

(h) *Responsibilities of the assignee.* Once the assignee files an appeal, the assignee becomes a party to the appeal. The assignee must meet all requirements for appeals that apply to any other party.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

INITIAL DETERMINATIONS

§ 405.920 Initial determinations.

After a claim is filed with the appropriate contractor in the manner and form described in subpart C of part 424 of this chapter, the contractor must—

- (a) Determine if the items and services furnished are covered or otherwise reimbursable under title XVIII of the Act;
- (b) Determine any amounts payable and make payment accordingly; and
- (c) Notify the parties to the initial determination of the determination in accordance with § 405.921.

§ 405.921 Notice of initial determination.

(a) *Notice of initial determination sent to the beneficiary.* (1) The notice must be written in a manner calculated to be understood by the beneficiary, and sent to the last known address of the beneficiary.

(2) *Content of the notice.* The notice of initial determination must contain all of the following:

- (i) The reasons for the determination, including whether a local medical review policy, a local coverage determination, or national coverage determination was applied.
- (ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination.
- (iii) Information on the right to a redetermination if the beneficiary is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination.
- (iv) Any other requirements specified by CMS.

(b) *Notice of initial determination sent to providers and suppliers.* (1) An electronic or paper remittance advice (RA) notice is the notice of initial deter-

mination sent to providers and suppliers that accept assignment.

(i) The electronic RA must comply with the format and content requirements of the standard adopted for national use by covered entities under the Health Insurance Portability and Accountability Act (HIPAA) and related CMS manual instructions.

(ii) When a paper RA is mailed, it must comply with CMS manual instructions that parallel the HIPAA data content and coding requirements.

(2) The notice of initial determination must contain all of the following:

- (i) The basis for any full or partial denial determination of services or items on the claim.
- (ii) Information on the right to a redetermination if the provider or supplier is dissatisfied with the outcome of the initial determination.
- (iii) All applicable claim adjustment reason and remark codes to explain the determination.
- (iv) The source of the RA and who may be contacted if the provider or supplier requires further information.

(v) All content requirements of the standard adopted for national use by covered entities under HIPAA.

(vi) Any other requirements specified by CMS.

(c) *Notice of initial determination sent to an applicable plan—*(1) *Content of the notice.* The notice of initial determination under § 405.924(b)(16) must contain all of the following:

- (i) The reasons for the determination.
- (ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination.
- (iii) Information on the right to a redetermination if the liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination.
- (iv) Any other requirements specified by CMS.

(2) [Reserved]

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015]

§ 405.922 Time frame for processing initial determinations.

The contractor issues initial determinations on clean claims within 30 calendar days of receipt if they are submitted by or on behalf of the beneficiary who received the items and/or services; otherwise, interest must be paid at the rate specified at 31 U.S.C. 3902(a) for the period beginning on the day after the required payment date and ending on the date payment is made.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009]

§ 405.924 Actions that are initial determinations.

(a) *Applications and entitlement of individuals.* SSA makes initial determinations and processes reconsiderations with respect to an individual on the following:

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance under Medicare.

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence requested by SSA to support the application. (SSA specifies in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence).

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance, or a denial of a request for cancellation of a request for withdrawal.

(4) A determination as to whether an individual, previously determined as entitled to hospital or supplementary medical insurance, is no longer entitled to those benefits, including a determination based on nonpayment of premiums.

(5) An adjustment of premium for hospital or supplementary medical insurance as outlined in §§ 406.32(d), 408.20(e), and 408.22 of this chapter, and 20 CFR 418.1301.

(b) *Claims made by or on behalf of beneficiaries.* The Medicare contractor makes initial determinations regarding claims for benefits under Medicare Part A and Part B. A finding that a re-

quest for payment or other submission does not meet the requirements for a Medicare claim as defined in § 424.32 of this chapter, is not considered an initial determination. An initial determination for purposes of this subpart includes, but is not limited to, determinations with respect to any of the following:

(1) If the items and/or services furnished are covered under title XVIII.

(2) In the case of determinations on the basis of section 1879(b) or (c) of the Act, if the beneficiary, or supplier who accepts assignment under § 424.55 of this chapter knew, or could reasonably have expected to know at the time the items or services were furnished, that the items or services were not covered.

(3) In the case of determinations on the basis of section 1842(l)(1) of the Act, if the beneficiary or physician knew, or could reasonably have expected to know at the time the services were furnished, that the services were not covered.

(4) Whether the deductible is met.

(5) The computation of the coinsurance amount.

(6) The number of days used for inpatient hospital, psychiatric hospital, or post-hospital extended care.

(7) Periods of hospice care used.

(8) Requirements for certification and plan of treatment for physician services, durable medical equipment, therapies, inpatient hospitalization, skilled nursing care, home health, hospice, and partial hospitalization services.

(9) The beginning and ending of a spell of illness, including a determination made under the presumptions established under § 409.60(c)(2) of this chapter, and as specified in § 409.60(c)(4) of this chapter.

(10) The medical necessity of services, or the reasonableness or appropriateness of placement of an individual at an acute level of patient care made by the Quality Improvement Organization (QIO) on behalf of the contractor in accordance with § 476.86(c)(1) of this chapter.

(11) Any other issues having a present or potential effect on the amount of benefits to be paid under Part A or Part B of Medicare, including a determination as to whether there

was an underpayment of benefits paid under Part A or Part B, and if so, the amount thereof.

(12) If a waiver of adjustment or recovery under sections 1870(b) and (c) of the Act is appropriate—

(i) When an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) was made for an individual; or

(ii) For a Medicare Secondary Payer recovery claim against a beneficiary or against a provider or supplier.

(13) If a particular claim is not payable by Medicare based upon the application of the Medicare Secondary Payer provisions of section 1862(b) of the Act.

(14) Under the Medicare Secondary Payer provisions of sections 1862(b) of the Act that Medicare has a recovery claim against a provider, supplier, or beneficiary for services or items that were already paid by the Medicare program, except when the Medicare Secondary Payer recovery claim against the provider or supplier is based upon failure to file a proper claim as defined in part 411 of this chapter because this action is a reopening.

(15) A claim not payable to a beneficiary for the services of a physician who has opted-out.

(16) Under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery claim if Medicare is pursuing recovery directly from an applicable plan. That is, there is an initial determination with respect to the amount and existence of the recovery claim.

(c) *Determinations by QIOs.* An initial determination for purposes of this subpart also includes a determination made by a QIO that:

(1) A provider can terminate services provided to an individual when a physician certified that failure to continue the provision of those services is likely to place the individual's health at significant risk; or

(2) A provider can discharge an individual from the provider of services.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009; 79 FR 68001, Nov. 13, 2014; 80 FR 10618, Feb. 27, 2015; 83 FR 16721, Apr. 16, 2018]

§ 405.925 Decisions of utilization review committees.

(a) *General rule.* A decision of a utilization review committee is a medical determination by a staff committee of the provider or a group similarly composed and does not constitute a determination by the Secretary within the meaning of section 1869 of the Act. The decision of a utilization review committee may be considered by CMS along with other pertinent medical evidence in determining whether or not an individual has the right to have payment made under Part A of title XVIII.

(b) *Applicability under the prospective payment system.* CMS may consider utilization review committee decisions related to inpatient hospital services paid for under the prospective payment system (see part 412 of this chapter) only as those decisions concern:

(1) The appropriateness of admissions resulting in payments under subparts D, E and G of part 412 of this chapter.

(2) The covered days of care involved in determinations of outlier payments under § 412.80(a)(1)(i) of this chapter; and

(3) The necessity of professional services furnished in high cost outliers under § 412.80(a)(1)(ii) of this chapter.

[48 FR 39831, Sept. 1, 1983. Redesignated at 77 FR 29028, May 16, 2012]

§ 405.926 Actions that are not initial determinations.

Actions that are not initial determinations and are not appealable under this subpart include, but are not limited to the following:

(a) Any determination for which CMS has sole responsibility, for example one of the following:

(1) If an entity meets the conditions for participation in the program.

(2) If an independent laboratory meets the conditions for coverage of services.

(3) Determination under the Medicare Secondary Payer provisions of section 1862(b) of the Act of the debtor for a particular recovery claim.

(b) The coinsurance amounts prescribed by regulation for outpatient services under the prospective payment system.

(c) Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A.

(d) Whether an individual's appeal meets the qualifications for expedited access to judicial review provided in § 405.990.

(e) Any determination regarding whether a Medicare overpayment claim must be compromised, or collection action terminated or suspended under the Federal Claims Collection Act of 1966, as amended.

(f) Determinations regarding the transfer or discharge of residents of skilled nursing facilities in accordance with § 483.5 definition of 'transfer and discharge' and § 483.15 of this chapter.

(g) Determinations regarding the readmission screening and annual resident review processes required by subparts C and E of part 483 of this chapter.

(h) Determinations for a waiver of Medicare Secondary Payer recovery under section 1862(b) of the Act.

(i) Determinations for a waiver of interest.

(j) Determinations for a finding regarding the general applicability of the Medicare Secondary Payer provisions (as opposed to the application of these provisions to a particular claim or claims for Medicare payment for benefits).

(k) Except as specified in § 405.924(b)(16), determinations under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery against an entity that was or is required or responsible (directly, as an insurer or self-insurer; as a third party administrator; as an employer that sponsors, contributes to or facilitates a group health plan or a large group health plan; or otherwise) to make payment for services or items that were already reimbursed by the Medicare program.

(l) A contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's de-

termination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, decision, or review decision.

(m) Determinations that CMS or its contractors may participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing or Council review.

(n) Determinations that a provider or supplier failed to submit a claim timely or failed to submit a timely claim despite being requested to do so by the beneficiary or the beneficiary's subrogee.

(o) Determinations with respect to whether an entity qualifies for an exception to the electronic claims submission requirement under part 424 of this chapter.

(p) Determinations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act.

(q) A contractor's prior determination related to coverage of physicians' services.

(r) Requests for anticipated payment under the home health prospective payment system under § 409.43(c)(ii)(2) of this chapter.

(s) Claim submissions on forms or formats that are incomplete, invalid, or do not meet the requirements for a Medicare claim and returned or rejected to the provider or supplier.

(t) A contractor's prior authorization determination with regard to—

(1) Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)); and

(2) Hospital outpatient department (OPD) services.

(u) Issuance of notice to an individual entitled to Medicare benefits under Title XVIII of the Act when such individual received observation services as an outpatient for more than 24 hours, as specified under § 489.20(y) of this chapter.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 80 FR 10618, Feb. 27, 2015; 80 FR 81706, Dec. 30, 2015; 81 FR 57267, Aug. 22, 2016; 81 FR 68847, Oct. 4, 2016; 82 FR 5107, Jan. 17, 2017; 84 FR 19869, May 7, 2019; 84 FR 61490, Nov. 12, 2019]

§ 405.927

§ 405.927 Initial determinations subject to the reopenings process.

Minor errors or omissions in an initial determination must be corrected only through the contractor's reopenings process under § 405.980(a)(3).

§ 405.928 Effect of the initial determination.

(a) An initial determination described in § 405.924(a) is binding unless it is revised or reconsidered in accordance with 20 CFR 404.907, or revised as a result of a reopening in accordance with 20 CFR 404.988.

(b) An initial determination described in § 405.924(b) is binding upon all parties to the initial determination unless—

(1) A redetermination is completed in accordance with § 405.940 through § 405.958; or

(2) The initial determination is revised as a result of a reopening in accordance with § 405.980.

(c) An initial determination listed in § 405.924(b) where a party submits a timely, valid request for redetermination under § 405.942 through § 405.944 must be processed as a redetermination under § 405.948 through § 405.958 unless the initial determination involves a clerical error or other minor error or omission.

§ 405.929 Post-payment review.

(a) A contractor may select a claim(s) for post-payment review, which is conducted under the reopening authority in § 405.980.

(b) In conducting a post-payment review, a contractor may issue an additional documentation request to a provider or supplier.

(1) A provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request, except as stated in paragraph (b)(2) and (c) of this section.

(2) A contractor may accept documentation received after 45 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.

42 CFR Ch. IV (10–1–24 Edition)

(c) A provider or supplier will be provided 30 calendar days to submit additional documentation in response to a UPIC's request for additional documentation. A UPIC may accept documentation received after 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

(d) The outcome of a contractor's review will result in either no change to the initial determination or a revised determination under § 405.984.

[86 FR 65660, Nov. 19, 2021]

§ 405.930 Failure to respond to additional documentation request.

If a contractor gives a provider or supplier notice and time to respond to an additional documentation request and the provider or supplier does not provide the additional documentation in a timely manner, the contractor has authority to deny the claim.

[86 FR 65660, Nov. 19, 2021]

REDETERMINATIONS

§ 405.940 Right to a redetermination.

A person or entity that may be a party to a redetermination in accordance with § 405.906(b) and that is dissatisfied with an initial determination may request a redetermination by a contractor in accordance with § 405.940 through § 405.958, regardless of the amount in controversy.

§ 405.942 Time frame for filing a request for a redetermination.

(a) *Time frame for filing a request.* Except as provided in paragraph (b) of this section, any request for redetermination must be filed within 120 calendar days from the date a party receives the notice of the initial determination.

(1) For purposes of this section, the date of receipt of the initial determination will be presumed to be 5 calendar days after the date of the notice of initial determination, unless there is evidence to the contrary.