

(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 non-compliance 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.

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(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