including but not limited to, if the submitted data:

(i) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies.

(ii) [Reserved]

(5) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii) of this section, will be terminated.

(f) *Auditing of entities submitting MIPS data.* Any third party intermediary must comply with the following procedures as a condition of its qualification and approval to participate in MIPS as a third party intermediary.

(1) The entity must make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email.

(2) The entity must retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(3) For the purposes of auditing, CMS may request any records or data retained for the purposes of MIPS for up to 6 years from the end of the MIPS performance period.

[86 FR 65677, Nov. 19, 2021, as amended at 87 FR 70229, Nov. 18, 2022]

§ 414.1405 Payment.

(a) *General.* Each MIPS eligible clinician receives a MIPS payment adjustment factor, and if applicable an additional MIPS payment adjustment factor for exceptional performance, for a MIPS payment year determined by comparing their final score to the performance threshold and additional performance threshold for the year.

(b) *Performance threshold.* A performance threshold will be specified for each MIPS payment year.

(1) MIPS eligible clinicians with a final score at or above the performance threshold receive a zero or positive MIPS payment adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a final score at the performance threshold and an adjustment factor of the applicable percent is assigned for a final score of 100.

(2) MIPS eligible clinicians with a final score below the performance threshold receive a negative MIPS payment adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a final score at the performance threshold and an adjustment factor of the negative of the applicable percent is assigned for a final score of 0; further, MIPS eligible clinicians with final scores that are equal to or greater than

zero, but not greater than one-fourth of the performance threshold, receive a negative MIPS payment adjustment factor that is equal to the negative of the applicable percent.

(3) A scaling factor not to exceed 3.0 may be applied to positive MIPS payment adjustment factors to ensure budget neutrality such that the estimated increase in aggregate allowed charges resulting from the application of the positive MIPS payment adjustment factors for the MIPS payment year equals the estimated decrease in aggregate allowed charges resulting from the application of negative MIPS payment adjustment factors for the MIPS payment year.

(4) The performance threshold for the 2019 MIPS payment year is 3 points.

(5) The performance threshold for the 2020 MIPS payment year is 15 points.

(6) The performance threshold for the 2021 MIPS payment year is 30 points.

(7) The performance threshold for the 2022 MIPS payment year is 45 points.

(8) The performance threshold for the 2023 MIPS payment year is 60 points.

(9) Pursuant to the methodology established at paragraph (g) of this section:

(i) The performance threshold for the 2024 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(ii) The performance threshold for the 2025 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(c) *Applicable percent.* For MIPS payment year 2019, 4 percent. For MIPS payment year 2020, 5 percent. For MIPS payment year 2021, 7 percent. For MIPS payment year 2022 and each subsequent MIPS payment year, 9 percent.

(d) *Additional performance threshold.* An additional performance threshold will be specified for each of the MIPS payment years 2019 through 2024.

(1) In addition to the MIPS payment adjustment factor, MIPS eligible clinicians with a final score at or above the additional performance threshold receive an additional MIPS payment adjustment factor for exceptional performance on a linear sliding scale such that an additional adjustment factor of 0.5 percent is assigned for a final score at the additional performance threshold and an additional adjustment factor of 10 percent is assigned for a final score of 100, subject to the application of a scaling factor as determined by CMS, such that the estimated aggregate increase in payments resulting from the application of the additional MIPS payment adjustment factors for the MIPS payment year shall not exceed $500,000,000 for each of the MIPS payment years 2019 through 2024.

(2) [Reserved]

(3) The additional performance threshold for the 2019 MIPS payment year is 70 points.

(4) The additional performance threshold for the 2020 MIPS payment year is 70 points.

(5) The additional performance threshold for the 2021 MIPS payment year is 75 points.

(6) The additional performance threshold for the 2022 and 2023 MIPS payment years is 85 points.

(7) The additional performance threshold for the 2024 MIPS payment year is 89 points.

(e) *Application of adjustments to payments.* Except as specified in paragraph (f) of this section, in the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of the MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100.

(f) *Exception to application of MIPS payment adjustment factors to model-specific payments under section 1115A APMs.* Beginning with the 2019 MIPS payment year, the payment adjustment factors specified under paragraph (e) of this section are not applicable to payments that meet all of the following conditions:

(1) Are made only to participants in a model tested under section 1115A of the Act;

(2) Would otherwise be subject to the requirement to apply the MIPS payment adjustment factors if the payment is made with respect to a MIPS eligible clinician participating in a section 1115A model; and

(3) Either have a specified payment amount or are paid according to a methodology for calculating a model-specific payment that is applied in a consistent manner to all model participants, such that application of the MIPS payment adjustment factors would potentially interfere with CMS's ability to effectively evaluate the impact of the APM.

(g) *Performance threshold methodology.* For each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53960, Nov. 16, 2017; 83 FR 60089, Nov. 23, 2018; 84 FR 63200, Nov. 15, 2019; 86 FR 65681, Nov. 19, 2021; 87 FR 70229, Nov. 18, 2022]

§ 414.1410 Advanced APM determination.

(a) *General.* An APM is an Advanced APM for a payment year if CMS determines that it meets the criteria in § 414.1415 during the QP Performance Period.

(b) *Advanced APM determination process.* CMS determines Advanced APMs in the following manner:

(1) *Advanced APM determination.* (i) No later than January 1, 2017, CMS will post on its Web site a list of all Advanced APMs for the first QP Performance Period.

(ii) CMS updates the Advanced APM list on its Web site at intervals no less than annually.

(iii) CMS will include notice of whether a new APM is an Advanced APM in the first public notice of the new APM.

(2) [Reserved]

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53960, Nov. 16, 2017]

§ 414.1415 Advanced APM criteria.

(a) *Use of certified electronic health record technology (CEHRT)*—(1) *Required use of CEHRT.* To be an Advanced APM, an APM must:

(i) Require at least 50 percent, or for QP Performance Periods beginning in 2019, 75 percent of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers; or

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity.

(b) *Payment based on quality measures.* (1) To be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (b)(1) of this section must:

(i) For QP Performance Periods before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in § 414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in § 414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) The quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must include at least one measure that is an outcome measure unless CMS determines that there are no available or

applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Beginning January 1, 2020, the included outcome measure must satisfy the criteria in paragraph (b)(2) of this section.

(4) A single quality measure that meets the criteria under both paragraphs (b)(2) and (3) of this section may be used to satisfy the requirements of paragraph (b)(1) of this section.

(c) *Financial risk.* To be an Advanced APM, except as described in paragraph (c)(6) of this section, an APM must either meet the financial risk standard under paragraph (c)(1) or (2) of this section and the nominal amount standard under paragraph (c)(3) or (4) of this section or be an expanded Medical Home Model under section 1115A(c) of the Act.

(1) *Generally applicable financial risk standard.* Except for paragraph (c)(2) of this section, to be an Advanced APM, an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, do one or more of the following:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or

(iii) Require the APM Entity to owe payment(s) to CMS.

(2) *Medical Home Model financial risk standard.* The APM Entity participates in a Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, which may include expected expenditures, does one or more of the following:

(i) Withholds payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Reduces payment rates to the APM Entity or the APM Entity's eligible clinicians;

(iii) Requires the APM Entity to owe payment(s) to CMS; or

(iv) Causes the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

(3) *Generally applicable nominal amount standard.* (i) Except as provided in paragraph (c)(4) of this section, the total amount an APM Entity potentially owes CMS or foregoes under an APM must be at least equal to either:

(A) For QP Performance Periods beginning in 2023, 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities; or

(B) 3 percent of the expected expenditures for which an APM Entity is responsible under the APM.

(ii) [Reserved]

(4) *Medical Home Model nominal amount standard.* (i) For a Medical Home Model to meet the Medical Home Model nominal amount standard, the total annual amount that an APM Entity potentially owes CMS or foregoes must be at least the following amounts:

(A) For QP Performance Period 2017, 2.5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(B) For QP Performance Period 2018, 2.5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(C) For QP Performance Period 2019, 3 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(D) For QP Performance Period 2020, 4 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(E) For QP Performance Periods 2021 and later, 5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(ii) [Reserved]

(5) For the purposes of this section, expected expenditures means the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under

the terms of the APM should not exceed the Medicare Part A and Part B expenditures for a participant in the absence of the APM. If the expected expenditures under the APM exceed the Medicare Part A and Part B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for purposes of Advanced APM determinations.

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this part, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program (part 422 of this title) are not considered capitation arrangements for purposes of this paragraph (c)(6).

(7) *Medical Home Model 50 eligible clinician limit.* Beginning in the 2023 QP Performance Period, notwithstanding paragraphs (c)(2) and (4) of this section, if an APM Entity participating in a Medical Home Model is comprised of more than 50 eligible clinicians, as determined by that APM Entity's Participation List on any of the three QP determination dates (March 31, June 30, and August 31 of the QP Performance Period), the requirements of paragraphs (c)(1) and (3) of this section apply.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53960, Nov. 16, 2017; 83 FR 60090, Nov. 23, 2018; 84 FR 540, Jan. 31, 2019; 84 FR 63200, Nov. 15, 2019; 87 FR 70229, Nov. 18, 2022]

§ 414.1420 Other payer advanced APM criteria.

(a) *Other Payer Advanced APM criteria.* A payment arrangement with a payer other than Medicare is an Other Payer Advanced APM for a QP Performance Period if CMS determines that the arrangement meets the following criteria during the QP Performance Period:

(1) Use of CEHRT, as described in paragraph (b) of this section;

(2) Quality measures comparable to measures under the MIPS quality performance category apply, as described in paragraph (c) of this section; and

(3) Either:

(i) Requires APM Entities to bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures as described in paragraph (d) of this section; or

(ii) Is a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act as described in paragraph (d) of this section.

(b) *Use of CEHRT.* To be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent, or for QP Performance Periods on or after January 1, 2020, 75 percent of participants in each participating APM Entity group, or each hospital if hospitals are the APM Entities, in the other payer arrangement to document and communicate clinical care.

(c) *Use of quality measures.* (1) To be an Other Payer Advanced APM, a payment arrangement must apply quality measures comparable to measures under the MIPS quality performance category, as described in paragraph (c)(2) of this section.

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (c)(1) of this section must:

(i) For QP Performance Period before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in § 414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January 1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in §414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) To meet the quality measure use criterion under paragraph (c)(1) of this section, a payment arrangement must:

(i) For QP Performance Periods before January 1, 2020, use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. This criterion also applies for payment arrangements determined to be Other Payer Advanced APMs on or before January 1, 2020, but only for the Other Payer Advanced APM determination made with respect to the arrangement for the CY 2020 QP Performance Period (regardless of whether that determination is a single- or multi-year determination).

(ii) For QP Performance Periods on or after January 1, 2020, use at least one measure that is an outcome measure and meets the criteria in paragraph (c)(2)(ii) of this section if there is such an applicable outcome measure on the MIPS quality measure list.

(4) A single quality measure that meets the criteria under both paragraphs (c)(2) and (3) of this section may be used to satisfy the requirements of paragraph (c)(1) of this section.

(d) *Financial risk.* To be an Other Payer Advanced APM, except as described in paragraph (d)(7) of this section, a payment arrangement must meet either the financial risk standard under paragraph (d)(1) or (2) of this section and the nominal amount standard under paragraph (d)(3) or (4) of this section, or be a Medicaid Medical Home Model with criteria comparable to an expanded Medical Home Model under section 1115A(c) of the Act.

(1) *Generally applicable financial risk standard.* Except for APM Entities to which paragraph (d)(2) of this section applies, to be an Other Payer Advanced APM, an APM Entity must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the payment arrangement exceed expected expenditures during a specified period of performance do one or more of the following:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or

(iii) Require direct payment by the APM Entity to the payer.

(2) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model financial risk standard.* The APM Entity participates in a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, does one or more of the following:

(i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians;

(ii) Require direct payment by the APM Entity to the payer;

(iii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or

(iv) Require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

(3) *Generally applicable nominal amount standard.* Except for payment arrangements described in paragraph (d)(2) of this section, the total amount an APM Entity potentially owes a payer or foregoes under a payment arrangement must be at least:

(i) For QP Performance Periods beginning in 2023, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement if financial risk is expressly defined in terms of revenue; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

(ii) Except for risk arrangements described under paragraph (d)(2) of this section, the risk arrangement must have a marginal risk rate of at least 30 percent.

(4) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model nominal amount standard.* For a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model to meet the Medicaid Medical Home Model nominal amount standard, the total annual amount that an APM

Entity potentially owes a payer or forgoes must be at least the following amounts:

(i) For QP Performance Period 2019, 3 percent of the average estimated total revenue of the participating providers or other entities under the payer.

(ii) For QP Performance Period 2020, 4 percent of the average estimated total revenue of the participating providers or other entities under the payer.

(iii) For QP Performance Periods 2021 and later, 5 percent of the average estimated total revenue of the participating providers or other entities under the payer.

(5) *Marginal risk rate.* For purposes of this section, the marginal risk rate is defined as the percentage of actual expenditures that exceed expected expenditures for which an APM Entity is responsible under an other payer payment arrangement.

(i) In the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, with exceptions for large losses as described in paragraph (d)(5)(ii) of this section and small losses as described in paragraph (d)(5)(iii) of this section.

(ii) *Allowance for large losses.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the other payer payment arrangement greater than or equal to the total risk requirement under paragraph (d)(3)(i) of this section.

(iii) *Allowance for minimum loss rate.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by less than 4 percent of expected expenditures.

(6) *Expected expenditures.* For the purposes of this section, expected expenditures is defined as the Other Payer APM benchmark. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement. If expected expenditures under the payment arrangement exceed the expenditures that the participant would be expected to incur in the absence of the payment arrangement, such excess expenditures are not considered when assessing financial risk under the payment arrangement for Other Payer Advanced APM determinations.

(7) *Capitation.* A full capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the payment arrangement for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed for the purposes of reconciling or sharing losses incurred or savings earned by the participant. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (part 422 of this title) are not considered capitation arrangements for purposes of this paragraph.

(8) *Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit.* Beginning with the 2023 QP Performance Period, notwithstanding paragraphs (d)(2) and (4) of this section, if an APM Entity participating in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model is comprised of 50 or more eligible clinicians is comprised of more than 50 eligible clinicians, as determined by the information submitted for any of the three QP determination dates (March 31, June 30, and August 31 of the QP Performance Period) as specified in § 414.1440(e), the requirements of

paragraphs (d)(1) and (3) of this section apply.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53961, Nov. 16, 2017; 83 FR 23610, May 22, 2018; 83 FR 60090, Nov. 23, 2018; 84 FR 63200, Nov. 15, 2019; 87 FR 70230, Nov. 18, 2022]

§414.1425 Qualifying APM participant determination: In general.

(a) *List used for QP determination.* (1) For Advanced APMs in which all APM Entities may include eligible clinicians on a Participation List, the Participation List is used to identify the APM Entity group for purposes of QP determinations, regardless of whether the APM Entity may also include eligible clinicians on an Affiliated Practitioner List.

(2) For Advanced APMs in which APM Entities do not include eligible clinicians on a Participation List but do include eligible clinicians on an Affiliated Practitioner List, the Affiliated Practitioner List is used to identify the eligible clinicians for purposes of QP determinations.

(3) For Advanced APMs in which some APM Entities may include eligible clinicians on a Participation List and other APM Entities may only include eligible clinicians on an Affiliated Practitioner List depending on the type of APM Entity, paragraph (a)(1) of this section applies to APM Entities that may include eligible clinicians on a Participation List, and paragraph (a)(2) of this section applies to APM Entities that may only include eligible clinicians on an Affiliated Practitioner List.

(b) *Group or individual determination under the Medicare Option. (1) APM Entity group determination.* Except for paragraphs (b)(2) and (3) of this section and as set forth in §414.1440, for purposes of the QP determinations for a year, eligible clinicians are grouped and assessed through their collective participation in an APM Entity group that is in an Advanced APM. To be included in the APM Entity group for purposes of the QP determination, an eligible clinician's APM participant identifier must be present on a Participation List of an APM Entity group on one of the dates: March 31, June 30, or August 31 of the QP Performance Period. An eligible clinician included on a Participation List on any one of these dates is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior or later listed dates. CMS performs QP determinations for the eligible clinicians in an APM entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. An eligible clinician can only be determined to be a QP if the eligible clinician appears on the Participation List on a date (March 31, June 30, or August 31) CMS uses to determine the APM Entity group and to make QP determinations collectively for the APM Entity group based on participation in the Advanced APM.

(2) *Affiliated practitioner individual determination under the Medicare Option.* For Advanced APMs to which paragraph (a)(2) of this section applies, QP determinations are made individually for each eligible clinician. To be assessed as an Affiliated Practitioner, an eligible clinician must be identified on an Affiliated Practitioner List on one of the dates: March 31, June 30, or August 31 of the QP Performance Period. An eligible clinician included on an Affiliated Practitioner List on any one of these dates is assessed as an Affiliated Practitioner even if that eligible clinician is not included on the Affiliated Practitioner List at one of the prior or later listed dates. For such eligible clinicians, CMS performs QP determinations during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates that the eligible clinician is on the Affiliated Practitioner List: March 31, June 30, and August 31.

(c) *QP determination.* (1) CMS makes QP determinations as set forth in §§414.1435 and 414.1440.

(2) An eligible clinician cannot be both a QP and a Partial QP for a year. A determination that an eligible clinician is a QP means that the eligible clinician is not a Partial QP.

(3) An eligible clinician is a QP for a year under the Medicare Option if the eligible clinician is in an APM Entity group that achieves a Threshold Score

that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(1) and (3). An eligible clinician is a QP for the year under the All-Payer Combination Option if the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(1) and (3).

(4) Notwithstanding paragraph (c)(3) of this section, an eligible clinician is a QP for a year if:

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the QP payment amount threshold or the QP patient count threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the QP payment amount threshold or the QP patient count threshold.

(5) Beginning in the 2020 QP Performance Period, an eligible clinician in an APM Entity is not a QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that QP performance period under the terms of the Advanced APM, even if such termination date occurs within such QP Performance Period.

(6) Beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.

(7) Advanced APMs that start or end during the QP Performance Period:

(i) Notwithstanding paragraph (a) of this section and §§ 414.1435 and 414.1440, CMS makes QP determinations and Partial QP determinations for the APM Entity group or individual eligible clinician under § 414.1425(b) for Advanced APMs that start or end during the QP Performance Period and that are actively tested for 60 or more continuous days during the QP Performance Period using claims data for services furnished during those dates on which the Advanced APM is actively tested. For Advanced APMs that start active testing during the QP Performance Period, CMS performs QP and Partial QP determinations during the QP Performance Period using claims data for services furnished from the start of active testing of the Advanced APM through each of the QP determination dates that occur on or after the Advanced APM has been actively tested for 60 or more continuous days: March 31, June 30, and August 31. For Advanced APMs that end active testing during the QP Performance Period, CMS performs QP and Partial QP determinations using claims data for services furnished from January 1 or the start of active testing, whichever occurs later, through the final day of active testing of the Advanced APM for each of the QP determination dates that occur on or after the Advanced APM has been actively tested for 60 or more continuous days during that QP Performance Period: March 31, June 30, and August 31.

(ii) For QP determinations specified under paragraph (c)(4) of this section and Partial QP determinations under

paragraph (d)(2) of this section, QP determinations are made using claims data for the full QP Performance Period even if the eligible clinician participates in one or more Advanced APMs that start or end during the QP Performance Period.

(d) *Partial QP determination.* (1) An eligible clinician is a Partial QP for a year under the Medicare Option if the eligible clinician is in an APM Entity group that achieves Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in §414.1430(a)(2) and (4). An eligible clinician is a Partial QP for the year under the All-Payer Combination Option if the eligible clinician achieves individually, or as part of an APM Entity group, a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in §414.1430(b)(2) and (4).

(2) Notwithstanding paragraph (d)(1) of this section, an eligible clinician is a Partial QP for a year if:

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the corresponding QP or Partial QP threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the corresponding Partial QP Threshold.

(3) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.

(4) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining nonterminating APM Entities.

(e) *Notification of QP determination.* CMS notifies eligible clinicians determined to be QPs or Partial QPs for a year as soon as practicable following each QP determination date in the QP Performance Period.

(f) *Order of threshold options.* (1) For payment years 2019 and 2020, CMS performs QP determinations for an eligible clinicians only under the Medicare Option described in §414.1435.

(2) For payment years 2021 and later, CMS performs QP determinations for eligible clinicians under the Medicare Option, as described in §414.1435 and, except as specified in paragraphs (d)(2)(i) and (ii) of this section, the All-Payer Combination Option, described in §414.1440.

(i) If CMS determines the eligible clinician to be a QP under the Medicare Option, then CMS does not calculate a Threshold Score for such eligible clinician under the All-Payer Combination Option.

(ii) If the Threshold Score for an eligible clinician under the Medicare Option is less than the amount specified in §414.1430(b)(2)(ii) and (b)(3)(iii), then

CMS does not perform a QP determination for such eligible clinician(s) under the All-Payer Combination Option.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53961, Nov. 16, 2017; 84 FR 63201, Nov. 15, 2019]

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) *Medicare Option*—(1) *QP payment amount threshold.* The QP payment amount thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 25 percent.

(ii) 2021 and 2022: 50 percent.

(iii) 2023 and 2024: 50 percent.

(iv) 2025 and later: 75 percent.

(2) *Partial QP payment amount threshold.* The Partial QP payment amount thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 20 percent.

(ii) 2021 and 2022: 40 percent.

(iii) 2023 and 2024: 40 percent.

(iv) 2025 and later: 75 percent.

(3) *QP patient count threshold.* The QP patient count thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 20 percent

(ii) 2021 and 2022: 35 percent

(iii) 2023 and 2024: 35 percent.

(iv) 2025 and later: 50 percent.

(4) *Partial QP patient count threshold.* The Partial QP patient count thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 10 percent

(ii) 2021 and 2022: 25 percent

(iii) 2023 and 2024: 25 percent.

(iv) 2025 and later: 35 percent.

(b) *All-Payer Combination Option*—(1) *QP payment amount threshold.*

(i) The QP payment amount thresholds are the following values for the indicated payment years:

(A) 2021 through 2024: 50 percent.

(B) 2025 and later: 75 percent.

(ii) To meet the QP payment amount threshold under this option, the eligible clinician must also meet a 25 percent QP payment amount threshold under the Medicare Option.

(2) *Partial QP payment amount threshold.* (i) The Partial QP payment amount thresholds are the following values for the indicated payment years:

(A) 2021 through 2024: 35 percent.

(B) 2025 and later: 50 percent.

(ii) To meet the QP payment amount threshold under this option, the eligible clinician must also meet a 20 percent Partial QP payment amount threshold under the Medicare Option.

(3) *QP patient count threshold.* (i) The QP patient count thresholds are the following values for the indicated payment years:

(A) 2021 through 2024: 35 percent.

(B) 2025 and later: 50 percent.

(ii) To meet the QP patient count threshold under this option, the eligible clinician must also meet a 20 percent QP patient count threshold under the Medicare Option.

(4) *Partial QP patient count threshold.* (i) The Partial QP patient count thresholds are the following values for the indicated payment years:

(A) 2021 through 2024: 25 percent.

(B) 2025 and later: 35 percent.

(ii) To meet the Partial QP patient count threshold under this option, the eligible clinician group or eligible clinician must also meet a 10 percent QP patient count threshold under the Medicare Option.

[81 FR 77537, Nov. 4, 2016, as amended at 86 FR 65681, Nov. 19, 2021; 87 FR 70230, Nov. 18, 2022]

§ 414.1435 Qualifying APM participant determination: Medicare option.

(a) *Payment amount method.* The Threshold Score for an APM Entity or eligible clinician is calculated as a percent by dividing the value described under paragraph (a)(1) of this section by the value described under paragraph (a)(2) of this section.

(1) *Numerator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to attributed beneficiaries during the QP Performance Period.

(2) *Denominator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to all attribution-eligible beneficiaries during the QP Performance Period.

(3) *Claims and adjustments.* In the calculations under paragraphs (a)(1) and (2) of this section, CMS compiles claims and treats claims adjustments,

supplemental service payments, and alternative payment methods in the same manner as described in §414.1450.

(b) *Patient count method.* The Threshold Score for each eligible clinician in an APM Entity group is calculated as a percent under the patient count method by dividing the value described under paragraph (b)(1) of this section by the value described under paragraph (b)(2) of this section.

(1) *Numerator.* The number of attributed beneficiaries to whom the APM Entity group furnishes Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(2) *Denominator.* The number of attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnish Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(3) *Unique beneficiaries.* For each APM Entity group, a unique Medicare beneficiary is counted no more than one time for the numerator and no more than one time for the denominator.

(4) *Beneficiaries count multiple times.* Based on attribution under the terms of an Advanced APM, a single Medicare beneficiary may be counted in the numerator or denominator for multiple different APM Entity groups.

(c) *Attribution.*

(1) Attributed beneficiaries are determined from each Advanced APM Entity's attributed beneficiary lists generated by each Advanced APM's specific attribution methodology except as set forth in this paragraph (c)(1).(i) Beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

(ii) [Reserved]

(2) When operationally feasible, this attributed beneficiary list will be the final beneficiary list used for reconciliation purposes in the Advanced APM.

(3) When it is not operationally feasible to use the final attributed beneficiary list, the attributed beneficiary list will be taken from the Advanced APM's most recently available attributed beneficiary list at the end of the QP Performance Period.

(d) *Use of methods.* CMS calculates Threshold Scores for an APM Entity or eligible clinician as provided by §414.1425(b) under both the payment amount and patient count methods for each QP Performance Period. CMS then assigns to the eligible clinicians included in the APM Entity group or to the eligible clinician the score that results in the greater QP status. QP status is greater than Partial QP status, and Partial QP status is greater than no QP status.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53963, Nov. 16, 2017; 85 FR 85035, Dec. 28, 2020]

§414.1440 Qualifying APM participant determination: All-payer combination option.

(a) *Payments excluded from calculations.* (1) These calculations include a combination of both Medicare payments for Part B covered professional services and all other payments for all other payers, except for payments made by:

(i) The Secretary of Defense for the costs of Department of Defense health care programs;

(ii) The Secretary of Veterans Affairs for the cost of Department of Veterans Affairs health care programs; and

(iii) Under Title XIX in a State in which no Medicaid APM or Medicaid Medical Home Model that is an Other Payer Advanced APM is available.

(2) Payments and associated patient counts under paragraph (a)(1)(iii) of this section are included in the numerator and denominator as specified in paragraphs (b)(2) and (3) and paragraphs (c)(2) and (3) of this section for an eligible clinician if CMS determines that there is at least one Medicaid APM or Medicaid Medical Home Model that is an Other Payer Advanced APM available in the county where the eligible clinician sees the most patients during the QP Performance Period, and that the eligible clinician is not ineligible to participate in the Other Payer

Advanced APM based on their specialty.

(b) *Payment amount method*—(1) *In general.* The Threshold Score for either an APM Entity group or eligible clinician will be calculated by dividing the value described under the numerator by the value described under the denominator as specified in paragraphs (b)(2) and (3) of this section.

(2) *Numerator.* The aggregate amount of all payments from all payers, except those excluded under paragraph (a) of this section, attributable to the eligible clinician or to the APM Entity group under the terms of all Advanced APMs and Other Payer Advanced APMs during the QP Performance Period.

(3) *Denominator.* The aggregate amount of all payments from all payers, except those excluded under paragraph (a) of this section, made to the eligible clinician or to the APM Entity group during the QP Performance Period.

(c) *Patient count method*—(1) *In general.* The Threshold Score for either an APM Entity group or eligible clinician is calculated by dividing the value described under the numerator by the value described under the denominator as specified in paragraphs (c)(2) and (3) of this section.

(2) *Numerator.* The number of unique patients to whom an APM Entity group or eligible clinician furnishes services that are included in the measures of aggregate expenditures used under the terms of all Advanced APMs and Other Payer Advanced APMs during the QP Performance Period.

(3) *Denominator.* The number of unique patients to whom the APM Entity group or eligible clinician furnishes services under all non-excluded payers during the QP Performance Period.

(4) *Unique patients.* CMS may count a single patient in the numerator and/or denominator for multiple different payers.

(d) *QP Determinations under the All-Payer Combination Option.* (1) CMS performs QP determinations following the QP Performance Period using payment amount and/or patient count information submitted from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. CMS will use data for the same time periods for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. CMS will use the payment amount or patient count method, applying the more advantageous of the two for both the Medicare and other payer portions of the Threshold score calculation, regardless of the method used for the Medicare Threshold Score calculation.

(2) An APM Entity may request that CMS make QP determinations at the APM Entity level, an eligible clinician may request that CMS make QP determinations at the eligible clinician level, and an eligible clinician or an APM Entity may request that CMS makes QP determinations at the TIN-level in instances where all clinicians who reassigned billing rights to the TIN are participating in a single APM Entity. CMS makes QP determinations at either the APM Entity, eligible clinician, or TIN level. Eligible clinicians assessed at the eligible clinician level under the Medicare Option at § 414.1425(b)(2) will be assessed at the eligible clinician level only under the All-Payer Combination Option. Eligible Clinicians may meet the Medicare and the All-Payer Combination Option thresholds using the payment amount method for both thresholds, the patient account method for both thresholds, or the payment amount method for one threshold and the patient account method for the other threshold.

(3) CMS uses data at the same level for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. When QP determinations are made at the eligible clinician or, at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity; and if the Medicare Threshold score for the APM Entity group is higher than when calculated for the eligible clinician or TIN, CMS makes QP determinations using a weighted Medicare Threshold Score that is factored into an All-Payer Combination Option Threshold Score.

(e) *Information used to calculate Threshold Scores under the All-Payer*

Combination Option. (1) An APM Entity or eligible clinician may request as set forth in §414.1445(b)(2) that CMS determine whether a payment arrangement in which they participate meets the Other Payer Advanced APM criteria and may demonstrate participation in an Other Payer Advanced APM determined as a result of a request made in §414.1445(a)(1) or (b)(1) in a form and manner specified by CMS.

(2) To request a QP determination under the All-Payer Combination Option, for each payment arrangement submitted as set forth in paragraph (e)(1) of this section, the APM Entity or eligible clinician must include:

(i) The amount of revenue for services furnished through the payment arrangement, the total revenue received from all payers except those excluded as provided in paragraph (a)(2) of this section, the number of patients furnished any service through the arrangement, and the total number of patients furnished any services, except those excluded as provided in paragraph (a)(2) of this section; and

(ii) In the case of an APM Entity or eligible clinician requesting a QP determination under either a Medicaid Medical Home Model or Aligned Other Payer Medical Home Model pursuant to the criteria in §414.1420, information specified by CMS for purposes of compliance with the 50 eligible clinician limit specified at §414.1420(d)(8).

(3) An APM Entity or eligible clinician must submit the information specified in paragraph (e)(2) of this section in a form and manner specified by CMS. An APM Entity or eligible clinician may submit the information specified in paragraph (e)(2) of this section for the following periods of time in the relevant QP Performance Period: January 1 through March 31, January 1 through June 30, and January 1 through August 31.

(4) To request a QP determination under the All-Payer Combination Option, an APM Entity or eligible clinician must submit this information to CMS no later than the QP Determination Submission Deadline, which is December 1 of the calendar year that is 2 years prior to the payment year.

(f) *Requirement to submit sufficient information*—(1) *Sufficient Information*. CMS makes a QP determination with respect to the eligible clinician under the All-Payer Combination Option only if the APM Entity or eligible clinician submits the information required under paragraph (e) of this section sufficient for CMS to assess the eligible clinician under either the payment amount or patient count as described in paragraphs (b) and (c) of this section.

(2) *Certification*. The APM Entity or eligible clinician who submits information to request a QP determination under the All-Payer Combination Option must certify that the information submitted to CMS is true, accurate, and complete. Such certification must accompany the submission and be made at the time of submission. In the case of information submitted by an APM Entity, the certification must be made by an individual with the authority to bind the APM Entity.

(g) *Notification of QP determination*. CMS notifies eligible clinicians determined to be QPs or Partial QPs for a year as soon as practicable after QP calculations are conducted.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53963, Nov. 16, 2017; 83 FR 60091, Nov. 23, 2018; 87 FR 70230, Nov. 18, 2022]

§414.1445 Determination of other payer advanced APMs.

(a) *Determination of Medicaid APMs*. Beginning in 2018, and each year thereafter, at a time determined by CMS, a state, APM Entity, or eligible clinician may request, in a form and manner specified by CMS, that CMS determine whether a payment arrangement authorized under Title XIX is either a Medicaid APM or a Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria as set forth in §414.1420. A state must submit its request by April 1 of the year prior to the relevant QP Performance Period, and an APM Entity or eligible clinician must submit its request by November 1 of the year prior to the relevant QP Performance Period. CMS will not determine that a payment arrangement is a Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria as set forth in §414.1420 for a year

after the relevant QP Performance Period.

(b) *Determination of Other Payer Advanced APMs*—(1) *Payer initiated Other Payer Advanced APM determination process.* Beginning in 2018, and each year thereafter, at a time determined by CMS a payer with a Medicare Health Plan payment arrangement may request, in a form and manner specified by CMS, that CMS determine whether a Medicare Health Plan payment arrangement meets the Other Payer Advanced APM criteria set forth in § 414.1420. A payer with a Medicare Health Plan payment arrangement must submit its requests by the annual Medicare Advantage bid deadline of the year prior to the relevant QP Performance Period. A Medicare Health Plan is a Medicare Advantage plan, a section 1876 cost plan, a PACE organization operated under section 1894, and any similar plan which provides Medicare benefits under demonstration or waiver authority (other than an APM as defined in section 1833(z)(3)(C) of the Act).

(2) *Eligible clinician initiated Other Payer Advanced APM determination process.* Except as provided by paragraph (a) of this section, at a time specified by CMS, an APM Entity or eligible clinician may request that CMS determine whether a payment arrangement meets the Other Payer Advanced APM criteria as set forth in § 414.1420 in a form and manner specified by CMS. An APM Entity or eligible clinician must submit requests by December 1 of the calendar year of the relevant QP Performance Period.

(c) *Information required for Other Payer Advanced APM determinations.* (1) In order to make an Other Payer Advanced APM determination as set forth in paragraphs (a) and (b) of this section, a payer, APM Entity, or eligible clinician must submit the information specified by CMS in a form and manner specified by CMS. If a payer, APM Entity, or eligible clinician fails to submit the information required, CMS will not make a determination as to whether a payment arrangement meets the Other Payer Advanced APM criteria as set forth in § 414.1420.

(2) If an eligible clinician submits information showing that a payment arrangement requires that the eligible clinician must use CEHRT as defined in § 414.1305 to document and communicate clinical care, CMS will presume that the CEHRT criterion in § 414.1420(b) is satisfied for that payment arrangement.

(i) Based on the submission by an eligible clinician or payer of evidence that CMS determines sufficiently demonstrates that CEHRT is used as specified in § 414.1420(b) by participants in the payment arrangement, CMS will consider the CEHRT criterion in § 414.1420(b) is satisfied for that payment arrangement.

(ii) [Reserved]

(3) If a payment arrangement has no outcome measure, the payer, APM Entity, or eligible clinician requesting a determination of whether a payment arrangement meets the Other Payer Advanced APM criteria must certify that there is no available or applicable outcome measure on the MIPS measure list.

(d) *Certification.* A payer, APM Entity, or eligible clinician that submits information pursuant to paragraph (c) of this section must certify that the information it submitted to CMS is true, accurate, and complete. Such certification must accompany the submission and be made at the time of submission. In the case of information submitted by a payer or an APM Entity, the certification must be made by an individual with the authority to bind the payer or the APM Entity.

(e) *Timing of Other Payer Advanced APM determinations.* CMS makes Other Payer Advanced APM determinations prior to making QP determinations under § 414.1440.

(f) *Notification of Other Payer Advanced APM determinations.* CMS makes Other Payer Advanced APM determinations and notifies the requesting payer, APM Entity, or eligible clinician of such determinations as soon as practicable following the relevant submission deadline.

[82 FR 53964, Nov. 16, 2017, as amended at 83 FR 60091, Nov. 23, 2018]

§ 414.1450 APM incentive payment.

(a) *In general.* (1) CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section

in the manner described in paragraphs (d) and (e) of this section.

(2) CMS provides notice of the amount of the APM Incentive Payment to QPs as soon as practicable following the calculation and validation of the APM Incentive Payment amount, but in any event no later than 1 year after the incentive payment base period.

(b) *APM Incentive Payment amount.* (1) The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment.

(2) The estimated aggregate payment amount for covered professional services includes all such payments to any and all of the TIN/NPI combinations associated with the NPI of the QP.

(3) In calculating the estimated aggregate payment amount for a QP, CMS uses claims submitted with dates of service from January 1 through December 31 of the incentive payment base period, and processing dates of January 1 of the base period through March 31 of the subsequent payment year.

(4) The payment adjustment amounts, negative or positive, as described in sections 1848(m), (o), (p), and (q) of the Act are not included in calculating the APM Incentive Payment amount.

(5) Incentive payments made to eligible clinicians under sections 1833(m), (x), and (y) of the Act are not included in calculating the APM Incentive Payment amount.

(6) Financial risk payments such as shared savings payments or net reconciliation payments are excluded from the amount of covered professional services in calculating the APM Incentive Payment amount.

(7) Supplemental service payments in the amount of covered professional services are included in calculating the APM Incentive Payment amount according to this paragraph (b). Supplemental service payments are included in the amount of covered professional services when calculating the APM Incentive Payment amount when the supplemental service payment meets the following four criteria:

(i) Is payment for services that constitute physicians services authorized under section 1832(a) and defined under section 1861(s) of the Act.

(ii) Is made for only Part B services under the criterion in paragraph (b)(9)(i) of this section.

(iii) Is directly attributable to services furnished to an individual beneficiary.

(iv) Is directly attributable to an eligible clinician, including an eligible clinician that is a group of individual eligible clinicians.

(8) For payment amounts that are affected by a cash flow mechanism, the payment amounts that would have occurred if the cash flow mechanism were not in place are used in calculating the APM Incentive Payment amount.

(c) *APM Incentive Payment recipient.* CMS will pay the APM Incentive Payment amount for a payment year to a solvent TIN or TINs associated with the QP, identified based on Medicare Part B claims submitted for covered professional services during the base period or payment year, according to this section. If no TIN or TINs with which the QP has an association can be identified at a step, CMS will move to the next and successive steps listed in paragraphs (c)(1) through (8) of this section until CMS identifies a TIN or TINs with which the QP is associated, and to which CMS will make the APM Incentive Payment. If more than one TIN is identified at a step, the payment will be proportionately divided among the TINs according to the relative total paid amounts for Part B covered professional services paid to each TIN for services provided during the base year.

(1) Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(2) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(3) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the eligible clinician had achieved QP status;

(4) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated in an APM Entity in an Advanced APM;

(5) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the eligible clinician achieved QP status;

(6) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;

(7) Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then

(8) If we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information. The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment must then notify CMS of their claim as directed in the public notice by September 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

(d) *Timing of the APM Incentive Payment.* APM Incentive Payments made under this section are made as soon as practicable following the calculation and validation of the APM Incentive Payment amount, but in any event no later than 1 year after the incentive payment base period.

(e) *Treatment of APM Incentive Payment amount in APMs.* (1) APM Incentive Payments made under this section are not included in determining actual expenditures under an APM.

(2) APM Incentive Payments made under this section are not included in calculations for the purposes of rebasing benchmarks in an APM.

(f) *Treatment of APM Incentive Payment for other Medicare incentive payments and payment adjustments.* APM Incentive Payments made under this section will not be included in determining the amount of incentive payment made to eligible clinicians under section 1833(m), (x), and (y) of the Act.

[81 FR 77537, Nov. 4, 2016, as amended at 85 FR 85035, Dec. 28, 2020; 86 FR 65681, Nov. 19, 2021; 87 FR 70230, Nov. 18, 2022]

§ 414.1455 Limitation on review.

(a) There is no right to administrative or judicial review under sections 1869, 1878, or otherwise, of the Act of the following:

(1) The determination that an eligible clinician is a QP or Partial QP under § 414.1425.

(2) The determination of the amount of the APM Incentive Payment under § 414.1450, including any estimation as part of such determination.

(b)(1) An eligible clinician or APM Entity may request targeted review of a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List.

(2) If CMS determines that there was such a clerical error, if the QP determination for the eligible clinician would have been made at the APM Entity level under § 414.1425(b)(1), CMS will assign to the eligible clinician the most favorable QP status that was determined at the APM Entity level on any snapshot dates for the relevant QP Performance Period on which the eligible clinician participated in the APM Entity.

(3) The process for targeted review is as follows:

(i) An eligible clinician or APM Entity may submit a request for targeted review.

(ii) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins with the publication of MIPS performance feedback as described at

§ 414.1385(a)(2). The targeted review request submission period may be extended as specified by CMS.

(iii) All requests for targeted review must be submitted in accordance with the form and manner specified by CMS.

(iv) A request for targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not submitted during the targeted review request submission period; or the request is outside the scope of targeted review specified in this section. If the targeted review request is denied, CMS will make no changes to the QP status of the eligible clinician for whom targeted review was requested.

(v) CMS will respond to each timely submitted request for targeted review.

(vi) A request for targeted review may include additional information in support of the request at the time it is submitted. CMS may also request additional information from the requestor. If CMS requests additional information relating to the eligible clinician or the APM Entity group that is the subject of a request for targeted review, responsive information must be provided and received by CMS within 30 days of the request. If CMS does not receive a timely response to a request for additional information, CMS may make a final decision on the targeted review request based on the information available.

(vii) If targeted review requests reveal a pattern of CMS error with impacts that extend beyond the scope of eligible clinicians or APM Entities that submitted such targeted review requests, CMS may adjust the QP status of other affected eligible clinicians as provided in paragraph (b)(2) of this section.

(viii) Decisions on a targeted review request are final, and not subject to any further administrative or judicial review in accordance with paragraph (a) of this section.

[85 FR 85035, Dec. 28, 2020]

§ 414.1460 Monitoring and program integrity.

(a) *Vetting eligible clinicians.* Prior to payment of the APM Incentive Payment, CMS determines if eligible clinicians were in compliance with all Medicare conditions of participation and the terms of the relevant Advanced APMs in which they participated during the QP Performance Period. A determination under this provision is not binding for other purposes.

(b) *Rescinding QP Determinations.* CMS may rescind a QP determination if:

(1) Any of the information CMS relied on in making the QP determination was inaccurate or misleading.

(2) The QP is terminated from an Advanced APM or Other Payer Advanced APM during the QP Performance Period or Incentive Payment Base Period; or

(3) The QP is found to be in violation of the terms of the relevant Advanced APM or any relevant Federal, State, or tribal statute or regulation during the QP Performance Period or Incentive Payment Base Period.

(c) *Information submitted for All-Payer Combination Option.* Information submitted by payers, APM Entities, or eligible clinicians for purposes of the All-Payer Combination Option may be subject to audit by CMS.

(d) *Reducing, denying, and recouping of APM Incentive Payments.* (1) CMS may reduce or deny an APM Incentive Payment to an eligible clinician.

(i) Who CMS determines is not in compliance with all Medicare conditions of participation and the terms of the relevant Advanced APM in which they participate during the QP Performance Period or Incentive Payment Base Period;

(ii) Who is terminated by an APM or Advanced APM during the QP Performance Period or Incentive Payment Base Period; or

(iii) Whose APM Entity is terminated by an APM or Advanced APM for noncompliance with any Medicare condition of participation or the terms of the relevant Advanced APM in which they participate during the QP Performance Period or Incentive Payment Base Period.

(2) CMS may reopen, revise, and recoup an APM Incentive Payment that was made in error in accordance with procedures similar to those set forth at §§ 405.980 through § 405.986 and §§ 405.370 through 405.379 of this chapter or as established under the relevant APM.

(e) *Maintenance of records.* (1) A payer that submits information to CMS under § 414.1445 for assessment under the All-Payer Combination Option must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination. Such information and supporting documentation must be maintained for a period of 6 years after submission.

(2) An APM Entity or eligible clinician that submits information to CMS under § 414.1445 for assessment under the All-Payer Combination Option or § 414.1440 for QP determinations must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination, QP determinations, and the accuracy of APM Incentive Payments for a period of 6 years from the end of the QP Performance Period or from the date of completion of any audit, evaluation, or inspection, whichever is later.

(3) A payer, APM Entity or eligible clinician that submits information to CMS under §§ 414.1440 or 414.1445 must provide such information and supporting documentation to CMS upon request.

(f) *OIG authority.* None of the provisions of this part limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the Advanced APM Entity, its eligible clinicians, and other individuals or entities performing functions or services related to its APM activities.

[81 FR 77537, Nov. 4, 2016, as amended at 82 FR 53965, Nov. 16, 2017]

§ 414.1465 Physician-focused payment models.

(a) *Definition.* A physician-focused payment model (PFPM) is an Alternative Payment Model:

(1) In which Medicare is a payer;

(2) In which eligible clinicians that are eligible professionals as defined in section 1848(k)(3)(B) of the Act are participants and play a core role in implementing the APM's payment methodology; and

(3) Which targets the quality and costs of services that eligible professionals participating in the Alternative Payment Model provide, order, or can significantly influence.

(b) *Criteria.* In carrying out its review of physician-focused payment model proposals, the PTAC must assess whether the physician-focused payment model meets the following criteria for PFPMs sought by the Secretary. The Secretary seeks PFPMs that:

(1) *Incentives: Pay for higher-value care.* (i) Value over volume: provide incentives to practitioners to deliver high-quality health care.

(ii) Flexibility: provide the flexibility needed for practitioners to deliver high-quality health care.

(iii) Quality and Cost: are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

(iv) Payment methodology: pay APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

(v) Scope: aim to broaden or expand the CMS APM portfolio by addressing an issue in payment policy in a new way or including APM Entities whose opportunities to participate in APMs have been limited.

(vi) Ability to be evaluated: have evaluable goals for quality of care, cost, and any other goals of the PFPM.

(2) *Care delivery improvements: Promote better care coordination, protect patient safety, and encourage patient engagement.* (i) Integration and Care Coordination: encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

(ii) Patient Choice: encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

(iii) Patient Safety: aim to maintain or improve standards of patient safety.

(3) *Information Enhancements: Improving the availability of information to guide decision-making.* (i) Health Information Technology: encourage use of health information technology to inform care.

(ii) [Reserved]

Subpart P—Home Infusion Therapy Services Payment

SOURCE: 84 FR 60643, Nov. 8, 2019, unless otherwise noted.

CONDITIONS FOR PAYMENT

§ 414.1500 Basis, purpose, and scope.

This subpart implements section 1861(iii) of the Act with respect to the requirements that must be met for Medicare payment to be made for home infusion services furnished to eligible beneficiaries.

§ 414.1505 Requirement for payment.

In order for home infusion therapy services to qualify for payment under the Medicare program the services must be furnished to an eligible beneficiary by, or under arrangements with, a qualified home infusion therapy supplier that meets the following requirements:

(a) The health and safety standards for qualified home infusion therapy suppliers at § 486.520(a) through (c) of this chapter.

(b) All requirements set forth in §§ 414.1510 through 414.1550.

(c) The home infusion therapy supplier must be enrolled in Medicare consistent with the provisions of § 424.68 and part 424, subpart P of this chapter.

[84 FR 60643, Nov. 8, 2019, as amended at 85 FR 70355, Nov. 4, 2020]

§ 414.1510 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home infusion therapy services, a beneficiary must meet each of the following requirements:

(a) *Under the care of an applicable provider.* The beneficiary must be under the care of an applicable provider, as defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant.

(b) *Under a physician plan of care.* The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 414.1515.

§ 414.1515 Plan of care requirements.

(a) *Contents.* The plan of care must contain those items listed in § 486.520(b) of this chapter that specify the standards relating to a plan of care that a qualified home infusion therapy supplier must meet in order to participate in the Medicare program.

(b) *Physician's orders.* The physician's orders for services in the plan of care must specify at what frequency the services will be furnished, as well as the discipline that will furnish the ordered professional services. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished.

(c) *Plan of care signature requirements.* The plan of care must be signed and dated by the ordering physician prior to submitting a claim for payment. The ordering physician must sign and date the plan of care upon any changes to the plan of care.

PAYMENT SYSTEM

§ 414.1550 Basis of payment.

(a) *General rule.* For home infusion therapy services furnished on or after January 1, 2021, Medicare payment is made on the basis of 80 percent of the lesser of the following:

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

(2) The fee schedule amount for the item or service, as determined in accordance with the provisions of this section.

(b) *Unit of single payment.* A unit of single payment is made for items and services furnished by a qualified home infusion therapy supplier per payment category for each infusion drug administration calendar day, as defined at § 486.505 of this chapter.

(c) *Initial establishment of the payment amounts.* In calculating the initial single payment amounts for CY 2021, CMS determined such amounts using the

equivalent to 5 hours of infusion services in a physician's office as determined by codes and units of such codes under the annual fee schedule issued under section 1848 of the Act as follows:

(1) *Category 1.* (i) Includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; chelation drugs; and other intravenous drugs as added to the durable medicare equipment local coverage determination (DME LCD) for external infusion pumps.

(ii) Payment equals 1 unit of 96365 plus 4 units of 96366.

(2) *Category 2.* (i) Includes certain subcutaneous infusion drugs for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions.

(ii) Payment equals 1 unit of 96369 plus 4 units of 96370.

(3) *Category 3.* (i) Includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

(ii) Payment equals 1 unit of 96413 plus 4 units of 96415.

(4) *Initial visit.* (i) For each of the three categories listed in paragraphs (c)(1) through (3) of this section, the payment amounts are set higher for the first visit by the qualified home infusion therapy supplier to initiate the furnishing of home infusion therapy services in the patient's home and lower for subsequent visits in the patient's home. The difference in payment amounts is a percentage based on the relative payment for a new patient rate over an existing patient rate using the annual physician fee schedule evaluation and management payment amounts for a given year and calculated in a budget neutral manner.

(ii) The first visit payment amount is subject to the following requirements if a patient has previously received home infusion therapy services:

(A) The previous home infusion therapy services claim must include a patient status code to indicate a discharge.

(B) If a patient has a previous claim for HIT services, the first visit home infusion therapy services claim subsequent to the previous claim must show a gap of more than 60 days between the last home infusion therapy services claim and must indicate a discharge in the previous period before a HIT supplier may submit a home infusion therapy services claim for the first visit payment amount.

(d) *Required payment adjustments.* The single payment amount represents payment in full for all costs associated with the furnishing of home infusion therapy services and is subject to the following adjustments:

(1) An adjustment for a geographic wage index and other costs that may vary by region, using an appropriate wage index based on the site of service of the beneficiary.

(2) Beginning in 2022, an annual increase in the single payment amounts from the prior year by the percentage increase in the Consumer Price Index (CPI) for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

(3)(i) An annual reduction in the percentage increase described in paragraph (d)(2) of this section by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(ii) The application of the paragraph (c)(3)(i) of this section may result in the both of the following:

(A) A percentage being less than zero for a year.

(B) Payment being less than the payment rates for the preceding year.

(e) *Medical review.* All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Plan of care requirements.

(3) Medical necessity determinations.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

Subpart A—General Provisions

Sec.