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SUBCHAPTER B—MEDICARE PROGRAM

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

Sec.

405.201 Scope of subpart and definitions.
405.203 FDA categorization of investigational devices.
405.205 Coverage of a non-experimental/investigational (Category B) device.
405.207 Services related to a noncovered device.
405.209 Payment for a Category B (Non-experimental/investigational) device.
405.211 Coverage of items and services in FDA-approved IDE studies.
405.212 Medicare Coverage IDE study criteria.
405.213 Re-evaluation of a device categorization.
405.215 Confidential commercial and trade secret information.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

GENERAL PROVISIONS

405.301 Scope of subpart.

LIABILITY FOR PAYMENTS TO PROVIDERS AND SUPPLIERS, AND HANDLING OF INCORRECT PAYMENTS

405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.
405.351 Incorrect payments for which the individual is not liable.
405.352 Adjustment of title XVIII incorrect payments.
405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.
405.354 Procedures for adjustment or recovery—title II beneficiary.
405.355 Waiver of adjustment or recovery.
405.356 Principles applied in waiver of adjustment or recovery.
405.357 Notice of right to waiver consideration.
405.358 When waiver of adjustment or recovery may be applied.
405.359 Liability of certifying or disbursing officer.

SUSPENSION AND RECOUPMENT OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

405.370 Definitions.
405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.
405.372 Proceeding for suspension of payment.
405.373 Proceeding for offset or recoupment.
405.374 Opportunity for rebuttal.
405.375 Time limits for, and notification of, administrative determination after receipt of rebuttal statement.
405.376 Suspension and termination of collection action and compromise of claims for overpayment.
405.377 Withholding Medicare payments to recover Medicaid overpayments.
405.378 Interest charges on overpayment and underpayments to providers, suppliers, and other entities.
405.379 Limitation on recoupment of provider and supplier overpayments.

REPAYMENT OF SCHOLARSHIPS AND LOANS

405.380 Collection of past-due amounts on scholarship and loan programs.

Subpart D—Private Contracts

405.400 Definitions.
405.405 General rules.
405.410 Conditions for properly opting-out of Medicare.
405.415 Requirements of the private contract.
405.420 Requirements of the opt-out affidavit.
405.425 Effects of opting-out of Medicare.
405.430 Failure to properly opt-out.
405.435 Failure to maintain opt-out.
405.440 Emergency and urgent care services.
405.445 Cancellation of opt-out and early termination of opt-out.
405.450 Appeals.
405.455 Application to Medicare Advantage contracts

Subpart E—Criteria for Determining Reasonable Charges

405.500 Basis.
405.501 Determination of reasonable charges.
405.502 Criteria for determining reasonable charges.
405.503 Determining customary charges.
405.504 Determining prevailing charges.
405.505 Determination of locality
405.506 Charges higher than customary or prevailing charges or lowest charge levels.

405.507 Illustrations of the application of the criteria for determining reasonable charges.
405.508 Determination of comparable circumstances; limitation.
405.509 Determining the inflation-indexed charge.
405.511 Reasonable charges for medical services, supplies, and equipment.
405.512 Carriers' procedural terminology and coding systems.
405.515 Reimbursement for clinical laboratory services billed by physicians.
405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.
405.520 Payment for a physician assistant's, nurse practitioner's, and clinical nurse specialists' services and services furnished incident to their professional services.
405.534 Limitation on payment for screening mammography services.
405.535 Special rule for nonparticipating physicians and suppliers furnishing screening mammography services before January 1, 2002.

Subparts F–G [Reserved]

Subpart H—Appeals Under the Medicare Part B Program

405.800 Appeals of CMS or a CMS contractor.
405.803 Appeals rights.
405.806 Impact of reversal of contractor determinations on claims processing.
405.809 Reinstatement of provider or supplier billing privileges following corrective action.
405.812 Effective date for DMEPOS supplier's billing privileges.
405.815 Submission of claims.
405.818 Deadline for processing provider enrollment initial determinations.

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Parts A and B)

405.900 Basis and scope.
405.902 Definitions.
405.903 Prepayment review.
405.904 Medicare initial determinations, redeterminations and appeals: General description.
405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews.
405.908 Medicaid State agencies.
405.910 Appointed representatives.
405.912 Assignment of appeal rights.

INITIAL DETERMINATIONS

405.920 Initial determinations.
405.921 Notice of initial determination.
405.922 Time frame for processing initial determinations.
405.924 Actions that are initial determinations.
405.925 Decisions of utilization review committees.
405.926 Actions that are not initial determinations.
405.927 Initial determinations subject to the reopenings process.
405.928 Effect of the initial determination.
405.929 Post-payment review.
405.930 Failure to respond to additional documentation request.

RETROSPECTIVE APPEALS FOR CHANGES IN PATIENT STATUS THAT RESULTED IN DENIAL OF PART A COVERAGE FOR HOSPITAL SERVICES

405.931 Scope, basis, and definitions.
405.932 Right to appeal a denial of Part A coverage resulting from a change in patient status.
405.934 Reconsideration.
405.936 Hearings before an ALJ and decisions by an ALJ or Attorney Adjudicator.
405.938 Review by the Medicare Appeals Council and judicial review.

REDETERMINATIONS

405.940 Right to a redetermination.
405.942 Time frame for filing a request for a redetermination.
405.944 Place and method of filing a request for a redetermination.
405.946 Evidence to be submitted with the redetermination request.
405.947 Notice to the beneficiary of applicable plan's request for a redetermination.
405.948 Conduct of a redetermination.
405.950 Time frame for making a redetermination.
405.952 Withdrawal or dismissal of a request for a redetermination.
405.954 Redetermination.
405.956 Notice of a redetermination.
405.958 Effect of a redetermination.

RECONSIDERATION

405.960 Right to a reconsideration.
405.962 Time frame for filing a request for a reconsideration.
405.964 Place and method of filing a request for a reconsideration.
405.966 Evidence to be submitted with the reconsideration request.
405.968 Conduct of a reconsideration.
405.970 Timeframe for making a reconsideration following a contractor redetermination.
405.972 Withdrawal or dismissal of a request for reconsideration or review of a contractor's dismissal of a request for redetermination.

405.974 Reconsideration and review of a contractor's dismissal of a request for redetermination.
405.976 Notice of a reconsideration.
405.978 Effect of a reconsideration.

REOPENINGS

405.980 Reopening of initial determinations, redeterminations, reconsiderations, decisions, and reviews.
405.982 Notice of a revised determination or decision.
405.984 Effect of a revised determination or decision.
405.986 Good cause for reopening.

EXPEDITED ACCESS TO JUDICIAL REVIEW

405.990 Expedited access to judicial review.

ALJ HEARINGS

405.1000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.
405.1002 Right to an ALJ hearing.
405.1004 Right to a review of QIC notice of dismissal.
405.1006 Amount in controversy required for an ALJ hearing and judicial review.
405.1008 Parties to the proceedings on a request for an ALJ hearing.
405.1010 When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing.
405.1012 When CMS or its contractors may be a party to a hearing.
405.1014 Request for an ALJ hearing or a review of a QIC dismissal.
405.1016 Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration.
405.1018 Submitting evidence.
405.1020 Time and place for a hearing before an ALJ.
405.1022 Notice of a hearing before an ALJ.
405.1024 Objections to the issues.
405.1026 Disqualification of the ALJ or attorney adjudicator.
405.1028 Review of evidence submitted by parties.
405.1030 ALJ hearing procedures.
405.1032 Issues before an ALJ or attorney adjudicator.
405.1034 Requesting information from the QIC.
405.1036 Description of an ALJ hearing process.
405.1037 Discovery.
405.1038 Deciding a case without a hearing before an ALJ.
405.1040 Prehearing and posthearing conferences.
405.1042 The administrative record.
405.1044 Consolidated proceedings.
405.1046 Notice of an ALJ or attorney adjudicator decision.
405.1048 The effect of an ALJ's or attorney adjudicator's decision.
405.1050 Removal of a hearing request from OMHA to the Council.
405.1052 Dismissal of a request for a hearing before an ALJ or request for review of a QIC dismissal.
405.1054 Effect of dismissal of a request for a hearing or request for review of QIC dismissal.
405.1056 Remands of requests for hearing and requests for review.
405.1058 Effect of a remand.

APPLICABILITY OF MEDICARE COVERAGE POLICIES

405.1060 Applicability of nation coverage determinations (NCDs).
405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council.
405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

MEDICARE APPEALS COUNCIL REVIEW

405.1100 Medicare Appeals Council review: General.
405.1102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.
405.1106 Where a request for review or escalation may be filed.
405.1108 Council actions when request for review or escalation is filed.
405.1110 Council reviews on its own motion.
405.1112 Content of request for review.
405.1114 Dismissal of request for review.
405.1116 Effect of dismissal of request for Council review or request for hearing.
405.1118 Obtaining evidence from the Council.
405.1120 Filling briefs with the Council.
405.1122 What evidence may be submitted to the Council.
405.1124 Oral argument.
405.1126 Case remanded by the Council.
405.1128 Action of the Council.
405.1130 Effect of the Council's decision.
405.1132 Request for escalation to Federal court.
405.1134 Extension of time to file action in Federal district court.
405.1136 Judicial review.
405.1138 Case remanded by a Federal district court.

405.1140 Council review of ALJ decision in a case remanded by a Federal district court.

Subpart J—Procedures and Beneficiary Rights for Expedited Determinations and Reconsiderations When Coverage is Changed or Terminated

405.1200 Notifying beneficiaries of provider service terminations.
405.1202 Expedited determination procedures.
405.1204 Expedited reconsiderations.
405.1205 Notifying beneficiaries of hospital discharge appeal rights.
405.1206 Expedited determination procedures for inpatient hospital care.
405.1208 Hospital requests expedited QIO review.
405.1210 Notifying eligible beneficiaries of appeal rights when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.
405.1211 Expedited determination procedures when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.
405.1212 Expedited reconsideration procedures regarding Part A coverage when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

Subparts K–Q [Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

405.1801 Introduction.
405.1803 Contractor determination and notice of amount of program reimbursement.
405.1804 Matters not subject to administrative or judicial review under prospective payment.
405.1805 Parties to contractor determination.
405.1807 Effect of contractor determination.
405.1809 Contractor hearing procedures.
405.1811 Right to contractor hearing; contents of, and adding issues to, hearing request.
405.1813 Good cause extension of time limit for requesting a contractor hearing.
405.1814 Contractor hearing officer jurisdiction.
405.1815 Parties to proceedings before the contractor hearing officer(s).
405.1817 Hearing officer or panel of hearing officers authorized to conduct contractor hearing; disqualification of officers.
405.1819 Conduct of contractor hearing.
405.1821 Prehearing discovery and other proceedings prior to the contractor hearing.
405.1823 Evidence at contractor hearing.
405.1825 Witnesses at contractor hearing.
405.1827 Record of proceedings before the contractor hearing officer(s).
405.1829 Scope of authority of contractor hearing officer(s).
405.1831 Contractor hearing decision.
405.1832 Contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim.
405.1833 Effect of contractor hearing decision.
405.1834 CMS reviewing official procedure.
405.1835 Right to Board hearing; contents of, and adding issues to, hearing request.
405.1836 Good cause extension of time limit for requesting a Board hearing.
405.1837 Group appeals.
405.1839 Amount in controversy.
405.1840 Board jurisdiction.
405.1842 Expedited judicial review.
405.1843 Parties to proceedings in a Board appeal.
405.1845 Composition of Board; hearings, decisions, and remands.
405.1847 Disqualification of Board members.
405.1849 Establishment of time and place of hearing by the Board.
405.1851 Conduct of Board hearing.
405.1853 Board proceedings prior to any hearing; discovery.
405.1855 Evidence at Board hearing.
405.1857 Subpoenas.
405.1859 Witnesses.
405.1861 Oral argument and written allegations.
405.1863 Administrative policy at issue.
405.1865 Record of administrative proceedings.
405.1867 Scope of Board's legal authority.
405.1868 Board actions in response to failure to follow Board rules.
405.1869 Scope of Board's authority in a hearing decision.
405.1871 Board hearing decision.
405.1873 Board review of compliance with the reimbursement requirement of an appropriate cost report claim.
405.1875 Administrator review.
405.1877 Judicial review.
405.1881 Appointment of representative.
405.1883 Authority of representative.
405.1885 Reopening an intermediary determination or reviewing entity decision.
405.1887 Notice of reopening; effect of reopening.
405.1889 Effect of a revision; issue-specific nature of appeals of revised determinations and decisions.

Subparts S–T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

405.2100–405.2101 [Reserved]
405.2102 Definitions.

405.2110 Designation of ESRD networks.
405.2111 [Reserved]
405.2112 ESRD network organizations.
405.2113 Medical review board.
405.2114 [Reserved]
405.2131–405.2184 [Reserved]

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

405.2400 Basis.
405.2401 Scope and definitions.
405.2402 Rural health clinic basic requirements.
405.2403 Rural health clinic content and terms of the agreement with the Secretary.
405.2404 Termination of rural health clinic agreements.
405.2410 Application of Part B deductible and coinsurance.
405.2411 Scope of benefits.
405.2412 Physicians' services.
405.2413 Services and supplies incident to a physician's services.
405.2414 Nurse practitioner, physician assistant, and certified nurse midwife services.
405.2415 Incident to services and direct supervision.
405.2416 Visiting nurse services.
405.2417 Visiting nurse services: Determination of shortage of agencies.

FEDERALLY QUALIFIED HEALTH CENTER SERVICES

405.2430 Basic requirements.
405.2434 Content and terms of the agreement.
405.2436 Termination of agreement.
405.2440 Conditions for reinstatement after termination by CMS.
405.2442 Notice to the public.
405.2444 Change of ownership.
405.2446 Scope of services.
405.2448 Preventive primary services.
405.2449 Preventive services.
405.2450 Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.
405.2452 Services and supplies incident to clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

405.2460 Applicability of general payment exclusions.
405.2462 Payment for RHC and FQHC services.
405.2463 What constitutes a visit.
405.2464 Payment rate.
405.2466 Annual reconciliation.
405.2467 Requirements of the FQHC PPS.
405.2468 Allowable costs.
405.2469 FQHC supplemental payments.
405.2470 Reports and maintenance of records.
405.2472 Beneficiary appeals.

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Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C.1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

§ 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as Category B (Nonexperimental/investigational) device.

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

(b) *Definitions.* As used in this subpart—

Category A (Experimental) device refers to a device for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained

FDA premarket approval or clearance for that device type.

ClinicalTrials.gov refers to the National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Contractors refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

Investigational device exemption (IDE) refers to an FDA-approved IDE application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR part 812.

Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national noncoverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013; 86 FR 3009, Jan. 14, 2021; 86 FR 62958, Nov. 15, 2021]

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Category A (Experimental) devices.

(2) Category B (Nonexperimental/investigational) devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category A (Experimental) or Category B (Nonexperimental).

(c) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013

§ 405.205 Coverage of a Category B (Nonexperimental/investigational) device.

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category B (Nonexperimental/investigational).

(2) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at § 411.15(o) of this chapter, the FDA notifies the sponsor and CMS and the procedures described in paragraph (a)(2) of this section apply.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013

§ 405.207 Services related to a noncovered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for—

(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or

(2) Routine care items and services related to Category A (Experimental) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.

(3) Routine care items and services related to Category B (Nonexperimental/investigational) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.

[60 FR 48423, Sept. 19, 1995, as amended at 69 FR 66420, Nov. 15, 2004; 78 FR 74809, Dec. 10, 2013]

§ 405.209 Payment for a Category B (Nonexperimental/investigational) device.

Payment under Medicare for a Category B (Nonexperimental/investigational) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

[78 FR 74809, Dec. 10, 2013]

§ 405.211 Coverage of items and services in FDA-approved IDE studies.

(a) *Coverage of routine care items and services for Category A (Experimental) devices.* Medicare covers routine care items and services furnished in an FDA-approved Category A (Experimental) IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria in § 405.212 are met.

(b) *Coverage of Category B (Nonexperimental/investigational) IDE devices and routine care items and services.* Medicare may make payment for a Category B (Nonexperimental/investigational) IDE device and routine care items and services furnished in an FDA-approved Category B (Nonexperimental/investigational) IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria in § 405.212 are met.

(c) CMS (or its designated entity) must review the following to determine if the Medicare coverage IDE study criteria in § 405.212 are met for purposes of coverage of items and services described in paragraphs (a) and (b) of this section:

(1) FDA approval letter of the IDE.

(2) IDE study protocol.

(3) IRB approval letter.

(4) NCT number.

(5) Supporting materials, as needed.

(d) *Notification.* A listing of all CMS-approved Category A (Experimental) IDE studies and Category B (Nonexperimental/investigational) IDE studies shall be posted on the CMS Web site and published in the FEDERAL REGISTER.

[78 FR 74809, Dec. 10, 2013]

§ 405.212 Medicare Coverage IDE study criteria.

(a) For Medicare coverage of items and services described in § 405.211, a Category A (Experimental) or Category B (Nonexperimental/investigational) IDE study must meet all of the following criteria:

(1) The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.

(2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

(3) The study results are not anticipated to unjustifiably duplicate existing knowledge.

(4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.

(5) The study is sponsored by an organization or individual capable of successfully completing the study.

(6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812 and 45 CFR part 46.

(7) Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.

(8) The study is registered with the National Institutes of Health's National Library of Medicine's ClinicalTrials.gov.

(9) The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

(10) The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

(b) [Reserved]

[78 FR 74809, Dec. 10, 2013]

§ 405.213 Re-evaluation of a device categorization.

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as Category A (experimental) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by CMS only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor CMS's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both CMS and the sponsor of its decision.

(c) *Request to CMS.* If the FDA does not agree to recategorize the device, the sponsor may seek review from CMS. A device sponsor must submit its request in writing to CMS. CMS obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. CMS reviews all material submitted by the sponsor and the FDA's recommendation. CMS reviews only information in the FDA record to determine whether to change the categorization of the device. CMS issues a written decision and notifies the sponsor of the IDE and the FDA.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74810, Dec. 10, 2013]

§ 405.215 Confidential commercial and trade secret information.

To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1862, 1866, 1870, 1871, 1879 and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

EDITORIAL NOTE: Nomenclature changes to subpart C of part 405 appear at 76 FR 5961, Feb. 2, 2011.

GENERAL PROVISIONS

§ 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual

shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or

(2) The provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person must, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the fifth year following the year in which notice was sent to such individual that such amount had been paid.

[41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 49271, Sept. 19, 1996; 78 FR 74810, Dec. 10, 2013]

§ 405.351 Incorrect payments for which the individual is not liable.

Where an incorrect payment has been made to a provider of services or other person, the individual is liable only to the extent that he has benefited from such payment.

§ 405.352 Adjustment of title XVIII incorrect payments.

Where an individual is liable for an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) adjustment is made (to the extent of such liability) by:

(a) Decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937, to which the individual is entitled; or

(b) In the event of the individual's death before adjustment is completed, by decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937 payable to the estate of the individual or to any other person, that are based on the individual's earnings record (or compensation).

[31 FR 13534, Oct. 20, 1966, as amended at 41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.

As soon as practicable after any adjustment is determined to be necessary, the Secretary, for purposes of this subpart, shall certify the amount of the overpayment or payment (see § 405.350) with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1937, such certification shall be made to the Railroad Retirement Board.

§ 405.354 Procedures for adjustment or recovery—title II beneficiary.

The procedures applied in making an adjustment or recovery in the case of a title II beneficiary are the applicable procedures of 20 CFR 404.502.

[31 FR 13534, Oct. 20, 1966, as amended at 32 FR 18027, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.355 Waiver of adjustment or recovery.

(a) The provisions of § 405.352 may not be applied and there may be no adjustment or recovery of an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) in any case where such incorrect payment has been made with respect to an individual who is without fault, or where such adjustment or recovery would be made by decreasing payments to which another person who is without fault is entitled as provided in section 1870(b) of the Act where such adjustment or recovery would defeat the purpose of title II or title XVIII of the Act or would be against equity and good conscience. (See 20 CFR 404.509 and 404.512.)

(b) Adjustment or recovery of an incorrect payment (or only such part of

an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault will be deemed to be against equity and good conscience if the incorrect payment was made for items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act and if the determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual.

[41 FR 1493, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977; 78 FR 74810, Dec. 10, 2013]

§ 405.356 Principles applied in waiver of adjustment or recovery.

The principles applied in determining waiver of adjustment or recovery (§ 405.355) are the applicable principles of § 405.358 and 20 CFR 404.507–404.509, 404.510a, and 404.512.

[61 FR 49271, Sept. 19, 1996]

§ 405.357 Notice of right to waiver consideration.

Whenever an initial determination is made that more than the correct amount of payment has been made, notice of the provisions of section 1870(c) of the Act regarding waiver of adjustment or recovery shall be sent to the overpaid individual and to any other individual against whom adjustment or recovery of the overpayment is to be effected (see § 405.358).

[61 FR 49271, Sept. 19, 1996]

§ 405.358 When waiver of adjustment or recovery may be applied.

Section 1870(c) of the Act provides that there shall be no adjustment or recovery in any case where an incorrect payment under title XVIII (hospital and supplementary medical insurance benefits) has been made (including a payment under section 1814(e) of the Act with respect to an individual:

(a) Who is without fault, and

(b) Adjustment or recovery would either:

(1) Defeat the purposes of title II or title XVIII of the Act, or

(2) Be against equity and good conscience.

[61 FR 49271, Sept. 19, 1996]

§ 405.359 Liability of certifying or disbursing officer.

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person:

(a) Where the adjustment or recovery of such amount is waived (see § 405.355), or

(b) Where adjustment (see § 405.352) or recovery is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

SUSPENSION AND RECOUPMENT OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

§ 405.370 Definitions.

(a) For purposes of this subpart, the following definitions apply:

Credible allegation of fraud. A credible allegation of fraud is an allegation from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

Fraud hotline tip. A complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Medicare contractor. Unless the context otherwise requires, includes, but is not limited to the any of following:

(1) A fiscal intermediary.

(2) A carrier.

(3) Program safeguard contractor.

(4) Zone program integrity contractor.

(5) Part A/Part B Medicare administrative contractor.

Offset. The recovery by Medicare of a non-Medicare debt by reducing present

or future Medicare payments and applying the amount withheld to the indebtedness. (Examples are Public Health Service debts or Medicaid debts recovered by CMS).

Recoupment. The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Resolution of an investigation. An investigation of credible allegations of fraud will be considered resolved when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence to support the allegations of fraud.

Suspension of payment. The withholding of payment by a Medicare contractor from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists, or until the resolution of an investigation of a credible allegation of fraud.

(b) For purposes of §§ 405.378 and 405.379, the following terms apply:

Appellant means the beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Fiscal intermediary means an organization that has entered into a contract with CMS in accordance with section 1816 of the Act and is authorized to make determinations and payments for Part A of title XVIII of the Act, and Part B provider services as specified in § 421.5(c) of this chapter.

Medicare Appeals Council means the council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

Medicare contractor, unless the context otherwise requires, includes, but is not limited to, a fiscal intermediary, carrier, recovery audit contractor, and Medicare administrative contractor.

Party means an individual or entity listed in § 405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination.

Qualified Independent Contractor (QIC) Qualified Independent Contractor (QIC) means an entity which contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978.

Remand means to vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

Vacate means to set aside a previous action.

[61 FR 63745, Dec. 2, 1996, as amended at 74 FR 47468, Sept. 16, 2009; 76 FR 5961, Feb. 2, 2011; 86 FR 6093, Jan. 19, 2021]

§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) *General rules*—Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be one of the following:

(1) Suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor possesses reliable information that an overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination.

(2) In cases of suspected fraud, suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments.

(3) Offset or recouped, in whole or in part, by a Medicare contractor if the Medicare contractor or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

(4) Suspended, in whole or in part, by CMS or a Medicare contractor if the provider or supplier has been subject to a Medicaid payment suspension under § 455.23(a)(1) of this chapter.

(b) *Good cause exceptions applicable to payment suspensions.* (1) CMS may find that good cause exists not to suspend

payments or not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud if—

(i) OIG or other law enforcement agency has specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation;

(ii) It is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or part as to cause a danger to life or health;

(iii) It is determined that other available remedies implemented by CMS or a Medicare contractor more effectively or quickly protect Medicare funds than would implementing a payment suspension; or

(iv) CMS determines that a payment suspension or a continuation of a payment suspension is not in the best interests of the Medicare program.

(2) Every 180 days after the initiation of a suspension of payments based on credible allegations of fraud, CMS will—

(i) Evaluate whether there is good cause to not continue such suspension under this section; and

(ii) Request a certification from the OIG or other law enforcement agency that the matter continues to be under investigation warranting continuation of the suspension.

(3) Good cause not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud must be deemed to exist if a payment suspension has been in effect for 18 months and there has not been a resolution of the investigation, except CMS may extend a payment suspension beyond that point if—

(i) The case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties); or such administrative action is pending or

(ii) The Department of Justice submits a written request to CMS that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal or civil action or both or based on a pending criminal or civil action or both. At a minimum, the request must include the following:

(A) Identification of the entity under suspension.

(B) The amount of time needed for continued suspension in order to conclude the criminal or civil proceeding or both.

(C) A statement of why or how criminal or civil action or both may be affected if the requested extension is not granted.

(c) *Steps necessary for suspension of payment, offset, and recoupment.* (1) Except as provided in paragraphs (d) and (e) of this section, CMS or the Medicare contractor suspends payments only after it has complied with the procedural requirements set forth at § 405.372.

(2) The Medicare contractor offsets or recoups payments only after it has complied with the procedural requirements set forth at § 405.373.

(d) *Suspension of payment in the case of unfiled cost reports.* (1) If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled cost report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

(e) *Suspension of payment in the case of unfiled hospice cap determination reports.* (1) If a provider has failed to timely file an acceptable hospice cap determination report, payment to the provider is immediately suspended in whole or in part until a cap determination report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled hospice cap determination report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

[76 FR 5961, Feb. 2, 2011, as amended at 79 FR 50509, Aug. 22, 2014; 84 FR 47852, Sept. 10, 2019]i

§ 405.372 Proceeding for suspension of payment.

(a) *Notice of intention to suspend*—(1) *General rule.* Except as provided in paragraphs (a)(2) through (a)(4) of this

section, if the Medicare contractor, or CMS has determined that a suspension of payments under §405.371(a)(1) should be put into effect, the Medicare contractor must notify the provider or supplier of the intention to suspend payments, in whole or in part, and the reasons for making the suspension.

(2) *Failure to furnish information.* The notice requirement of paragraph (a)(1) of this section does not apply if the Medicare contractor suspends payments to a provider or supplier in accordance with section 1815(a) or section 1833(e) of the Act, respectively, because the provider or supplier has failed to submit information requested by the Medicare contractor that is needed to determine the amounts due the provider or supplier. (See §405.371(c) concerning failure to file timely acceptable cost reports.)

(3) *Harm to trust funds.* A suspension of payment may be imposed without prior notice if CMS, the intermediary, or carrier determines that the Medicare Trust Funds would be harmed by giving prior notice. CMS may base its determination on an intermediary's or carrier's belief that giving prior notice would hinder the possibility of recovering the money.

(4) *Fraud.* If the intended suspension of payment involves credible allegations of fraud under §405.371(a)(2), CMS—

(i) In consultation with OIG and, as appropriate, the Department of Justice, determines whether to impose the suspension and if prior notice is appropriate;

(ii) Directs the Medicare contractor as to the timing and content of the notification to the provider or supplier; and

(iii) Is the real party in interest and is responsible for the decision.

(b) *Rebuttal*—(1) *If prior notice is required.* If prior notice is required under paragraph (a) of this section, the Medicare contractor must give the provider or supplier an opportunity for rebuttal in accordance with §405.374. If a rebuttal statement is received within the specified time period, the suspension of payment goes into effect on the date stated in the notice, and the procedures and provisions set forth in §405.375 apply. If by the end of the period specified in the notice no statement has been received, the suspension goes into effect automatically, and the procedures set forth in paragraph (c) of this section are followed.

(2) *If prior notice is not required.* If, under the provisions of paragraphs (a)(2) through (a)(4) of this section, a suspension of payment is put into effect without prior notice to the provider or supplier, the Medicare contractor must, once the suspension is in effect, give the provider or supplier an opportunity to submit a rebuttal statement as to why the suspension should be removed.

(c) *Subsequent action.* (1) If a suspension of payment is put into effect under §405.371(a)(1), CMS or the Medicare contractor takes timely action after the suspension to obtain the additional information it may need to make a determination as to whether an overpayment exists or the payments may be made.

(i) CMS or the Medicare contractor makes all reasonable efforts to expedite the determination.

(ii) As soon as the determination is made, CMS or the Medicare contractor informs the provider or supplier and, if appropriate, the suspension is rescinded or any existing recoupment or offset is adjusted to take into account the determination.

(2)(i) If a suspension of payment is based upon credible allegations of fraud in accordance with §405.371(a)(2), subsequent action must be taken by CMS or the Medicare contractor to make a determination as to whether an overpayment exists.

(ii) The rescission of the suspension and the issuance of a final overpayment determination to the provider or supplier may be delayed until resolution of the investigation.

(d) *Duration of suspension of payment*—(1) *General rule.* Except as provided in paragraphs (d)(2) and (d)(3) of this section, a suspension of payment is limited to 180 days, starting with the date the suspension begins.

(2) *180-day extension.* (i) An intermediary, a carrier, or, in cases of fraud and misrepresentation, OIG or a law enforcement agency, may request a one-time only extension of the suspension period for up to 180 additional

days if it is unable to complete its examination of the information or investigation, as appropriate, within the 180-day time limit. The request must be submitted in writing to CMS.

(ii) Upon receipt of a request for an extension, CMS notifies the provider or supplier of the requested extension. CMS then either extends the suspension of payment for up to an additional 180 days or determines that the suspended payments are to be released to the provider or supplier.

(3) *Exceptions to the time limits.* (i) The time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply if the suspension of payments is based upon credible allegations of fraud under § 405.371(a)(2).

(ii) Although the time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply to suspensions based on credible allegations of fraud, all suspensions of payment in accordance with § 405.371(a)(2) will be temporary and will not continue after the resolution of an investigation, unless a suspension is warranted because of reliable evidence of an overpayment or that the payments to be made may not be correct, as specified in § 405.371(a)(1).

(e) *Disposition of suspended payments.* Payments suspended under the authority of § 405.371(a) are first applied to reduce or eliminate any overpayments determined by the Medicare contractor, or CMS, including any interest assessed under the provisions of § 405.378, and then applied to reduce any other obligation to CMS or to HHS. In the absence of a legal requirement that the excess be paid to another entity, the excess is released to the provider or supplier.

[61 FR 63746, Dec. 2, 1996, as amended at 76 FR 5962, Feb. 2, 2011]

§ 405.373 Proceeding for offset or recoupment.

(a) *General rule.* Except as specified in paragraphs (b) and (f) of this section, if the Medicare Administrative Contractor or CMS has determined that an offset or recoupment of payments under § 405.371(a)(3) should be put into effect, the Medicare Administrative Contractor must—

(1) Notify the provider or supplier of its intention to offset or recoup payment, in whole or in part, and the reasons for making the offset or recoupment; and

(2) Give the provider or supplier an opportunity for rebuttal in accordance with § 405.374.

(b) *Exception to recouping payment.* Paragraph (a) of this section does not apply if the Medicare Administrative Contractor, after furnishing a provider a written notice of the amount of program reimbursement in accordance with § 405.1803, recoups payment under paragraph (c) of § 405.1803. (For provider rights in this circumstance, see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843.)

(c) *Actions following receipt of rebuttal statement.* If a provider or supplier submits, in accordance with § 405.374, a statement as to why an offset or recoupment should not be put into effect on the date specified in the notice, the Medicare contractor must comply with the time limits and notification requirements of § 405.375.

(d) *No rebuttal statement received.* If, by the end of the time period specified in the notice, no statement has been received, the recoupment or offset goes into effect automatically.

(e) *Duration of recoupment or offset.* Except as provided in § 405.379, if a recoupment or offset is put into effect, it remains in effect until the earliest of the following:

(1) The overpayment and any assessed interest are liquidated.

(2) The Medicare contractor obtains a satisfactory agreement from the provider or supplier for liquidation of the overpayment.

(3) The Medicare contractor, on the basis of subsequently acquired evidence or otherwise, determines that there is no overpayment.

(f) *Exception to offset or recoupment of payments for shared Taxpayer Identification Number.* Paragraph (a) of this section does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services

or supplier share the same Taxpayer Identification Number.

[61 FR 63747, Dec. 2, 1996, as amended at 74 FR 47468, Sept. 16, 2009; 81 FR 80551, Nov. 15, 2016]

§ 405.374 Opportunity for rebuttal.

(a) *General rule.* If prior notice of the suspension of payment, offset, or recoupment is given under § 405.372 or § 405.373, the Medicare contractor must give the provider or supplier an opportunity, before the suspension, offset, or recoupment takes effect, to submit any statement (to include any pertinent information) as to why it should not be put into effect on the date specified in the notice. Except as provided in paragraph (b) of this section, the provider or supplier has at least 15 days following the date of notification to submit the statement.

(b) *Exception.* The Medicare contractor may for cause—

(1) Impose a shorter period for rebuttal; or

(2) Extend the time within which the statement must be submitted.

[61 FR 63747, Dec. 2, 1996]

§ 405.375 Time limits for, and notification of, administrative determination after receipt of rebuttal statement.

(a) *Submission and disposition of evidence.* If the provider or supplier submits a statement, under § 405.374, as to why a suspension of payment, offset, or recoupment should not be put into effect, or, under § 405.372(b)(2), why a suspension should be terminated, CMS, the intermediary, or carrier must within 15 days, from the date the statement is received, consider the statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and determine whether the facts justify the suspension, offset, or recoupment or, if already initiated, justify the termination of the suspension, offset, or recoupment. Suspension, offset, or recoupment is not delayed beyond the date stated in the notice in order to review the statement.

(b) *Notification of determination.* The Medicare contractor must send written notice of the determination made under paragraph (a) of this section to the provider or supplier. The notice must—

(1) In the case of offset or recoupment, contain rationale for the determination; and

(2) In the case of suspension of payment, contain specific findings on the conditions upon which the suspension is initiated, continued, or removed and an explanatory statement of the determination.

(c) *Determination is not appealable.* A determination made under paragraph (a) of this section is not an initial determination and is not appealable.

[61 FR 63747, Dec. 2, 1996]

§ 405.376 Suspension and termination of collection action and compromise of claims for overpayment.

(a) *Basis and purpose.* This section contains requirements and procedures for the compromise of, or suspension or termination of collection action on, claims for overpayments against a provider or a supplier under the Medicare program. It is adopted under the authority of the Federal Claims Collection Act (31 U.S.C. 3711). Collection and compromise of claims against Medicare beneficiaries are explained at 20 CFR 404.515.

(b) *Definitions.* As used in this section, *debtor* means a provider of services or a physician or other supplier of services that has been overpaid under title XVIII of the Social Security Act. It includes an individual, partnership, corporation, estate, trust, or other legal entity.

(c) *Basic conditions.* A claim for recovery of Medicare overpayments against a debtor may be compromised, or collection action on it may be suspended or terminated, by the Centers for Medicare & Medicaid Services (CMS) if;

(1) The claim does not exceed $100,000, or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest; and

(2) There is no indication of fraud, the filing of a false claim, or misrepresentation on the part of the debtor or any director, partner, manager, or other party having an interest in the claim.

(d) *Basis for compromise.* A claim may be compromised for one or more of the following reasons:

(1) The debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount within a reasonable time;

(2) The debtor refuses to pay the claim in full and the United States is unable to collect the full amount within a reasonable time by legal proceedings;

(3) There is real doubt the United States can prove its case in court; or

(4) The cost of collecting the claim does not justify enforced collection of the full amount.

(e) *Basis for termination of collection action.* Collection action may be terminated for one or more of the following reasons:

(1) The United States cannot enforce collection of any significant sum;

(2) The debtor cannot be located, there is no security to be liquidated, the statute of limitations has run, and the prospects of collecting by offset are too remote to justify retention of the claim;

(3) The cost of further collection action is likely to exceed any recovery;

(4) It is determined the claim is without merit; or

(5) Evidence to substantiate the claim is no longer available.

(f) *Basis for suspension of collection action.* Collection action may be suspended for either of the following reasons if future collection action is justified based on potential productivity, including foreseeable ability to pay, and size of claim:

(1) The debtor cannot be located; or

(2) The debtor is unable to make payments on the claim or to fulfill an acceptable compromise.

(g) *Factors considered.* In determining whether a claim will be compromised, or collection action terminated or suspended, CMS will consider the following factors:

(1) Age and health of the debtor, present and potential income, inheritance prospects, possible concealment or fraudulent transfer of assets, and the availability of assets which may be reached by enforced collection proceedings, for compromise under paragraph (d)(1) of this section, termination under paragraph (e)(1) of this section, and suspension under paragraph (f)(2) of this section;

(2) Applicable exemptions available to a debtor and uncertainty concerning the price of the property in a forced sale, for compromise under paragraph (d)(2) of this section and termination under paragraph (e)(1) of this section; and

(3) The probability of proving the claim in court, the probability of full or partial recovery, the availability of necessary evidence, and related pragmatic considerations, for compromise under paragraph (d)(3) of this section.

(h) *Amount of compromise.* The amount accepted in compromise will be reasonable in relation to the amount that can be recovered by enforced collection proceedings.

Consideration shall be given to the following:

(1) The exemptions available to the debtor under State or Federal law;

(2) The time necessary to collect the overpayment;

(3) The litigative probabilities involved; and

(4) The administrative and litigative costs of collection where the cost of collecting the claim is a basis for compromise.

(i) *Payment of compromise*—(1) *Time and manner.* Payment of the amount that CMS has agreed to accept as a compromise in full settlement of a Medicare overpayment claim must be made within the time and in the manner prescribed by CMS. An overpayment claim is not compromised or settled until the full payment of the compromised amount has been made within the time and in the manner prescribed by CMS.

(2) *Failure to pay compromised amount.* Failure of the debtor or the estate to make payment as provided by the comprise reinstates the full amount of the overpayment claim, less any amounts paid prior to the default.

(j) *Effect of compromise, or suspension, or termination of collection action.* Any action taken by CMS under this section regarding the compromise of an overpayment claim, or termination or suspension of collection action on an overpayment claim, is not an initial

determination for purposes of the appeal procedures under subparts G, H, and R of this part.

[43 FR 59381, Dec. 20, 1978, as amended at 57 FR 56998, Dec. 2, 1992. Redesignated and amended at 61 FR 63745, 63747, Dec. 2, 1996]

§ 405.377 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* This section implements section 1885 of the Act, which provides for withholding Medicare payments to certain Medicaid providers that have not arranged to repay Medicaid overpayments as determined by the Medicaid State agency or have failed to provide information necessary to determine the amount (if any) of overpayments.

(b) *When withholding may be used.* CMS may withhold Medicare payment to offset Medicaid overpayments that a Medicaid agency has been unable to collect if—

(1) The Medicaid agency has followed the procedure specified in § 447.31 of this chapter; and

(2) The institution or person is one described in paragraph (c) of this section and either—

(i) Has not made arrangements satisfactory to the Medicaid agency to repay the overpayment; or

(ii) Has not provided information to the Medicaid agency necessary to enable the agency to determine the existence or amount of Medicaid overpayment.

(c) *Institutions or persons affected.* Withholding under paragraph (b) of this section may be made with respect to any of the following entities that has or had in effect an agreement with a Medicaid agency to furnish services under an approved Medicaid State plan:

(1) An institutional provider that has in effect an agreement under section 1866 of the Act. (Part 489 (Provider and Supplier Agreements) implements section 1866 of the Act.)

(2) A physician or supplier that has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act. (Section 424.55 sets forth the conditions a supplier agrees to in accepting assignment.)

(d) *Amount to be withheld.* (1) CMS contacts the appropriate Medicare contractor to determine the amount of Medicare payment to which the institution or person is entitled.

(2) CMS may require the Medicare contractor to withhold Medicare payments to the institution or person by the lesser of the following amounts:

(i) The amount of the Medicare payments to which the institution or person would otherwise be entitled.

(ii) The total Medicaid overpayment to the institution or person.

(e) *Notice of withholding.* If CMS intends to withhold payments under this section, it notifies by certified mail, return receipt requested, the institution or person and the appropriate Medicare contractor of the intention to withhold Medicare payments and follows the procedure in § 405.374. The notice includes—

(1) Identification of the institution or person; and

(2) The amount of Medicaid overpayment to be withheld from payments to which the institution or person would otherwise be entitled under Medicare.

(f) *Termination of withholding.* CMS terminates the withholding if—

(1) The Medicaid overpayment is completely recovered;

(2) The institution or person enters into an agreement satisfactory to the Medicaid agency to repay the overpayment; or

(3) The Medicaid agency determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(g) *Disposition of funds withheld.* CMS releases amounts withheld under this section to the Medicaid agency to be applied against the Medicaid overpayment made by the State agency.

[61 FR 63747, Dec. 2, 1996]

§ 405.378 Interest charges on overpayment and underpayments to providers, suppliers, and other entities.

(a) *Basis and purpose.* This section, which implements sections 1815(d), 1833(j) and 1893(f)(2)(B) of the Act and common law, and authority granted under the Federal Claims Collection Act, provides for the charging and payment of interest on overpayments and underpayments to Medicare providers, suppliers, HMOs, competitive medical

plans (CMPs), and health care prepayment plans (HCPPs).

(b) *Basic rules.* (1) CMS will charge interest on overpayments, and pay interest on underpayments, to providers and suppliers of services (including physicians and other practitioners), except as specified in paragraphs (f) and (h) of this section.

(2) Except as provided in paragraph (j) of this section, interest accrues from the date of the final determination as defined in paragraph (c) of this section, and either is charged on the overpayment balance or paid on the underpayment balance for each full 30-day period that payment is delayed.

(c) *Definition of final determination.* (1) For purposes of this section, any of the following constitutes a final determination:

(i) A Notice of Amount of Program Reimbursement (NPR) is issued, as discussed in §§ 405.1803, 417.576, and 417.810, and either—

(A) A written demand for payment is made; or

(B) A written determination of an underpayment is made by the intermediary after a cost report is filed.

(ii) In cases in which an NPR is not used as a notice of determination (that is, primarily under part B), one of the following constitutes a final determination—

(A) A written determination that an overpayment exists and a written demand for payment; or

(B) A written determination of an underpayment.

(iii) Other examples of cases in which an NPR is not used are carrier reasonable charge determinations under subpart E of this part, interim cost settlements made for HMOs, CMPs, and HCPPs under §§ 417.574 and 417.810(e) of this chapter, and initial retroactive adjustment determinations under § 413.64(f)(2) of this chapter. In the case of interim cost settlements and initial retroactive adjustment determinations, if the debtor does not dispute the adjustment determination within the timeframe designated in the notice of the determination (generally at least 15 days), a final determination is deemed to have been made. If the provider or supplier does dispute portions of the determination, a final determination is deemed to have been made on those portions when the intermediary issues a new determination in response to the dispute.

(iv) The due date of a timely-filed cost report that indicates an amount is due CMS, and is not accompanied by payment in full. (If an additional overpayment or underpayment is determined by the carrier or intermediary, a final determination on the additional amount is made in accordance with paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii), of this section.)

(v) With respect to a cost report that is not filed on time, the day following the date the cost report was due (plus a single extension of time not to exceed 30 days if granted for good cause), until the time as a cost report is filed. (When the cost report is subsequently filed, there is an additional determination as specified in paragraphs (c)(1) (i), (ii), (iii), or (iv) of this section.)

(2) Except as required by any subsequent administrative or judicial reversal and specifically as provided in paragraphs (i) and (j) of this section, interest accrues from the date of final determination as specified in this section.

(d) *Rate of interest.* (1) The interest rate on overpayments and underpayments is the higher of—

(i) The rate as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of final determination as defined in paragraph (c) of this section (this rate is published quarterly in the FEDERAL REGISTER by the Department under 45 CFR 30.13(a)); or

(ii) The current value of funds rate (this rate is published annually in the FEDERAL REGISTER by the Secretary of the Treasury, subject to quarterly revisions).

(2) [Reserved]

(e) *Accrual of interest.* (1) If a cost report is filed that does not indicate an amount is due CMS but the intermediary makes a final determination that an overpayment exists, or if a carrier makes a final determination that an overpayment to a physician or supplier exists, interest will accrue beginning with the date of such final determination. Interest will continue to accrue during periods of administrative

and judicial appeal and until final disposition of the claim.

(2)(i) If a cost report is filed and indicates that an amount is due CMS, interest on the amount due will accrue from the due date of the cost report unless—

(A) Full payment on the amount due accompanies the cost report; or

(B) The provider and the intermediary agree in advance to liquidate the overpayment through a reduction in interim payments over the next 30-day period.

(ii) If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination.

(iii) The interest rate on each of the final determinations of an overpayment will be the rate of interest in effect on the date the determination is made.

(3) In the case of a cost report that is not filed on time, interest also will accrue on a determined overpayment from the day following the due date of the report (plus a single extension of time not to exceed 30 days if granted for good cause, as specified in § 413.24(f)) of this chapter, to the time the cost report is filed.

(4) If an intermediary or a carrier makes a final determination that an underpayment exists, interest to the provider or the supplier will accrue from the date of notification of the underpayment.

(f) *Waiver of interest charges.* (1) When an intermediary or a carrier makes a final determination that an overpayment or underpayment exists, as specified in paragraphs (e)(1), (e)(2)(ii), and (e)(4)—

(i) Interest charges will be waived if the overpayment or underpayment is completely liquidated within 30 days from the date of the final determination.

(ii) CMS may waive interest charges if it determines that the administrative cost of collecting them exceeds the interest charges.

(2) Interest will not be waived for that period of time during which the cost report was due but remained unfiled for more than 30 days, as specified in paragraph (e)(3) of this section.

(g) *Rules applicable to partial payments.* If an overpayment is repaid in installments or recouped by withholding from several payments due the provider or supplier of services—

(1) Each payment or recoupment will be applied first to accrued interest and then to the principal; and

(2) After each payment or recoupment, interest will accrue on the remaining unpaid balance.

(h) *Nonallowable cost.* As specified in §§ 412.113 and 413.153 of this chapter, interest accrued on overpayments and interest on funds borrowed specifically to repay overpayments are not considered allowable costs, up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(See § 413.153(a)(2) of this chapter for exceptions based on administrative or judicial reversal.)

(i) *Exceptions to applicability.* (1) The provisions of this section do not apply to the time period for which interest is payable under § 413.64(j) of this chapter because the provider seeks judicial review of a decision of the Provider Reimbursement Review Board, or a subsequent reversal, affirmance, or modification of that decision by the Administrator. Prior to that time, until the provider seeks judicial review, interest accrues at the rate specified in this section on outstanding unpaid balances resulting from final determinations as defined in paragraph (c) of this section.

(2) If an overpayment or an underpayment determination is reversed administratively or judicially, and the reversal is no longer subject to appeal, appropriate adjustments will be made with respect to the overpayment or underpayment and the amount of interest charged.

(j) *Special rule for provider or supplier overpayments subject to § 405.379.* If an overpayment determination subject to the limitation on recoupment under § 405.379 is reversed in whole or in part by an Administrative Law Judge (ALJ) or at subsequent administrative or judicial levels of appeal and if funds have been recouped and retained by the Medicare contractor, interest will be paid to the provider or supplier as follows:

(1) The applicable rate of interest is that provided in paragraph (d) of this section.

(2) The interest rate in effect on the date the ALJ, the Medicare Appeals Council, the Federal district court or subsequent appellate court issues a decision reversing the overpayment determination in whole or in part is the rate used to calculate the interest due the provider or supplier.

(3) Interest will be calculated as follows:

(i) Interest will be paid on the principal amount recouped only.

(ii) Interest will be calculated on a simple rather than a compound basis.

(iii) Interest will be calculated in full 30-day periods and will not be payable on amounts recouped for any periods of less than 30 days in which the Medicare contractor had possession of the funds.

(iv) In calculating the period in which the amount was recouped, days in which the ALJ's adjudication period to conduct a hearing are tolled under 42 CFR 405.1014 shall not be counted.

(v) In calculating the period in which the amount was recouped, days in which the Medicare Appeals Council's adjudication period to conduct a review are tolled under 42 CFR 405.1106 shall not be counted.

(4) If the decision by the ALJ, Medicare Appeals Council, Federal district court or a subsequent Federal reviewing court, reverses the overpayment determination, as modified by prior levels of administrative or judicial review, in part, the Medicare contractor in effectuating the decision may allocate recouped monies to that part of the overpayment determination affirmed by the decision. Interest will be paid to the provider or supplier on recouped amounts that remain after this allocation in accordance with this paragraph (j) of this section.

[47 FR 54814, Dec. 6, 1982, as amended at 49 FR 36102, Sept. 14, 1984; 49 FR 44472, Nov. 7, 1984; 51 FR 34792, Sept. 30, 1986; 56 FR 31336, July 10, 1991. Redesignated at 61 FR 63745, Dec. 2, 1996; 69 FR 45607, July 30, 2004; 74 FR 47468, Sept. 16, 2009]

§ 405.379 Limitation on recoupment of provider and supplier overpayments.

(a) *Basis and purpose.* This section implements section 1893(f)(2)(A) of the Act which limits recoupment of Medicare overpayments if a provider of services or supplier seeks a reconsideration until a decision is rendered by a Qualified Independent Contractor (QIC). This section also limits recoupment of Medicare overpayments when a provider or supplier seeks a redetermination until a redetermination decision is rendered.

(b) *Overpayments subject to limitation.* (1) This section applies to overpayments that meet the following criteria:

(i) Is one of the following types of overpayments:

(A) Post-pay denial of claims for benefits under Medicare Part A which is determined and for which a written demand for payment has been made on or after November 24, 2003; or

(B) Post-pay denial of claims for benefits under Medicare Part B which is determined and for which a written demand for payment has been made on or after October 29, 2003; or

(C) Medicare Secondary Payer (MSP) recovery where the provider or supplier received a duplicate primary payment and for which a written demand for payment was issued on or after October 10, 2003; or

(D) Medicare Secondary Payer (MSP) recovery based on the provider's or supplier's failure to file a proper claim with the third party payer plan, program, or insurer for payment and, if Part A, demanded on or after November 24, 2003, or, if Part B, demanded on or after October 29, 2003; and

(ii) The provider or supplier can appeal the overpayment as a revised initial determination under the Medicare claims appeal process at 42 CFR parts 401 and 405 or as an initial determination for provider/supplier MSP duplicate primary payment recoveries.

(2) This section does not apply to all other overpayments including, but not limited to, the following:

(i) All Medicare Secondary Payer recoveries except those expressly identified in paragraphs (b)(1)(i)(C) and (D) of this section;

(ii) Beneficiary overpayments; and

(iii) Overpayments that arise from a cost report determination and are appealed under the provider reimbursement process of 42 CFR part 405 Subpart R—Provider Reimbursement Determinations and Appeals.

(c) *Rules of construction.* (1) For purposes of this section, what constitutes a valid and timely request for a redetermination is to be determined in accordance with § 405.940 through § 405.958.

(2) For purposes of this section, what constitutes a valid and timely request for a reconsideration is to be determined in accordance with § 405.960 through § 405.978.

(d) *General rules.* (1) Medicare contractors can begin recoupment no earlier than 41 days from the date of the initial overpayment demand but shall cease recoupment of the overpayment in question, upon receipt of a timely and valid request for a redetermination of an overpayment. If the recoupment has not yet gone into effect, the contractor shall not initiate recoupment.

(2) If the redetermination decision is an affirmation in whole or in part of the overpayment determination, recoupment may be initiated or resumed in accordance with paragraph (e) of this section.

(3) Upon receipt of a timely and valid request for a reconsideration of an overpayment, the Medicare contractor shall cease recoupment of the overpayment in question. If the recoupment has not yet gone into effect, the contractor must not initiate recoupment.

(4) The contractor may initiate or resume recoupment following action by the QIC in accordance with paragraph (f) of this section.

(5) If the provider or supplier subsequently appeals the overpayment to the ALJ, the Medicare Appeals Council, or Federal court, recoupment remains in effect as provided in § 405.373(e).

(6) If an overpayment determination is appealed and recoupment stopped, the contractor may continue to recoup other overpayments owed by the provider or supplier in accordance with this section.

(7) Amounts recouped prior to a reconsideration decision may be retained by the Medicare contractor in accordance with paragraph (g) of this section.

(8) If either the redetermination or reconsideration decision is a full reversal of the overpayment determination or if the overpayment determination is reversed in whole or in part at subsequent levels of administrative or judicial appeal, adjustments shall be made with respect to the overpayment and the amount of interest charged.

(9) Interest accrues and is payable in accordance with the provisions of § 405.378.

(e) *Initiating or resuming recoupment after redetermination decision.* (1) Recoupment that has been deferred or stopped may be initiated or resumed if the debt (remaining unpaid principal balance and interest) has not been satisfied in full and the provider or supplier has been afforded the opportunity for rebuttal in accordance with the requirements of § 405.373 through § 405.375. Recoupment may be resumed under any of the following circumstances:

(i) Immediately upon receipt by the Medicare contractor of the provider's or supplier's request for a withdrawal of a request for a redetermination in accordance with § 405.952(a).

(ii) On the 60th calendar day after the date of the notice of redetermination issued under § 405.956 if the redetermination decision is an affirmation in whole of the overpayment determination in question.

(iii) On the 60th calendar day after the date of the written notice to the provider or supplier of the revised overpayment amount, if the redetermination decision is an affirmation in part, which has the effect of reducing the amount of the overpayment.

(2) Notwithstanding paragraphs (e)(i), (ii) and (iii) of this section, recoupment must not be resumed, or if resumed, must cease upon receipt of a timely and valid request for a reconsideration by the QIC.

(f) *Initiating or resuming recoupment following action by the QIC on the reconsideration request.* (1) Recoupment may be initiated or resumed upon action by the QIC subject to the following limitations:

(i) The provider or supplier has been afforded the opportunity for rebuttal in accordance with the requirements of § 405.373 through § 405.375; and

(ii) The debt (remaining unpaid principal balance and interest) has not been satisfied in full; and

(iii) If the action by the QIC is the notice of the reconsideration, the reconsideration decision either affirms in whole or in part the overpayment determination, including the redetermination, in question.

(2) For purposes of this paragraph (f), the action by the QIC on the reconsideration request is the earliest to occur of the following:

(i) The QIC mails or otherwise transmits written notice of the dismissal of the reconsideration request in its entirety in accordance with § 405.972; or

(ii) The QIC receives a timely and valid request to withdraw the request for the reconsideration in accordance with § 405.972; or

(iii) The QIC transmits written notice of the reconsideration in accordance with § 405.976; or

(iv) The QIC notifies the parties in writing that the reconsideration is being escalated to an ALJ in accordance with § 405.970.

(g) *Disposition of funds recouped.* (1) If the Medicare contractor recouped funds before a timely and valid request for a redetermination was received, the amount recouped may be retained and applied first to accrued interest and then to reduce or eliminate the principal balance of the overpayment subject to the following:

(i) If the redetermination results in a reversal, the amount recouped may be applied to any other debt, including interest, owed by the provider or supplier before any excess is released to the provider.

(ii) If the redetermination results in a partial reversal and the decision reduces the overpayment plus assessed interest below the amount already recouped, the excess may be applied to any other debt, including interest, owed by the provider or supplier before any excess is released to the provider or supplier.

(iii) If the redetermination results in an affirmation and the provider or supplier subsequently requests a reconsideration, the Medicare contractor may retain the amount recouped and apply the funds first to accrued interest and then to outstanding principal pending action by the QIC on the reconsideration request.

(2) If the Medicare contractor also recouped funds in accordance with paragraph (e) of this section, the amount recouped may be retained by the Medicare contractor and applied first to accrued interest and then to reduce or eliminate the outstanding principal balance pending action by the QIC on the reconsideration request.

(3) If the action by the QIC is a dismissal, receipt of a withdrawal, a notice that the reconsideration is being escalated to an ALJ, or a reconsideration which affirms in whole the overpayment determination, including the redetermination, in question, the amount recouped is applied to interest first, then to reduce the outstanding principal balance and recoupment may be resumed as provided under paragraph (f) of this section.

(4) If the action by the QIC is a reconsideration, which reverses in whole the overpayment determination, including the redetermination, in question, the amount recouped may be applied to any other debt, including interest, owed by the provider or supplier to CMS or to HHS before any excess is released to the provider or supplier.

(5) If the action by the QIC is a reconsideration which results in a partial reversal and the decision reduces the overpayment plus assessed interest below the amount already recouped, the excess may be applied to any other debt, including interest, owed by the provider or supplier to CMS or to HHS before any excess is released to the provider or supplier.

(h) *Relationship to extended repayment schedules.* Notwithstanding § 401.607 (c)(2)(v) of this chapter regarding an extended repayment schedule (ERS), a provider or supplier will not be deemed in default if recoupment of an overpayment is not effectuated or stopped in accordance with this section, and the following conditions are met:

(1) The provider or supplier has been granted an ERS under § 401.607(c) of this chapter.

(2) The ERS has been granted for an overpayment that is listed in paragraph (b) of this section.

(3) The provider or supplier has submitted a valid and timely request to

the Medicare contractor for a redetermination of the overpayment in accordance with §§ 405.940 through 405.958 or reconsideration of the overpayment in accordance with §§ 405.960 through 405.978.

[74 FR 47469, Sept. 16, 2009]

REPAYMENT OF SCHOLARSHIPS AND LOANS

§ 405.380 Collection of past-due amounts on scholarship and loan programs.

(a) *Basis and purpose.* This section implements section 1892 of the Act, which authorizes the Secretary to deduct from Medicare payments for services amounts considered as past-due obligations under the National Health Service Corps Scholarship program, the Physician Shortage Area Scholarship program, and the Health Education Assistance Loan program.

(b) *Offsetting against Medicare payment.* (1) Medicare carriers and intermediaries offset against Medicare payments in accordance with the signed repayment agreement between the Public Health Service and individuals who have breached their scholarship or loan obligations and who—

(i) Accept Medicare assignment for services;

(ii) Are employed by or affiliated with a provider, HMO, or Competitive Medical Plan (CMP) that receives Medicare payment for services; or

(iii) Are members of a group practice that receives Medicare payment for services.

(2) For purposes of this section, ''provider'' includes all entities eligible to receive Medicare payment in accordance with an agreement under section 1866 of the Act.

(c) *Beginning of offset.* (1) The Medicare carrier offsets Medicare payments beginning six months after it notifies the individual or the group practice of the amount to be deducted and the particular individual to whom the deductions are attributable.

(2) The Medicare intermediary offsets payments beginning six months after it notifies the provider, HMO, CMP or group practice of the amount to be deducted and the particular individuals to whom the deductions are attributable. Offset of payments is made in accordance with the terms of the repayment agreement. If the individual ceases to be employed by the provider, HMO, or CMP, or leaves the group practice, no deduction is made.

(d) *Refusal to offset against Medicare payment.* If the individual refuses to enter into a repayment agreement, or breaches any provision of the agreement, or if Medicare payment is insufficient to maintain the offset collection according to the agreed upon formula, then—

(1) The Department, within 30 days if feasible, informs the Attorney General; and

(2) The Department excludes the individual from Medicare until the entire past due obligation has been repaid, unless the individual is a sole community practitioner or the sole source of essential specialized services in a community and the State requests that the individual not be excluded.

[57 FR 19092, May 4, 1992]

Subpart D—Private Contracts

AUTHORITY: Secs. 1102, 1802, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395a, and 1395hh).

SOURCE: 63 FR 58901, Nov. 2, 1998, unless otherwise noted.

§ 405.400 Definitions.

For purposes of this subpart, the following definitions apply:

Beneficiary means an individual who is enrolled in Part B of Medicare.

Emergency care services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

Legal representative means one or more individuals who, as determined by applicable State law, has the legal authority to enter into the contract with the physician or practitioner on behalf of the beneficiary.

Opt-out means the status of meeting the conditions specified in § 405.410.

Opt-out period means, with respect to an affidavit that meets the requirements of § 405.420, a 2-year period beginning on the date the affidavit is signed, as specified by § 405.410(c)(1) or (2) as applicable, and each successive 2-year period unless the physician or practitioner properly cancels opt-out in accordance with § 405.445.

Participating physician means a ''physician'' as defined in this section who has signed an agreement to participate in Part B of Medicare.

Physician means a doctor of medicine; doctor of osteopathy; doctor of dental surgery or of dental medicine; doctor of podiatric medicine; or doctor of optometry who is legally authorized to practice medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, or optometry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions.

Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, mental health counselor, registered dietitian or nutrition professional, who is currently legally authorized to practice in that capacity by each State in which he or she furnishes services to patients or clients.

Private contract means a document that meets the criteria specified in § 405.415.

Properly opt-out means to complete, without defect, the requirements for opt-out as specified in § 405.410.

Properly terminate opt-out means to complete, without defect, the requirements for terminating opt-out as specified in § 405.445.

Urgent care services means services furnished to an individual who requires services to be furnished within 12 hours in order to avoid the likely onset of an emergency medical condition.

[63 FR 58901, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004; 71 FR 69782, Dec. 1, 2006; 79 FR 68001, Nov. 13, 2014; 80 FR 71370, Nov. 16, 2015; 88 FR 79523, Nov. 16, 2023]

§ 405.405 General rules.

(a) A physician or practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare, provided the conditions of this subpart are met.

(b) A physician or practitioner who enters into at least one private contract with a Medicare beneficiary under the conditions of this subpart, and who submits one or more affidavits in accordance with this subpart, opts out of Medicare for the opt-out period described in § 405.400 unless the opt-out is terminated early according to § 405.445.

(c) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void if the physician or practitioner fails to properly opt-out in accordance with the conditions of this subpart.

(d) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void for the remainder of the opt-out period if the physician or practitioner fails to remain in compliance with the conditions of this subpart during the opt-out period.

(e) Services furnished under private contracts meeting the requirements of this subpart are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly, except as permitted in accordance with § 405.435(c).

[63 FR 58901, Nov. 2, 1998, as amended at 80 FR 71370, Nov. 16, 2015]

§ 405.410 Conditions for properly opting-out of Medicare.

The following conditions must be met for a physician or practitioner to properly opt-out of Medicare:

(a) Each private contract between a physician or a practitioner and a Medicare beneficiary that is entered into prior to the submission of the affidavit described in paragraph (b) of this section must meet the specifications of § 405.415.

(b) The physician or practitioner must submit an affidavit that meets the specifications of § 405.420 to each

Medicare Administrative Contractor with which he or she would file claims absent the opt-out.

(c) A nonparticipating physician or a practitioner may opt-out of Medicare at any time in accordance with the following:

(1) The initial 2-year opt-out period begins the date the affidavit meeting the requirements of § 405.420 is signed, provided the affidavit is filed within 10 days after he or she signs his or her first private contract with a Medicare beneficiary.

(2) If the physician or practitioner does not timely file the opt-out affidavit(s) as specified in the previous paragraph, the initial 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit, and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

(d) A participating physician may properly opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in § 405.420 is submitted to the participating physician's Medicare Administrative Contractors at least 30 days before the beginning of the selected calendar quarter. A private contract entered into before the beginning of the selected calendar quarter becomes effective at the beginning of the selected calendar quarter, and the furnishing of any items or services to a Medicare beneficiary under such contract before the beginning of the selected calendar quarter is subject to standard Medicare rules.

[63 FR 58901, Nov. 2, 1998, as amended at 80 FR 71370, Nov. 16, 2015]

§ 405.415 Requirements of the private contract.

A private contract under this subpart must:

(a) Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract.

(b) Clearly state whether the physician or practitioner is excluded from Medicare under sections 1128, 1156, or 1892 or any other section of the Social Security Act.

(c) State that the beneficiary or his or her legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician or practitioner.

(d) State that the beneficiary or his or her legal representative understands that Medicare limits do not apply to what the physician or practitioner may charge for items or services furnished by the physician or practitioner.

(e) State that the beneficiary or his or her legal representative agrees not to submit a claim to Medicare or to ask the physician or practitioner to submit a claim to Medicare.

(f) State that the beneficiary or his or her legal representative understands that Medicare payment will not be made for any items or services furnished by the physician or practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted.

(g) State that the beneficiary or his or her legal representative enters into this contract with the knowledge that he or she has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted-out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted-out.

(h) State the expected or known effective date and the expected or known expiration date of the current 2-year opt-out period.

(i) State that the beneficiary or his or her legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare.

(j) Be signed by the beneficiary or his or her legal representative and by the physician or practitioner.

(k) Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician or practitioner may

furnish emergency or urgent care services to a Medicare beneficiary in accordance with § 405.440.)

(l) Be provided (a photocopy is permissible) to the beneficiary or to his or her legal representative before items or services are furnished to the beneficiary under the terms of the contract.

(m) Be retained (original signatures of both parties required) by the physician or practitioner for the duration of the current 2-year opt-out period.

(n) Be made available to CMS upon request.

(o) Be entered into for each 2-year opt-out period.

[63 FR 58901, Nov. 2, 1998, as amended at 80 FR 71370, Nov. 16, 2015]

§ 405.420 Requirements of the opt-out affidavit.

An affidavit under this subpart must:

(a) Be in writing and be signed by the physician or practitioner.

(b) Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number, if one has been assigned, uniform provider identification number (UPIN) if one has been assigned, or, if neither an NPI nor a UPIN has been assigned, the physician's or practitioner's tax identification number (TIN).

(c) State that, except for emergency or urgent care services (as specified in § 405.440), during the opt-out period the physician or practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of paragraph § 405.415 for services that, but for their provision under a private contract, would have been Medicare-covered services.

(d) State that the physician or practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician or practitioner permit any entity acting on his or her behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 405.440.

(e) State that, during the opt-out period, the physician or practitioner understands that he or she may receive no direct or indirect Medicare payment for services that he or she furnishes to Medicare beneficiaries with whom he or she has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan.

(f) State that a physician or practitioner who opts-out of Medicare acknowledges that, during the opt-out period, his or her services are not covered under Medicare and that no Medicare payment may be made to any entity for his or her services, directly or on a capitated basis.

(g) State a promise by the physician or practitioner to the effect that, during the opt-out period, the physician or practitioner agrees to be bound by the terms of both the affidavit and the private contracts that he or she has entered into.

(h) Acknowledge that the physician or practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician or practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom he or she has not previously privately contracted) without regard to any payment arrangements the physician or practitioner may make.

(i) With respect to a physician who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit.

(j) Acknowledge that the physician or practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of § 405.440 apply if the physician furnishes such services.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014]

§ 405.425 Effects of opting-out of Medicare.

If a physician or practitioner opts-out of Medicare in accordance with this

subpart, the following results obtain during the opt-out period:

(a) Except as provided in § 405.440, no payment may be made directly by Medicare or by any Medicare Advantage plan to the physician or practitioner or to any entity to which the physician or practitioner reassigns his right to receive payment for services.

(b) The physician or practitioner may not furnish any item or service that would otherwise be covered by Medicare (except for emergency or urgent care services) to any Medicare beneficiary except through a private contract that meets the requirements of this subpart.

(c) The physician or practitioner is not subject to the requirement to submit a claim for items or services furnished to a Medicare beneficiary, as specified in § 424.5(a)(6) of this chapter, except as provided in § 405.440.

(d) The physician or practitioner is prohibited from submitting a claim to Medicare for items or services furnished to a Medicare beneficiary except as provided in § 405.440.

(e) In the case of a physician, he or she is not subject to the limiting charge provisions of § 414.48 of this chapter, except for services provided under § 405.440.

(f) The physician or practitioner is not subject to the prohibition-on-reassignment provisions of § 414.80 of this chapter, except for services provided under § 405.440.

(g) In the case of a practitioner, he or she is not prohibited from billing or collecting amounts from beneficiaries (as provided in 42 U.S.C. 1395u(b)(18)(B)).

(h) The death of a beneficiary who has entered into a private contract (or whose legal representative has done so) does not invoke § 424.62 or § 424.64 of this chapter with respect to the physician or practitioner with whom the beneficiary (or legal representative) has privately contracted.

(i) The physician or practitioner who has not been excluded under sections 1128, 1156 or 1892 of the Act and whose Medicare enrollment is not revoked under § 424.535 of this chapter may order, certify the need for, prescribe, or refer a beneficiary for Medicare-covered items, services, and drugs, provided the physician or practitioner is not paid, directly or indirectly, for such services (except as provided in § 405.440).

(j) The physician or practitioner who is excluded under sections 1128, 1156 or 1892 of the Act or whose Medicare enrollment is revoked under § 424.535 of this chapter may not order, prescribe or certify the need for Medicare-covered items, services, and drugs except, with respect to exclusions, as provided in § 1001.1901 of this title, and must otherwise comply with the terms of any exclusion in accordance with § 1001.1901 of this title effective with the date of the exclusion.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014; 80 FR 71370, Nov. 16, 2015; 84 FR 47852, Sept. 10, 2019]

§ 405.430 Failure to properly opt-out.

(a) A physician or practitioner fails to properly opt-out if—

(1) Any private contract between the physician or practitioner and a Medicare beneficiary, that was entered into before the affidavit described in § 405.420 was filed, does not meet the specifications of § 405.415; or

(2) He or she fails to submit the affidavit(s) in accordance with § 405.420.

(b) If a physician or practitioner fails to properly opt-out in accordance with paragraph (a) of this section, the following results obtain:

(1) The physician's or practitioner's attempt to opt-out of Medicare is nullified, and all of the private contracts between the physician or practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt-out are deemed null and void.

(2) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician is subject to the limiting charge provisions of § 414.48 of this chapter. A participating physician is subject to the limitations on charges of the participation agreement he or she signed.

(3) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(4) The practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts.

(5) The physician or practitioner may make another attempt to properly opt-out at any time.

§ 405.435 Failure to maintain opt-out.

(a) A physician or practitioner fails to maintain opt-out under this subpart if, during the opt-out period—

(1) He or she knowingly and willfully—

(i) Submits a claim for Medicare payment (except as provided in § 405.440); or

(ii) Receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in § 405.440).

(2) He or she fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into contracts that fail to meet the specifications of § 405.415; or

(3) He or she fails to comply with the provisions of § 405.440 regarding billing for emergency care services or urgent care services; or

(4) He or she fails to retain a copy of each private contract that he or she has entered into for the duration of the current 2-year period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

(b) If a physician or practitioner fails to maintain opt-out in accordance with paragraph (a) of this section, then, for the remainder of the opt-out period, except as provided by paragraph (d) of this section—

(1) All of the private contracts between the physician or practitioner and Medicare beneficiaries are deemed null and void.

(2) The physician's or practitioner's opt-out of Medicare is nullified.

(3) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

(4) The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as provided in paragraph (c) of this section.

(5) The physician is subject to the limiting charge provisions of § 414.48 of this chapter.

(6) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(7) The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.

(8) The physician or practitioner may not attempt to once more meet the criteria for properly opting-out until the current 2-year period expires.

(c) Medicare payment may be made for the claims submitted by a beneficiary for the services of an opt-out physician or practitioner when the physician or practitioner did not privately contract with the beneficiary for services that were not emergency care services or urgent care services and that were furnished no later than 15 days after the date of a notice by the carrier that the physician or practitioner has opted-out of Medicare.

(d) If a physician or practitioner demonstrates that he or she has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract) within 45 days of a notice from the Medicare Administrative Contractor of a violation of paragraph (a) of this section, then the requirements of paragraphs (b)(1) through (8) of this section are not applicable. In situations where a violation of paragraph (a) of this section is not discovered by the Medicare Administrative Contractor during the current 2-year period when the violation actually occurred, then the requirements of paragraphs (b)(1) through (8) of this section are applicable from the date that the first violation of paragraph (a) of this section occurred until the end of the 2-year period during which the violation occurred unless the physician or practitioner takes good faith efforts, within 45 days of any notice from the Medicare Administrative Contractor that the physician or practitioner failed to maintain opt-out, or within 45 days of the physician's or practitioner's discovery of the failure to

maintain opt-out, whichever is earlier, to correct his or her violations of paragraph (a) of this section. Good faith efforts include, but are not limited to, refunding any amounts collected in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract.

[63 FR 58901, Nov. 2, 1998, as amended at 70 FR 70329, Nov. 21, 2005; 80 FR 71370, Nov. 16, 2015]

§ 405.440 Emergency and urgent care services.

(a) A physician or practitioner who has opted-out of Medicare under this subpart need not enter into a private contract to furnish emergency care services or urgent care services to a Medicare beneficiary. Accordingly, a physician or practitioner will not be determined to have failed to maintain opt-out if he or she furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, provided the physician or practitioner complies with the billing requirements specified in paragraph (b) of this section.

(b) When a physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, he or she:

(1) Must submit a claim to Medicare in accordance with both 42 CFR part 424 and Medicare instructions (including but not limited to complying with proper coding of emergency or urgent care services furnished by physicians and practitioners who have opted-out of Medicare).

(2) May collect no more than—

(i) The Medicare limiting charge, in the case of a physician; or

(ii) The deductible and coinsurance, in the case of a practitioner.

(c) Emergency care services or urgent care services furnished to a Medicare beneficiary with whom the physician or practitioner has previously entered into a private contract (that is, entered into before the onset of the emergency medical condition or urgent medical condition), are furnished under the terms of the private contract.

(d) Medicare may make payment for emergency care services or urgent care services furnished by a physician or practitioner who has properly opted-out when the services are furnished and the claim for services is made in accordance with this section. A physician or practitioner who has been excluded must comply with the regulations at §1001.1901 (Scope and effect of exclusion) of this title when he or she furnishes emergency services to beneficiaries and may not bill and be paid for urgent care services.

§ 405.445 Cancellation of opt-out and early termination of opt-out.

(a) A physician or practitioner may cancel opt-out by submitting a written notice to each Medicare Administrative Contractor to which he or she would file claims absent the opt-out, not later than 30 days before the end of the current 2-year opt-out period, indicating that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.

(b) To properly terminate opt-out a physician or practitioner must:

(1) Not have previously opted out of Medicare.

(2) Notify all Medicare Administrative Contractors, with which he or she filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the initial 2-year period.

(3) Refund to each beneficiary with whom he or she has privately contracted all payment collected in excess of:

(i) The Medicare limiting charge (in the case of physicians); or

(ii) The deductible and coinsurance (in the case of practitioners).

(4) Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner's decision to terminate opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out

and the effective date of the termination of the opt-out period.

(c) When the physician or practitioner properly terminates opt-out in accordance with paragraph (b), he or she will be reinstated in Medicare as if there had been no opt-out, and the provision of § 405.425 shall not apply unless the physician or practitioner subsequently properly opts out.

(d) A physician or practitioner who has completed opt-out on or before January 1, 1999 may terminate opt-out during the 90 days following January 1, 1999 if he or she notifies all carriers to whom he or she would otherwise submit claims of the intent to terminate opt-out and complies with paragraphs (b)(3) and (4) of this section. Paragraph (c) of this section applies in these cases.

[63 FR 58901, Nov. 2, 1998, as amended at 80 FR 71371, Nov. 16, 2015]

§ 405.450 Appeals.

(a) A determination by CMS that a physician or practitioner has failed to properly opt out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, failed to properly terminate opt-out, or failed to properly cancel opt-out is an initial determination for purposes of § 498.3(b) of this chapter.

(b) A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted-out is an initial determination for purposes of § 405.924.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014; 80 FR 71371, Nov. 16, 2015]

§ 405.455 Application to Medicare Advantage contracts.

An organization that has a contract with CMS to provide one or more Medicare Advantage (M + C) plans to beneficiaries (part 422 of this chapter):

(a) Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted-out of Medicare.

(b) Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted-out of Medicare.

(c) May make payment to a physician or practitioner who furnishes emergency or urgent care services to a beneficiary who has not previously entered into a private contract with the physician or practitioner in accordance with § 405.440.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014]

Subpart E—Criteria for Determining Reasonable Charges

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 32 FR 12599, Aug. 31, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.500 Basis.

Subpart E is based on the provisions of the following sections of the Act: Section 1814(b) provides for Part A payment on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1832 establishes the scope of benefits provided under the Part B supplementary medical insurance program. Section 1833(a) sets forth the amounts of payment for supplementary medical insurance services on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1834(a) specifies how payments are made for the purchase or rental of new and used durable medical equipment for Medicare beneficiaries. Section 1834(b) provides for payment for radiologist services on a fee schedule basis. Section 1834(c) provides for payments and standards for screening mammography. Section 1842(b) sets forth the provisions for a carrier to enter into a contract with the Secretary and to make determinations with respect to Part B claims. Section 1842(h) sets forth the requirements for a physician or supplier to voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. Section 1842(i) sets forth the provisions for the payment of Part B claims. Section 1848 establishes a fee schedule for payment of physician services. Section 1861(b) sets forth the inpatient hospital services covered by the Medicare program. Section 1861(s) sets forth medical and other health

services covered by the Medicare program. Section 1861(v) sets forth the general authority under which CMS may establish limits on provider costs recognized as reasonable in determining Medicare program payments. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program. Section 1861(jj) defines the term ''covered osteoporosis drug.'' Section 1862(a)(14) lists services that are excluded from coverage. Section 1866(a) specifies the terms for provider agreements. Section 1881 authorizes special rules for the coverage of and payment for services furnished to patients with end-stage renal disease. Section 1886 sets forth the requirements for payment to hospitals for inpatient hospital services. Section 1887 sets forth requirements for payment of provider-based physicians and payment under certain percentage arrangements. Section 1889 provides for Medicare and Medigap information by telephone.

[60 FR 63175, Dec. 8, 1995]

§ 405.501 Determination of reasonable charges.

(a) Except as specified in paragraphs (b), (c), and (d) of this section, Medicare pays no more for Part B medical and other health services than the ''reasonable charge'' for such service. The reasonable charge is determined by the carriers (subject to any deductible and coinsurance amounts as specified in §§ 410.152 and 410.160 of this chapter).

(b) Part B of Medicare pays on the basis of ''reasonable cost'' (see part 413 of this chapter) for certain institutional services, certain services furnished under arrangements with institutions, and services furnished by entities that elect to be paid on a cost basis (including health maintenance organizations, rural health clinics, FQHCs that are authorized to bill under a reasonable cost system, and end-stage renal disease facilities).

(c) Carriers will determine the reasonable charge on the basis of the criteria specified in § 405.502, and the customary and prevailing charge screens in effect when the service was furnished. (Also see §§ 415.55 through 415.70 and §§ 415.100 through 415.130 of this chapter, which pertain to the determination of reimbursement for services performed by hospital-based physicians.) However, when services are furnished more than 12 months before the beginning of the fee screen year (January 1 through December 30) in which a request for payment is made, payment is based on the customary and prevailing charge screens in effect for the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is made.

(d) Payment under Medicare Part B for durable medical equipment and prosthetic and orthotic devices is determined in accordance with the provisions of subpart D of part 414 of this chapter.

[47 FR 63274, Dec. 31, 1981, as amended at 51 FR 34978, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986; 54 FR 9003, Mar. 2, 1989; 57 FR 24975, June 12, 1992; 57 FR 33896, July 31, 1992; 57 FR 57688, Dec. 7, 1992; 60 FR 63176, Dec. 8, 1995; 79 FR 25473, May 2, 2014]

§ 405.502 Criteria for determining reasonable charges.

(a) *Criteria.* The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:

(1) The customary charges for similar services generally made by the physician or other person furnishing such services.

(2) The prevailing charges in the locality for similar services.

(3) In the case of physicians' services, the prevailing charges adjusted to reflect economic changes as provided under § 405.504 of this subpart.

(4) In the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services), the inflation-indexed charge as determined under § 405.509.

(5) [Reserved]

(6) In the case of medical services, supplies, and equipment (including equipment servicing) that the Secretary judges do not generally vary significantly in quality from one supplier

to another, the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality.

(7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by CMS or a carrier if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in the grossly deficient or excessive charges. The determination of these limits is described in paragraphs (g) and (h) of this section.

(8) In the case of laboratory services billed by a physician but performed by an outside laboratory, the payment levels established in accordance with the criteria stated in § 405.515.

(9) Except as provided in paragraph (a)(10) of this section, in the case of services of assistants-at-surgery as defined in § 405.580 in teaching and nonteaching settings, charges that are not more than 16 percent of the prevailing charge in the locality, adjusted by the economic index, for the surgical procedure performed by the primary surgeon. Payment is prohibited for the services of an assistant-at-surgery in surgical procedures for which CMS has determined that assistants-at-surgery on average are used in less than 5 percent of such procedures nationally.

(10) In the case of services of assistants at surgery that meet the exception under § 415.190(c)(2) or (c)(3) of this chapter because the physician is performing a unique, necessary, specialized medical service in the total care of a patient during surgery, reasonable charges consistent with prevailing practice in the carrier's service area rather than the special assistant at surgery rate.

(b) *Comparable services limitation.* The law also specifies that the reasonable charge cannot be higher than the charge applicable for a comparable service under comparable circumstances to the carriers' own policyholders and subscribers.

(c) *Application of criteria.* In applying these criteria, the carriers are to exercise judgment based on factual data on the charges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable.

(d) *Responsibility of Administration and carriers.* Determinations by carriers of reasonable charge are not reviewed on a case-by-case basis by the Centers for Medicare & Medicaid Services, although the general procedures and performance of functions by carriers are evaluated. In making determinations, carriers apply the provisions of the law under broad principles issued by the Centers for Medicare & Medicaid Services. These principles are intended to assure overall consistency among carriers in their determinations of reasonable charge. The principles in §§ 405.503 through 405.507 establish the criteria for making such determinations in accordance with the statutory provisions.

(e) *Determination of reasonable charges under the End-Stage Renal Disease (ESRD) Program*—(1) *General.* Reasonable charges for renal-related items and services (furnished in connection with transplantation or dialysis) must be related to costs and allowances that are reasonable when the treatments are furnished in an effective and economical manner.

(2) *Nonprovider (independent) dialysis facilities.* Reasonable charges for renal-related items and services furnished before August 1, 1983 must be determined related to costs and charges prior to July, 1973, in accordance with the regulations at § 405.541. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(3) *Provider services and (hospital-based) dialysis facilities.* Renal-related items and services furnished by providers, or by ESRD facilities based in hospitals, before August 1, 1983 are paid for under the provider reimbursement provisions found generally in part 413 of this chapter. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(4) *Physicians' services.* Reasonable charges for renal-related physicians' services must be determined considering charges made for other services involving comparable physicians' time and skill requirements, in accordance with regulations at §§ 405.542 and 405.543.

(5) *Health maintenance organizations (HMOs).* For special rules concerning the reimbursement of ESRD services furnished by risk-basis HMOs, or by facilities owned or operated by or related to such HMOs by common ownership or control, see §§ 405.2042(b)(14) and 405.2050(c).

(f) *Determining payments for certain physician services furnished in outpatient hospital settings*—(1) *General rule.* If physician services of the type routinely furnished in physicians' offices are furnished in outpatient hospital settings before January 1, 1992, carriers determine the reasonable charge for those services by applying the limits described in paragraph (f)(5) of this section.

(2) *Definition.* As used in this paragraph (f), *outpatient settings* means—

(i) Hospital outpatient departments, including clinics and emergency rooms; and

(ii) Comprehensive outpatient rehabilitation facilities.

(3) *Services covered by limits.* The carrier establishes a list of services routinely furnished in physicians' offices in the area. The carrier has the discretion to determine which professional services are routinely furnished in physicians' offices, based on current medical practice in the area. Listed below are some examples of routine services furnished by office-based physicians.

Examples

Review of recent history, determination of blood pressure, ausculation of heart and lungs, and adjustment of medication.

Brief history and examination, and initiation of diagnostic and treatment programs.

Treatment of an acute respiratory infection.

(4) *Services excluded from limits.* The limits established under this paragraph do not apply to the following:

(i) Rural health clinic services.

(ii) Surgical services included on the ambulatory surgical center list of procedures published under § 416.65(c) of this chapter.

(iii) Services furnished in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the patient's health in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(iv) Anesthesiology services and diagnostic and therapeutic radiology services.

(v) Federally qualified health center services paid under the rules in part 405 subpart X.

(5) *Methodology for developing limits*—(i) *Development of a charge base.* The carrier establishes a charge base for each service identified as a routine office-based physician service. The charge base consists of the prevailing charge in the locality for each such service adjusted by the economic index. The carrier uses the prevailing charges that apply to services by nonspecialists in office practices in the locality in which the outpatient setting is located.

(ii) *Calculation of the outpatient limits.* The carrier calculates the charge limit for each service by multiplying the charge base amount for each service by .60.

(6) *Application of limits.* The reasonable charge for physician services of the type described in paragraph (f)(3) of this section that are furnished in an outpatient setting is the lowest of the actual charges, the customary charges in accordance with § 405.503, the prevailing charges applicable to these services in accordance with § 405.504, or the charge limits calculated in paragraph (f)(5)(ii) of this section.

(g) *Determination of payment amounts in special circumstances*—(1) *General.* (i) For purposes of this paragraph (g), a ''category of items or services'' may consist of a single item or service or any number of items or services.

(ii) CMS or a carrier may determine that the standard rules for calculating

payment amounts set forth in this subpart for a category of items or services identified in section 1861(s) of the Act (other than physicians' services paid under section 1848 of the Act and those items and services for which payment is made under a prospective payment system, such as outpatient hospital services or home health services) will result in grossly deficient or excessive amounts. A payment amount will not be considered grossly excessive or deficient if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount. For CMS-initiated adjustments, CMS will publish in the FEDERAL REGISTER an analysis of payment adjustments that exceed $100 million per year in compliance with Executive Order 12866. If CMS makes adjustments that have a significant effect on a substantial number of small entities, it will publish an analysis in compliance with the Regulatory Flexibility Act.

(iii) If CMS or the carrier determines that the standard rules for calculating payment amounts for a category of items or services will result in grossly deficient or excessive amounts, CMS, or the carrier, may establish special payment limits that are realistic and equitable for a category of items or services. If CMS makes a determination, it is considered a national determination. A carrier determination is one made by a carrier or intermediary or groups of carriers or intermediaries even if the determination applies to payment in all States.

(iv) The limit on the payment amount is either an upper limit to correct a grossly excessive payment amount or a lower limit to correct a grossly deficient payment amount.

(v) The limit is either a specific dollar amount or is based on a special method to be used in determining the payment amount.

(vi) Except as provided in paragraph (h) of this section, a payment limit for a given year may not vary by more than 15 percent from the payment amount established for the preceding year.

(vii) *Examples of excessive or deficient payment amounts.* Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to, the following:

(A) The marketplace is not competitive. This includes circumstances in which the marketplace for a category of items or services is not truly competitive because a limited number of suppliers furnish the item or service.

(B) Medicare and Medicaid are the sole or primary sources of payment for a category of items or services.

(C) The payment amounts for a category of items or services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.

(D) The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services, taking into account the relative costs of furnishing the category of items or services in the different localities.

(E) Payment amounts for a category of items or services are grossly higher or lower than acquisition or production costs for the category of items or services.

(F) There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology.

(G) The payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

(H) A new technology exists which is not reflected in the existing payment allowances.

(2) *Establishing a limit.* In establishing a payment limit for a category of items or services, CMS or a carrier considers the available information that is relevant to the category of items or services and establishes a payment amount that is realistic and equitable. The factors CMS or a carrier considers in establishing a specific dollar amount or special payment method for a category of items or services may include, but are not limited to, the following:

(i) *Price markup.* Price markup is the relationship between the retail and

wholesale prices or manufacturer's costs of a category of items or services. If information on a particular category of items or services is not available, CMS or a carrier may consider the price markup on a similar category of items or services and information on general industry pricing trends.

(ii) *Differences in charges.* CMS or a carrier may consider the differences in charges for a category of items or services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* CMS or a carrier may consider resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items or services.

(iv) *Use.* CMS or a carrier may impute a reasonable rate of use for a category of items or services and consider unit costs based on efficient use.

(v) *Payment amounts in other localities.* CMS or a carrier may consider payment amounts for a category of items or services furnished in another locality.

(3) *Notification of limits*—(i) *National limits.* CMS publishes in the FEDERAL REGISTER proposed and final notices announcing a special payment limit described in paragraph (g) of this section before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services.

(ii) *Carrier-level limits.* (A) A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and Medicaid agencies of the proposed payment amounts and the factors it considered in proposing the particular limit, as described in paragraphs (g)(1) through (g)(4) of this section and must solicit comments. The notice must also consider the following:

(*1*) The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

(*2*) What entities would be affected, such as classes of providers or suppliers and beneficiaries.

(*3*) How significantly would these entities be affected.

(*4*) How would the adjustment affect beneficiary access to items or services.

(B) Before publication of a final notice, the carrier must—

(*1*) Evaluate the comments it receives on the proposed notice.

(*2*) Notify CMS in writing of any final limits it plans to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification.

(*3*) After receipt of CMS' acknowledgement, inform the affected suppliers and State Medicaid agencies of any final limits it establishes.

(C) The effective date for a final payment limit may apply to services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit.

(4) *Use of valid and reliable data.* In determining whether a payment amount is grossly excessive or deficient and in establishing an appropriate payment amount, valid and reliable data are used. To ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

(5) *Review of market prices.* If CMS or a carrier makes a payment adjustment of more than 15 percent under this paragraph (g), CMS or the carrier will review market prices in the years subsequent to the year that the initial reduction is effective in order to ensure that further reductions continue to be appropriate.

(h) *Special payment limit adjustments greater than 15 percent of the payment amount.* In addition to applying the general rules under paragraphs (g)(1) through (g)(5) of this section, CMS applies the following rules in establishing a payment adjustment greater than 15 percent of the payment amount for a category of items or services within a year:

(1) *Potential impact of special limit.* CMS considers the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

(2) *Supplier consultation.* Before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consults with representatives of the supplier industry likely to be affected by the change in the payment amount.

(3) *Publication of national limits.* If CMS determines under this paragraph (h) to establish a special payment limit for a category of items or services, it publishes in the FEDERAL REGISTER the proposed and final notices of a special payment limit before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to the limit for the category of items or services.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Paramedic intercept ambulance services.* (1) CMS establishes its payment allowance on a carrier-wide basis by using the median allowance from all

localities within an individual carrier's jurisdiction.

(2) CMS's payment allowance is equal to the advanced life support rate minus 40 percent of the basic life support rate.

(3) CMS bases payment on the lower of the actual charge or the amount described in paragraph (i)(1) and (i)(2) of this section.

(Secs. 1102, 1814(b), 1833(a), 1842(b), and (h), and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, as amended, 79 Stat. 296, 302, 310, 331; 86 Stat. 1395, 1454; 42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1).

[32 FR 12599, Aug. 31, 1967]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 405.502, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 405.503 Determining customary charges.

(a) *Customary charge defined.* The term ''customary charges'' will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service. In determining such uniform amount, token charges for charity patients and substandard charges for welfare and other low income patients are to be excluded. The reasonable charge cannot, except as provided in § 405.506, be higher than the individual physician's or other person's customary charge. The customary charge for different physicians or other persons may, of course, vary. Payment for covered services would be based on the actual charge for the service when, in a given instance, that charge is less than the amount which the carrier would otherwise have found to be within the limits of acceptable charges for the particular service. Moreover, the income of the individual beneficiary is not to be taken into account by the carrier in determining the amount which is considered to be a reasonable charge for a service rendered to him. There is no provision in the law for a carrier to evaluate the reasonableness of charges in light of an individual beneficiary's economic status.

(b) *Variation of charges.* If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a ''customary charge'' for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's ''customary'' charge. Use of relative value scales will help in arriving at a decision in such instances.

(c) *Use of relative value scales.* If, for a particular medical procedure or service, the carrier is unable to determine the customary charge on the basis of reliable statistical data (for example, because the carrier does not yet have sufficient data or because the performance of the particular medical procedure or service by the physician or other person is infrequent), the carrier may use appropriate relative value scales to determine the customary charge for such procedure or service in relation to customary charges of the same physician or person for other medical procedures and services.

(d) *Revision of customary charge.* A physician's or other person's customary charge is not necessarily a static amount. Where a physician or other person alters his charges, a revised pattern of charges for his services may develop. Where on the basis of adequate evidence, the carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered thereafter to supplementary insurance beneficiaries. If the new customary charge is not above the top of the range of prevailing charges (see § 405.504(a)), it should be deemed to be reasonable by the carrier, subject to the provisions of § 405.508.

§ 405.504 Determining prevailing charges.

(a) *Ranges of charges.* (1) In the case of physicians' services furnished beginning January 1, 1987, the prevailing charges for a nonparticipating physician as defined in this paragraph will be no higher than the same level that was set for services furnished during the previous calendar year for a physician who was a participating physician during that year. A nonparticipating physician is a physician who has not entered into an agreement with the Medicare program to accept payment on an assignment-related basis (in accordance with § 424.55 of this chapter) for all items and services furnished to individuals enrolled under Part B of Medicare during a given calendar year.

(2) No charge for Part B medical or other health services may be considered to be reasonable if it exceeds the higher of:

(i) The prevailing charge for similar services in the same locality in effect on December 31, 1970, provided such prevailing charge had been found acceptable by CMS; or

(ii) The prevailing charge that, on the basis of statistical data and methodology acceptable to CMS, would cover:

(A) 75 percent of the customary charges made for similar services in the same locality during the 12-month period of July 1 through June 30 preceding the fee screen year (January 1 through December 31) in which the service was furnished; or

(B) In the case of services furnished more than 12 months before the beginning of the fee screen year (January 1 through December 31) in which the claim or request for payment is submitted, 75 percent of the customary charges made for similar services in the same locality during the 12 month period of July 1 through June 30 preceding the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is submitted.

(3)(i) In the case of physicians' services, furnished before January 1, 1992, each prevailing charge in each locality may not exceed the prevailing charge determined for the FY ending June 30, 1973 (without reference to the adjustments made in accordance with the economic stabilization program then in effect), except on the basis of appropriate economic index data that demonstrate the higher prevailing charge level is justified by:

(A) Changes in general earnings levels of workers that are attributable to factors other than increases in their productivity; and

(B) changes in expenses of the kind incurred by physicians in office practice. The office-expense component and the earnings component of such index shall be given the relative weights shown in data on self-employed physicians' gross incomes.

Example. The available data indicate the office-expense and earnings components of the index should be given relative weights of 40 percent and 60 percent, respectively, and it is calculated that the aggregate increase in expenses of practice for a particular July through June period was 112 percent over the expenses of practice for calendar year 1971 and the increase in earnings (less increases in workers' productivity was 110 percent over the earnings for calendar year 1971. The allowable increase in any prevailing charge that could be recognized during the next fee screen year would be 110.8 percent $((.40 \times 112) + (.60) \times 110) = 110.8)$ above the prevailing charge recognized for fiscal year 1973.

(ii)(A) If the increase in the prevailing charge in a locality for a particular physician service resulting from an aggregate increase in customary charges for that service does not exceed the index determined under paragraph (a)(3)(i) of this section, the increase is permitted and any portion of the allowable increase not used is carried forward and is a basis for justifying increases in that prevailing charge in the future. However, if the increase in the prevailing charge exceeds the allowable increase, the increase will be reduced to the allowable amount. Further increases will be justified only to the degree that they do not exceed further rises in the economic index. The prevailing charge for physicians' services furnished during the 15-month period beginning July 1, 1984 may not exceed the prevailing charge for physicians' services in effect for the 12-month period beginning July 1, 1983. The increase in prevailing charges for physicians' services for subsequent fee screen years similarly may

not reflect the rise in the economic index that would have otherwise been provided for the period beginning July 1, 1984, and must be treated as having fully provided for the rise in the economic index which would have been otherwise taken into account.

(B) Notwithstanding the provisions of paragraphs (a)(3)(i) and (ii)(A) of this section, the prevailing charge in the case of a physician service in a particular locality determined pursuant to paragraphs (a)(2) and (3)(i) of this section for the fiscal year beginning July 1, 1975, and for any subsequent fee screen years, if lower than the prevailing charge for the fiscal year ending June 30, 1975, by reason of the application of economic index data, must be raised to such prevailing charge which was in effect for the fiscal year ending June 30, 1975. (If the amount paid on any claim processed by a carrier after the original reasonable charge update for the fiscal year beginning July 1, 1975, and prior to the adjustments required by the preceding sentence, was at least $1 less than the amount due pursuant to the preceding sentence, the difference between the amount previously paid and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously paid and the amount due is less than $1.)

(iii) If, for any reason, a prevailing charge for a service in a locality has no precise counterpart in the carrier's charge data for calendar year 1971 (the data on which the prevailing charge calculations for fiscal year 1973 were based), the limit on the prevailing charge will be estimated, on the basis of data and methodology acceptable to CMS, to seek to produce the effect intended by the economic index criterion. The allowance or reduction of an increase in a prevailing charge for any individual medical item or service may affect the allowance or reduction of an increase in the prevailing charges for other items or services if, for example, the limit on the prevailing charge is estimated, or if the prevailing charges for more than one item or service are established through the use of a relative value schedule and dollar conversion factors.

(b) *Variation in range of prevailing charges.* The range of prevailing charges in a locality may be different for physicians or other persons who engage in a specialty practice or service than for others. Existing differentials in the level of charges between different kinds of practice or service could, in some localities, lead to the development of more than one range of prevailing charges for application by the carrier in its determinations of reasonable charges. Carrier decisions in this respect should be responsive to the existing patterns of charges by physicians and other persons who render covered services, and should establish differentials in the levels of charges between different kinds of practice or service only where in accord with such patterns.

(c) *Re-evaluation and adjustment of prevailing charges.* Determinations of prevailing charges by the carrier are to be re-evaluated and adjusted from time to time on the basis of factual information about the charges made by physicians and other persons to the public in general. This information should be obtained from all possible sources including a carrier's experience with its own programs as well as with the supplementary medical insurance program.

(d) *Computation and issuance of the MEI after CY 1992*—(1) For update years after CY 1992, the MEI is a physician input price index, in which the annual percent changes for the direct-labor price components are adjusted by an annual percent change in a 10-year moving average index of labor productivity in the nonfarm business sector.

(2) The MEI is constructed, using as a base year, CY 1989 weights and annual percent changes in the economic price proxies as shown on the following chart:

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense category	1989 weights [1] [2] (percent)	Price proxy [3]
Total	100.0	
1. Physician's Own Time (net income, general earnings).	54.2	
a. Wages and Salaries	45.3	Average hourly earnings, total private non-farm. [4]
b. Fringe Benefits	8.8	Employment Cost Index, fringe benefits, private non-farm. [4]
2. Physician Practice Expense	45.8	
a. Non-physician Employee Compensation	16.3	
(1) Wages and Salaries	13.8	Employment Cost Index, wages and salaries weighted for occupational mix of non-physician employees. [4]
(2) Fringe Benefits	2.5	Employment Cost Index, fringe benefits, white collar. [4]
b. Office Expense	10.3	CPI-U, housing.
c. Medical Materials and Supplies	5.2	PPI, ethical drugs; PPI, surgical appliances and supplies; and CPI-U medical equipment and supplies (equally weighted).
d. Professional Liability Insurance	4.8	CMS survey of change in average liability premiums for $100,000/$300,000 liability coverage among 9 major insurers.
e. Medical Equipment	2.3	PPI, medical instruments and equipment.
f. Other Professional Expense	6.9	
(1) Professional Car	1.4	CPI-U, private transportation.
(2) Other	5.5	CPI-U, all items less food and energy.

[1] Sources: Martin L. Gonzalez, ed.: *Physician Marketplace Statistics, Fall, 1990.* Center for Health Policy Research, Chicago, American Medical Association, 1990; Mark Holoweiko, ''Practice Expenses Take the Leap of the Decade,'' *Medical Economics,* November 12, 1990; and CMS, OACT special study.
[2] Due to rounding, weights may not sum to 100.0%
[3] All price proxies are for *annual* percent changes for the 12 months ending June 30th.
[4] Annual percent change values for Physicians' Own Time and Non-physician Employee Compensation are net of the change in the 10-year moving average of output per man-hour to exclude changes in non-farm business sector labor productivity.

(3) If there is no methodological change, CMS publishes a notice in the FEDERAL REGISTER to announce the annual increase in the MEI before the beginning of the update year to which it applies. If there are changes in the base year weights or price proxies, or if there are any other MEI methodological changes, they are published in the FEDERAL REGISTER with an opportunity for public comment.

[32 FR 12600, Aug. 31, 1967, as amended at 40 FR 25447, June 16, 1975; 42 FR 18275, Apr. 6, 1977. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 4430, Feb. 2, 1978; 47 FR 63274, Dec. 31, 1982; 51 FR 34978, Oct. 1, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 55912, Nov. 25, 1992]

§ 405.505 Determination of locality.

''Locality'' is the geographical area for which the carrier is to derive the reasonable charges or fee schedule amounts for services or items. Usually, a locality may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical services areas (interstate or otherwise), comparable in concept to ''trade areas.'' Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore shall delineate localities on the basis of their knowledge of local conditions. However, distinctions between localities are not to be so finely made that a locality includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

[57 FR 27305, June 18, 1992]

§ 405.506 Charges higher than customary or prevailing charges or lowest charge levels.

A charge which exceeds the customary charge of the physician or other person who rendered the medical

or other health service, or the prevailing charge in the locality, or an applicable lowest charge level may be found to be reasonable, but only where there are unusual circumstances, or medical complications requiring additional time, effort or expense which support an additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. The mere fact that the physician's or other person's customary charge is higher than prevailing would not justify a determination that it is reasonable.

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331; 86 Stat. 1395, 1454; (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978]

§ 405.507 Illustrations of the application of the criteria for determining reasonable charges.

The following examples illustrate how the general criteria on customary charges and prevailing charges might be applied in determining reasonable charges under the supplementary medical insurance program. Basically, these examples demonstrate that, except where the actual charge is less, reasonable charges will reflect current customary charges of the particular physician or other person within the ranges of the current prevailing charges in the locality for that type and level of service:

The prevailing charge for a specific medical procedure ranges from $80 to $100 in a certain locality.

Doctor A's bill is for $75 although he customarily charges $80 for the procedure.

Doctor B's bill is his customary charge of $85

Doctor C's bill is his customary charge of $125

Doctor D's bill is for $100, although he customarily charges $80, and there are no special circumstances in the case.

The reasonable charge for Doctor A would be limited to $75 since under the law the reasonable charge cannot exceed the actual charge, even if it is lower than his customary charge and below the prevailing charges for the locality.

The reasonable charge for Doctor B would be $85, because it is his customary charge and it falls within the range of prevailing charges for that locality.

The reasonable charge for Doctor C could not be more than $100, the top of the range of prevailing charges.

The reasonable charge for Doctor D would be $80, because that is his customary charge. Even though his actual charge of $100 falls within the range of prevailing charges, the reasonable charge cannot exceed his customary charge in the absence of special circumstances.

§ 405.508 Determination of comparable circumstances; limitation.

(a) *Application of limitation.* The carrier may not in any case make a determination of reasonable charge which would be higher than the charge upon which it would base payment to its own policyholders for a comparable service in comparable circumstances. The charge upon which it would base payment, however, does not necessarily mean the amount the carrier would be obligated to pay. Under certain circumstances, some carriers pay amounts on behalf of individuals who are their policyholders, which are below the customary charges of physicians or other persons to other individuals. Payment under the supplementary medical insurance program would not be limited to these lower amounts.

(b) *When comparability exists.* ''Comparable circumstances,'' as used in the Act and this subpart, refers to the circumstances under which services are rendered to individuals and the nature of the carrier's health insurance programs and the method it uses to determine the amounts of payments under these programs. Generally, comparability would exist where:

(1) The carrier bases payment under its program on the customary charges, as presently constituted, of physicians or other persons and on current prevailing charges in a locality, and

(2) The determination does not preclude recognition of factors such as speciality status and unusual circumstances which affect the amount charged for a service.

(c) *Responsibility for determining comparability.* Responsibility for determining whether or not a carrier's program has comparability will in the first instance fall upon the carrier in reporting pertinent information about

its programs to the Centers for Medicare & Medicaid Services. When the pertinent information has been reported, the Centers for Medicare & Medicaid Services will advise the carrier whether any of its programs have comparability.

§ 405.509 Determining the inflation-indexed charge.

(a) *Definition.* For purposes of this section, *inflation-indexed charge* means the lowest of the fee screens used to determine reasonable charges (as determined in § 405.503 for the customary charge, § 405.504 for the prevailing charge, this section for the inflation-indexed charge, and § 405.511 for the lowest charge level) for services, supplies, and equipment reimbursed on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor, as described in paragraph (b) of this section.

(b) *Application of inflation adjustment factor to determine inflation-indexed charge.* (1) For fee screen years beginning on or after January 1, 1987, the inflation-indexed charge is determined by updating the fee screen used to determine the reasonable charges in effect on December 31 of the previous fee screen year by application of an inflation adjustment factor, that is, the annual change in the level of the consumer price index for all urban consumers, as compiled by the Bureau of Labor Statistics, for the 12-month period ending on June 30 of each year.

(2) For services, supplies, and equipment furnished from October 1, 1985 through December 31, 1986 the inflation adjustment factor is zero.

(c) The inflation-indexed charge does not apply to any services, supplies, or equipment furnished after December 31, 1991, that are covered under or limited by the fee schedule for physicians' services established under section 1848 of the Act and part 415 of this chapter. These services are subject to the Medicare Economic Index described in § 415.30 of this chapter.

[51 FR 34979, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986, as amended at 56 FR 59621, Nov. 25, 1991]

§ 405.511 Reasonable charges for medical services, supplies, and equipment.

(a) *General rule.* (1) A charge for any medical service, supply, or equipment (including equipment servicing) that in the judgment of CMS generally does not vary significantly in quality from one supplier to another (and that is identified by a notice published in the FEDERAL REGISTER) may not be considered reasonable if it exceeds:

(i) The customary charge of the supplier (see § 405.503);

(ii) The prevailing charge in the locality (see § 405.504);

(iii) The charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the carrier (see § 405.508);

(iv) The lowest charge level at which the item or service is widely and consistently available in the locality (see paragraph (c) of this section); or

(v) The inflation-indexed charge, as determined under § 405.509, in the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services).

(2) In the case of laboratory services, paragraph (a)(1) of this section is applicable to services furnished by physicians in their offices, by independent laboratories (see § 405.1310(a)) and to services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital. Allowance of additional charges exceeding the lowest charge level can be approved by the carrier on the basis of unusual circumstances or medical complications in accordance with § 405.506.

(b) *Public notice of items and services subject to the lowest charge level rule.* Before the Secretary determines that lowest charge levels should be established for an item or service, notice of the proposed determination will be published with an opportunity for public comment. The descriptions or specifications of items or services in the notice will be in sufficient detail to permit a determination that items or services conforming to the descriptions will not vary significantly in quality.

(c) *Calculating the lowest charge level.* The lowest charge level at which an

item or service is widely and consistently available in a locality is calculated by the carrier in accordance with instructions from CMS as follows:

(1) *For items or services furnished on or before December 31, 1986.* (i) A lowest charge level is calculated for each identified item or service in January and July of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the second calendar quarter preceding the determination date. Accordingly, the January calculations will be based on charges for the July through September quarter of the previous calendar year, and the July calculations will be based on charges for the January through March quarter of the same calendar year.

(2) *For items or services furnished on or after January 1, 1987.* (i) A lowest charge level is calculated for each identified item or service in January of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the 3-month period of July 1 through September 30 preceding the fee screen year (January 1 through December 31) for which the item or service was furnished.

(3) *Lowest charge levels for laboratory services.* In setting lowest charge levels for laboratory services, the carrier will consider only charges made for laboratory services performed by physicians in their offices, by independent laboratories which meet coverage requirements, and for services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital.

(d) *Locality.* Subject to the approval of the Secretary, the carrier may designate its entire service area as the locality for purposes of this section, or may otherwise modify the localities used for calculating prevailing charges. (The modified locality for an item or service will also be used for calculating the prevailing charge for that item or service.)

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331, 86 Stat. 1395, 1454 (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978, as amended at 50 FR 40174, Oct. 1, 1985; 51 FR 34979, Oct. 1, 1986]

§ 405.512 Carriers' procedural terminology and coding systems.

(a) *General.* Procedural terminology and coding systems are designed to provide physicians and third party payers with a common language that accurately describes the kinds and levels of services provided and that can serve as a basis for coverage and payment determinations.

(b) *Modification of terminology and/or coding systems.* A carrier that wishes to modify its system of procedural terminology and coding shall submit its request to the Centers for Medicare & Medicaid Services with all pertinent data and information for approval before the revision is implemented. The Centers for Medicare & Medicaid Services will evaluate the proposal in the light of the guidelines specified in paragraph (c) of this section and such other considerations as may be pertinent, and consult with the Assistant Secretary for Health. The Centers for Medicare & Medicaid Services will approve such a revision if it determines that the potential advantages of the proposed new system, outweigh the disadvantages.

(c) *Guidelines.* The following considerations and guidelines are taken into account in evaluating a carrier's proposal to change its system of procedural terminology and coding:

(1) The rationale for converting to the new terminology and coding;

(2) The estimated short-run and long-run impact on the cost of the health insurance program, other medical care costs, administrative expenses, and the reliability of the estimates;

(3) The degree to which the conversion to the proposed new terminology and coding can be accomplished in a way that permits full implementation of the reasonable charge criteria in accordance with the provisions of this subpart;

(4) The degree to which the proposed new terminology and coding are accepted by physicians in the carrier's area (physician acceptance is assumed only if a majority of the Medicare and non-Medicare bills and claims completed by physicians in the area and submitted to the carrier can reasonably be expected to utilize the proposed new terminology and coding);

(5) The extent to which the proposed new terminology and coding system is used by the carrier in its non-Medicare business;

(6) The clarity with which the proposed system defines its terminology and whether the system lends itself to:

(i) Accurate determinations of coverage;

(ii) Proper assessment of the appropriate level of payment; and

(iii) Meeting the carrier's or Professional Standards Review Organizations' review needs and such other review needs as may be appropriate;

(7) Compatibility of the new terminology and coding system with other systems that the carrier and other carriers may utilize in the administration of the Medicare program—e.g., its compatibility with systems and statistical requirements and with the historical data in the carrier's processing system; and

(8) Compatibility of the proposed system with the carriers methods for determining payment under the fee schedule for physicians' services for services which are identified by a single element of terminology but which may vary in content.

[40 FR 7639, Feb. 21, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 10298, Mar. 4, 1994]

§ 405.515 Reimbursement for clinical laboratory services billed by physicians.

This section implements section 1842(h) of the Social Security Act, which places a limitation on reimbursement for markups on clinical laboratory services billed by physicians. If a physician's bill, or a request for payment for a physician's services, includes a charge for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as follows (subject to the coinsurance and deductible provisions at §§ 410.152 and 410.160 of this chapter):

(a) If the bill or request for payment indicates that the test was personally performed or supervised either by the physician who submitted the bill (or for whose services the request for payment was made), or by another physician with whom that physician shares his or her practice, the payment will be based on the physician's reasonable charge for the test (as determined in accordance with § 405.502).

(b) If the bill or request for payment indicates that the test was performed by an outside laboratory, and identifies both the laboratory and the amount the laboratory charged, payment for the test will be based on the lower of—

(1) The laboratory's reasonable charge for the service (as determined in accordance with § 405.502), or

(2) The amount that the laboratory charged the physician for the service.

(c) If the bill or request for payment does not indicate that the conditions specified in paragraph (a) of this section were met, and does not identify both the laboratory and the amount the laboratory charged, payment will be based on the lowest charge at which the carrier estimates the test could have been secured from a laboratory serving the physician's locality. The carrier will estimate this lowest amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier's area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier's service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with § 405.511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this

section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.

(a) *Applicability*—(1) *Payment for drugs and biologicals before January 1, 2004.* Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician's service, a drug or biological furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.

(2) *Payment for drugs and biologicals on or after January 1, 2004.* Effective January 1, 2004, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with part 414, subpart I of this chapter.

(3) *Payment for drugs and biologicals on or after January 1, 2005.* Effective January 1, 2005, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with part 414, subpart K of this chapter.

(b) *Methodology.* Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.

(c) *Multiple-source drugs.* For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

[63 FR 58905, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004; 69 FR 66420, Nov. 15, 2004]

§ 405.520 Payment for a physician assistant's, nurse practitioner's, and clinical nurse specialists' services and services furnished incident to their professional services.

(a) *General rule.* A physician assistant's, nurse practitioner's, and clinical nurse specialists' services, and services and supplies furnished incident to their professional services, are paid in accordance with the physician fee schedule. The payment for a physician assistants' services may not exceed the limits at § 414.52 of this chapter. The payment for a nurse practitioners' and clinical nurse specialists' services may not exceed the limits at § 414.56 of this chapter.

(b) *Requirements.* Medicare payment is made only if all claims for payment are made on an assignment-related basis in accordance with § 424.55 of this chapter, that sets forth, respectively, the conditions for coverage of physician assistants' services, nurse practitioners' services and clinical nurse specialists' services, and services and supplies furnished incident to their professional services.

(c) *Civil money penalties.* Any person or entity who knowingly and willingly bills a Medicare beneficiary amounts in excess of the appropriate coinsurance and deductible is subject to a civil money penalty as described in §§ 402.1(c)(11), 402.105(d)(2)(viii), and 402.107(b)(8) of this chapter.

[63 FR 58905, Nov. 2, 1998, as amended at 66 FR 49547, Sept. 28, 2001]

§ 405.534 Limitation on payment for screening mammography services.

The provisions in paragraphs (a), (b), and (c) of this section apply for services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are paid under the physician fee schedule in accordance with § 414.2 of this chapter.

(a) *Basis and scope.* This section implements section 1834(c) of the Act by establishing a limit on payment for

screening mammography examinations. There are three categories of billing for screening mammography services. Those categories and the payment limitations on each are set forth in paragraphs (b) through (d) of this section.

(b) *Global or complete service billing representing both the professional and technical components of the procedure.* If a fee is billed for a global service, the amount of payment subject to the deductible is equal to 80 percent of the least of the following:

(1) The actual charge for the service.

(2) The amount established for the global procedure for a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at part 414, subpart A.

(3) The payment limit for the procedure. For screening mammography services furnished in CY 1994, the payment limit is $59.63. On January 1 of each subsequent year, the payment limit is updated by the percentage increase in the Medicare Economic Index (MEI) and reflects the relationship between the relative value units for the professional and technical components of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(c) *Professional component billing representing only the physician's interpretation for the procedure.* If the professional component of screening mammography services is billed separately, the amount of payment for that professional component, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the professional component of the service.

(2) The amount established for the professional component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The professional component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

(d) *Technical component billing representing other resources involved in furnishing the procedure.* If the technical component of screening mammography services is billed separately, the amount of payment, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the technical component of the service.

(2) The amount established for the technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The technical component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

[55 FR 53521, Dec. 31, 1990, as amended at 59 FR 49833, Sept. 30, 1994; 66 FR 55328, Nov. 1, 2001]

§ 405.535 Special rule for nonparticipating physicians and suppliers furnishing screening mammography services before January 1, 2002.

The provisions in this section apply for screening mammography services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are physician services pursuant to § 414.2 of this chapter paid under the physician fee schedule. If screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier that does not accept assignment, a limiting charge applies to the charges billed to the beneficiary. The limiting charge is the lesser of the following:

(a) 115 percent of the payment limit set forth in § 405.534(b)(3), (c)(3), and (d)(3) (limitations on the global service, professional component, and technical component of screening mammography services, respectively).

(b) The limiting charge for the global service, professional component, and technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at § 414.48(b) of this chapter.

[59 FR 49833, Sept. 30, 1994, as amended at 62 FR 59098, Oct. 31, 1997; 66 FR 55328, Nov. 1, 2001]

Subparts F– G [Reserved]

Subpart H—Appeals Under the Medicare Part B Program

AUTHORITY: Secs. 1102, 1866(j), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395cc(j), and 1395hh).

SOURCE: 77 FR 29028, May 16, 2012, unless otherwise noted.

§ 405.800 Appeals of CMS or a CMS contractor.

A CMS contractor's (that is, a carrier, Fiscal Intermediary or Medicare Administrative Contractor (MAC)) determination that a provider or supplier fails to meet the requirements for Medicare billing privileges.

(a) *Denial of a provider or supplier enrollment application.* If CMS or a CMS contractor denies a provider's or supplier's enrollment application, CMS or the CMS contractor notifies the provider or supplier by certified mail. The notice includes the following:

(1) The reason for the denial in sufficient detail to allow the provider or supplier to understand the nature of its deficiencies.

(2) The right to appeal in accordance with part 498 of this chapter.

(3) The address to which the written appeal must be mailed.

(b) *Revocation of Medicare billing privileges*—(1) *Notice of revocation.* If CMS or a CMS contractor revokes a provider's or supplier's Medicare billing privileges, CMS or a CMS contractor notifies the supplier by certified mail. The notice must include the following:

(i) The reason for the revocation in sufficient detail for the provider or supplier to understand the nature of its deficiencies.

(ii) The right to appeal in accordance with part 498 of this chapter.

(iii) The address to which the written appeal must be mailed.

(2) *Effective date of revocation.* The revocation of a provider's or supplier's billing privileges is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational. When a revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

(3) *Payment after revocation.* Medicare does not pay, and the CMS contractor rejects, claims for services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

(c) *Additional years applied to a reenrollment bar.* (1) If, under § 424.535(c)(2)(i) of this chapter, CMS or a CMS contractor applies additional years to a provider's or supplier's existing reenrollment bar, CMS or the CMS contractor notifies the provider or supplier by certified mail. The notice includes the following:

(i) The reason for the application of additional years in sufficient detail to allow the provider or supplier to understand the nature of the action.

(ii) The right to appeal in accordance with part 498 of this chapter.

(iii) The address to which the written appeal must be mailed.

(2) Paragraph (c)(1) of this section applies only to the years added to the existing reenrollment bar under § 424.535(c)(2)(i) of this chapter and not to the original length of the reenrollment bar, which is not subject to appeal.

(d) *Scope of supplier.* For purposes of this subpart, the term ''supplier'' includes all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202 of this chapter.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

[77 FR 29028, May 16, 2012, as amended at 84 FR 47852, Sept. 10, 2019; 88 FR 79523, Nov. 16, 2023]

§ 405.803 Appeals rights.

(a) A provider or supplier may appeal the initial determination to deny a

provider or supplier's enrollment application, or if applicable, to revoke current billing privileges by following the procedures specified in part 498 of this chapter.

(b) The reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges is handled by a CMS Regional Office or a contractor hearing officer not involved in the initial determination.

(c) Providers and suppliers have the opportunity to submit evidence related to the enrollment action. Providers and suppliers must, at the time of their request, submit all evidence that they want to be considered.

(d) If supporting evidence is not submitted with the appeal request, the contractor contacts the provider or supplier to try to obtain the evidence.

(e) If the provider or supplier fails to submit the evidence before the contractor issues its decision, the provider or supplier is precluded from introducing new evidence at higher levels of the appeals process.

§ 405.806 Impact of reversal of contractor determinations on claims processing.

(a) Claims for services furnished to Medicare beneficiaries during a period in which the supplier billing privileges were not effective are rejected.

(b) If a supplier is determined not to have qualified for billing privileges in one period but qualified in another, Medicare contractors process claims for services furnished to beneficiaries during the period for which the supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for the recovery of overpayments.

(c) If a revocation of a supplier's billing privileges is reversed upon appeal, the supplier's billing privileges are reinstated back to the date that the revocation became effective.

(d) If the denial of a supplier's billing privileges is reversed upon appeal and becomes binding, then the appeal decision establishes the date that the supplier's billing privileges become effective.

§ 405.809 Reinstatement of provider or supplier billing privileges following corrective action.

(a) *General rule.* A provider or supplier—

(1) May only submit a corrective action plan for a revocation for noncompliance under § 424.535(a)(1) of this chapter; and

(2) Subject to paragraph (a)(1) of this section, has only one opportunity to correct all deficiencies that served as the basis of its revocation through a corrective action plan.

(b) *Review of a corrective action plan.* Subject to paragraph (a)(1) of this section, CMS or its contractor reviews a submitted corrective action plan and does either of the following:

(1) Reinstates the provider or supplier's billing privileges if the provider or supplier provides sufficient evidence to CMS or its contractor that it has complied fully with the Medicare requirements, in which case—

(i) The effective date of the reinstatement is based on the date the provider or supplier is in compliance with all Medicare requirements; and

(ii) CMS or its contractor may pay for services furnished on or after the effective date of the reinstatement.

(2) Refuses to reinstate a provider or supplier's billing privileges. The refusal of CMS or its contractor to reinstate a provider or supplier's billing privileges based on a corrective action plan is not an initial determination under part 498 of this chapter.

[79 FR 72530, Dec. 5, 2014]

§ 405.812 Effective date for DMEPOS supplier's billing privileges.

If a CMS contractor, contractor hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in § 424.57 of this chapter and any other requirements that may apply, the determination establishes the effective date of the billing privileges as not earlier than the date the carrier made the determination to deny the DMEPOS supplier's enrollment application. Claims are rejected for services furnished before that effective date.

§ 405.815 Submission of claims.

A provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed in a binding decision, or in having its billing privileges reinstated, may submit claims to the CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims. If the claims previously were filed timely but were rejected, they are considered filed timely upon resubmission. Previously denied claims for items or services furnished during a period of denial or revocation may be resubmitted to CMS within 1 year after the date of reinstatement or reversal.

§ 405.818 Deadline for processing provider enrollment initial determinations.

Contractors approve or deny complete provider or supplier enrollment applications to approval or denial within the following timeframes:

(a) *Initial enrollments.* Contractors process new enrollment applications within 180 days of receipt.

(b) *Revalidation of existing enrollments.* Contractors process revalidations within 180 days of receipt.

(c) *Change-of-information and reassignment of payment request.* Contractors process change-of-information and reassignment of payment requests within 90 days of receipt.

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the following provisions of the Act:

(1) Section 1869(a) through (e) and (g) of the Act.

(2) Section 1862(b)(2)(B)(viii) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under Part A or Part B, including an initial determination made by a quality improvement organization under section 1154(a)(2) of the Act or by an entity under contract with the Secretary (other than a contract under section 1852 of the Act) to administer provisions of titles XVIII or XI of the Act.

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

§ 405.902 Definitions.

For the purposes of this subpart, the term—

Additional documentation means any information requested by a contractor when conducting a prepayment review or post-payment review.

Additional documentation request (ADR) means a contractor's initial documentation request in reviewing claims selected for prepayment review or post-payment review.

ALJ means an Administrative Law Judge of the Department of Health and Human Services.

Appellant means the beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Applicable plan means liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan.

Appointed representative means an individual appointed by a party to represent the party in a Medicare claim or claim appeal.

Assignee means:

(1) A supplier that furnishes items or services to a beneficiary and has accepted a valid assignment of a claim or

(2) A provider or supplier that furnishes items or services to a beneficiary, who is not already a party, and has accepted a valid assignment of the right to appeal a claim executed by the beneficiary.

Assignment of a claim means the transfer by a beneficiary of his or her claim for payment to the supplier in return for the latter's promise not to charge more for his or her services than what the carrier finds to be the Medicare-approved amount, as provided in §§ 424.55 and 424.56 of this chapter.

Assignment of appeal rights means the transfer by a beneficiary of his or her right to appeal under this subpart to a provider or supplier who is not already a party, as provided in section 1869(b)(1)(C) of the Act.

Assignor means a beneficiary whose provider of services or supplier has taken assignment of a claim or an appeal of a claim.

Attorney Adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals.

Authorized representative means an individual authorized under State or other applicable law to act on behalf of a beneficiary or other party involved in the appeal. The authorized representative will have all of the rights and responsibilities of a beneficiary or party, as applicable, throughout the appeals process.

Beneficiary means an individual who is enrolled to receive benefits under Medicare Part A or Part B.

Carrier means an organization that has entered into a contract with the Secretary in accordance to section 1842 of the Act and is authorized to make determinations for Part B of title XVIII of the Act.

Clean claim means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under title XVIII within the time periods specified in sections 1816(c) and 1842(c) of the Act.

Contractor means an entity that contracts with the Federal government to review and/or adjudicate claims, determinations and/or decisions.

Council stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

Family member means for purposes of the QIC reconsideration panel under § 405.968 the following persons as they relate to the physician or healthcare provider.

(1) The spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance);

(2) Children (including stepchildren and legally adopted children);

(3) Grandchildren;

(4) Parents; and

(5) Grandparents.

Fiscal Intermediary means an organization that has entered into a contract with CMS in accordance with section 1816 of the Act and is authorized to make determinations and payments for Part A of title XVIII of the Act, and Part B provider services as specified in § 421.5(c) of this chapter.

OMHA stands for the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act.

Party means an individual or entity listed in § 405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination.

Post-payment medical review (or post-payment review) means a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate.

Prepayment medical review (or prepayment review) means a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made.

Provider means a hospital, critical access hospital, skilled nursing facility,

comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Qualified Independent Contractor (QIC) means an entity which contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978.

Quality Improvement Organization (QIO) means an entity that contracts with the Secretary in accordance with sections 1152 and 1153 of the Act and 42 CFR subchapter F, to perform the functions described in section 1154 of the Act and 42 CFR subchapter F, including expedited determinations as described in § 405.1200 through § 405.1208.

Reliable evidence means evidence that is relevant, credible, and material.

Remand means to vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

Similar fault means to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim as defined in part 411 of this chapter.

Supplier means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under Medicare.

Vacate means to set aside a previous action.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009; 80 FR 10617, Feb. 27, 2015; 82 FR 5106, Jan. 17, 2017; 86 FR 65659, Nov. 19, 2021]

§ 405.903 Prepayment review.

(a) A contractor may select a claim(s) for prepayment review.

(b) In conducting a prepayment review, a contractor may issue additional documentation requests 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.

(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 the 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) A contractor's prepayment review will result in an initial determination under § 405.920.

[86 FR 65660, Nov. 19, 2021]

§ 405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) *General overview*—(1) *Entitlement appeals.* The SSA makes an initial determination on an application for Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of

the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or an attorney adjudicator, he or she may request the Council to review the case. Following the action of the Council, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ. If the beneficiary obtains a hearing before the ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator, he or she may request the Council to review the case. If the Council reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

(b) *Non-beneficiary appellants.* In general, the procedures described in paragraph (a) of this section are also available to parties other than beneficiaries either directly or through a representative acting on a party's behalf, consistent with the requirements of this subpart I. A provider generally has the right to judicial review only as provided under section 1879(d) of the Act; that is, when a determination involves a finding that services are not covered because—

(1) They were custodial care (see §411.15(g) of this chapter); they were not reasonable and necessary (see §411.15(k) of this chapter); they did not qualify as covered home health services because the beneficiary was not confined to the home or did not need skilled nursing care on an intermittent basis (see §409.42(a) and (c)(1) of this chapter); or they were hospice services provided to a non-terminally ill individual (see §418.22 of this chapter); and

(2) Either the provider or the beneficiary, or both, knew or could reasonably be expected to know that those services were not covered under Medicare.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5106, Jan. 17, 2017]

§ 405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews.

(a) *Parties to the initial determination.* The parties to the initial determination are the following individuals and entities:

(1) A beneficiary who files a claim for payment under Medicare Part A or Part B or has had a claim for payment filed on his or her behalf, or in the case of a deceased beneficiary, when there is no estate, any person obligated to make or entitled to receive payment in accordance with part 424, subpart E of this chapter. Payment by a third party payer does not entitle that entity to party status.

(2) A supplier who has accepted assignment for items or services furnished to a beneficiary that are at issue in the claim.

(3) A provider of services who files a claim for items or services furnished to a beneficiary.

(4) An applicable plan for an initial determination under §405.924(b)(16) where Medicare is pursuing recovery directly from the applicable plan. The applicable plan is the sole party to an initial determination under §405.924(b)(16) (that is, where Medicare is pursuing recovery directly from the applicable plan).

(b) *Parties to the redetermination, reconsideration, proceedings on a request for hearing, and Council review.* The parties to the redetermination, reconsideration, proceedings on a request for hearing, and Council review are—

(1) The parties to the initial determination in accordance with paragraph

(a) of this section, except under paragraph (a)(1) of this section where a beneficiary has assigned appeal rights under § 405.912;

(2) A State agency in accordance with § 405.908;

(3) A provider or supplier that has accepted an assignment of appeal rights from the beneficiary according to § 405.912;

(4) A non-participating physician not billing on an assigned basis who, in accordance with section 1842(l) of the Act, may be liable to refund monies collected for services furnished to the beneficiary because those services were denied on the basis of section 1862(a)(1) of the Act; and

(5) A non-participating supplier not billing on an assigned basis who, in accordance with sections 1834(a)(18) and 1834(j)(4) of the Act, may be liable to refund monies collected for items furnished to the beneficiary.

(c) *Appeals by providers and suppliers when there is no other party available.* If a provider or supplier is not already a party to the proceeding in accordance with paragraphs (a) and (b) of this section, a provider of services or supplier may appeal an initial determination relating to services it rendered to a beneficiary who subsequently dies if there is no other party available to appeal the determination. This paragraph (c) does not apply to an initial determination with respect to an applicable plan under § 405.924(b)(16).

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015; 82 FR 5106, Jan. 17, 2017]

§ 405.908 Medicaid State agencies.

When a beneficiary is enrolled to receive benefits under both Medicare and Medicaid, the Medicaid State agency may file a request for an appeal with respect to a claim for items or services furnished to a dually eligible beneficiary only for services for which the Medicaid State agency has made payment, or for which it may be liable. A Medicaid State agency is considered a party only when it files a timely redetermination request with respect to a claim for items or services furnished to a beneficiary in accordance with 42 CFR parts 940 through 958. If a State agency files a request for redetermination, it may retain party status at the QIC, OMHA, Council, and judicial review levels.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5106, Jan. 17, 2017]

§ 405.910 Appointed representatives.

(a) *Scope of representation.* An appointed representative may act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. Appointed representatives do not have party status and may take action only on behalf of the individual or entity that they represent.

(b) *Persons not qualified.* A party may not name as an appointed representative, an individual who is disqualified, suspended, or otherwise prohibited by law from acting as a representative in any proceedings before DHHS, or in entitlement appeals, before SSA.

(c) *Completing a valid appointment.* For purposes of this subpart, an appointment of representation must:

(1) Be in writing and signed and dated by both the party and individual agreeing to be the representative;

(2) Provide a statement appointing the representative to act on behalf of the party, and in the case of a beneficiary, authorizing the adjudicator to release identifiable health information to the appointed representative.

(3) Include a written explanation of the purpose and scope of the representation;

(4) Contain both the party's and appointed representative's name, phone number, and address;

(5) Identify the beneficiary's Medicare number when the beneficiary is the party appointing a representative, or identify the Medicare National Provider Identifier number of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative;

(6) Include the appointed representative's professional status or relationship to the party;

(7) Be filed with the entity processing the party's initial determination or appeal.

(d) *Curing a defective appointment of representative.* (1) If any one of the seven elements named in paragraph (c)

of this section is missing from the appointment, the adjudicator should contact the party and provide a description of the missing documentation or information.

(2) Unless the defect is cured, the prospective appointed representative lacks the authority to act on behalf of the party, and is not entitled to obtain or receive any information related to the appeal, including the appeal decision.

(3) If an adjudication time frame applies, the time from the later of the date that a defective appointment of representative was filed or the current appeal request was filed by the prospective appointed representative, to the date when the defect was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative does not count towards the adjudication time frame.

(e) *Duration of appointment.* (1) Unless revoked, an appointment is considered valid for 1 year from the date that the Appointment of Representative (AOR) form or other conforming written instrument contains the signatures of both the party and the appointed representative.

(2) To initiate an appeal within the 1-year time frame, the representative must file a copy of the AOR form, or other conforming written instrument, with the appeal request. Unless revoked, the representation is valid for the duration of an individual's appeal of an initial determination.

(3) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed in connection with the party's efforts to make a claim for third party payment is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

(4) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed by an applicable plan which has party status in accordance with § 405.906(a)(4) is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

(f) *Appointed representative fees*—(1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the OMHA level are not considered proceedings before the Secretary.

(2) *No fees or costs against trust funds.* No award of attorney or any other representative's fees or any costs in connection with an appeal may be made against the Medicare trust funds.

(3) *Special rules for providers and suppliers.* A provider or supplier that furnished the items or services to a beneficiary that are the subject of the appeal may represent that beneficiary in an appeal under this subpart, but the provider or supplier may not charge the beneficiary any fee associated with the representation. If a provider or supplier furnishes services or items to a beneficiary, the provider or supplier may not represent the beneficiary on the issues described in section 1879(a)(2) of the Act, unless the provider or supplier waives the right to payment from the beneficiary for the services or items involved in the appeal.

(4) *Special rules for purposes of third party payment.* The Secretary does not review fee arrangements made by a beneficiary for purposes of making a claim for third party payment (as defined in 42 CFR 411.21) even though the representation may ultimately include representation for a Medicare Secondary Payer recovery claim.

(5) *Reasonableness of representative fees.* In determining the reasonableness of a representative's fee, the Secretary will not apply the test specified in sections 206(a)(2) and (a)(3) of the Act.

(g) *Responsibilities of an appointed representative.* (1) An appointed representative has an affirmative duty to—

(i) Inform the party of the scope and responsibilities of the representation;

(ii) Inform the party of the status of the appeal and the results of actions taken on behalf of the party, including, but not limited to, notification of appeal determinations, decisions, and further appeal rights;

(iii) Disclose to a beneficiary any financial risk and liability of a non-assigned claim that the beneficiary may have;

(iv) Not act contrary to the interest of the party; and

(v) Comply with all laws and CMS regulations, CMS Rulings, and instructions.

(2) An appeal request filed by a provider or supplier described in paragraph (f)(3) of this section must also include a statement signed by the provider or supplier stating that no financial liability is imposed on the beneficiary in connection with that representation. If applicable, the appeal request must also include a signed statement that the provider or supplier waives the right to payment from the beneficiary for services or items regarding issues described in section 1879(a)(2) of the Act.

(h) *Authority of an appointed representative.* An appointed representative may, on behalf of the party—

(1) Obtain appeals information about the claim to the same extent as the party;

(2) Submit evidence;

(3) Make statements about facts and law; and

(4) Make any request, or give, or receive, any notice about the appeal proceedings.

(i) *Notice or request to an appointed representative*—(1) *Initial determinations.* When a contractor takes an action or issues an initial determination, it sends the action or notice to the party.

(2) *Appeals.* When a contractor, QIC, ALJ or attorney adjudicator, or the Council takes an action or issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or attorney adjudicator, or Council sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

(4) For initial determinations and appeals involving Medicare Secondary Payer recovery claims where the beneficiary is a party, the adjudicator sends notices and requests to both the beneficiary and the beneficiary's representative, if the beneficiary has a representative.

(j) *Effect of notice or request to an appointed representative.* A notice or request sent to the appointed representative has the same force and effect as if was sent to the party.

(k) *Information available to the appointed representative.* An appointed representative may obtain any and all appeals information applicable to the claim at issue that is available to the party.

(l) *Delegation of appointment by appointed representative.* (1) An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(i) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual, which contains the name of the designee and the designee's acceptance to be obligated by and comply with the requirements of representation under this subpart; and

(ii) The party accepts the designation as evidenced by a written statement signed by the party. The written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice described in paragraph (l)(1)(i) of this section so indicates.

(2) A delegation is not effective until the adjudicator receives a copy of the acceptance described in paragraph (l)(1)(ii) of this section, unless the appointed representative and designee are attorneys in the same law firm or organization, in which case the notice described in paragraph (l)(1)(i) of this section may be submitted even though the acceptance described in paragraph (l)(1)(ii) of this section is not required.

(3) A party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated is not good cause for missing a deadline or not appearing at a hearing.

(m) *Revoking the appointment of representative.* (1) A party may revoke an appointment of representative without cause at any time.

(2) *Revocation.* Revocation is not effective until the adjudicator receives a signed, written statement from the party.

(3) *Death of the party.* (i) The death of a party terminates the authority of the appointed representative, except as specified in paragraph (m)(3)(ii) of this section.

(ii) A party's death does not terminate an appeal that is in progress if another individual or entity may be entitled to receive or obligated to make payment for the items or services that are the subject of the appeal. The appointment of representative remains in effect for the duration of the appeal except for MSP recovery claims.

(4) A party's or representative's failure to notify the adjudicator that an appointment of representative has been revoked is not good cause for missing a deadline or not appearing at a hearing.

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015; 82 FR 5106, Jan. 17, 2017; 84 FR 19869, May 7, 2019]

§ 405.912 Assignment of appeal rights.

(a) *Who may be an assignee.* Only a provider, or supplier that—

(1) Is not a party to the initial determination as defined in § 405.906; and

(2) Furnished an item or service to the beneficiary may seek assignment of appeal rights from the beneficiary for that item or service.

(b) *Who may not be an assignee.* An individual or entity who is not a provider or supplier may not be an assignee. A provider or supplier that furnishes an item or service to a beneficiary may not seek assignment for that item or service when considered a party to the initial determination as defined in § 405.906.

(c) *Requirements for a valid assignment of appeal right.* The assignment of appeal rights must—

(1) Be executed using a CMS standard form;

(2) Be in writing and signed by both the beneficiary assigning his or her appeal rights and by the assignee;

(3) Indicate the item or service for which the assignment of appeal rights is authorized;

(4) Contain a waiver of the assignee's right to collect payment from the assignor for the specific item or service that are the subject of the appeal except as set forth in paragraph (d)(2) of this section; and

(5) Be submitted at the same time the request for redetermination or other appeal is filed.

(d) *Waiver of right to collect payment.* (1) Except as specified in paragraph (d)(2) of this section, the assignee must waive the right to collect payment for the item or service for which the assignment of appeal rights is made. If the assignment is revoked under paragraph (g)(2) or (g)(3) of this section, the waiver of the right to collect payment nevertheless remains valid. A waiver of the right to collect payment remains in effect regardless of the outcome of the appeal decision.

(2) The assignee is not prohibited from recovering payment associated with coinsurance or deductibles or when an advance beneficiary notice is properly executed.

(e) *Duration of a valid assignment of appeal rights.* Unless revoked, the assignment of appeal rights is valid for all administrative and judicial review associated with the item or service as indicated on the standard CMS form, even in the event of the death of the assignor.

(f) *Rights of the assignee.* When a valid assignment of appeal rights is executed, the assignor transfers all appeal rights involving the particular item or service to the assignee. These include, but are not limited to—

(1) Obtaining information about the claim to the same extent as the assignor;

(2) Submitting evidence;

(3) Making statements about facts or law; and

(4) Making any request, or giving, or receiving any notice about appeal proceedings.

(g) *Revocation of assignment.* When an assignment of appeal rights is revoked, the rights to appeal revert to the assignor. An assignment of appeal rights may be revoked in any of the following ways:

(1) *In writing by the assignor.* The revocation of assignment must be delivered to the adjudicator and the assignee, and is effective on the date of receipt by the adjudicator.

(2) By abandonment if the assignee does not file an appeal of an unfavorable decision.

(3) By act or omission by the assignee that is determined by an adjudicator to be contrary to the financial interests of the assignor.

(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 determination 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 request 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 determination 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 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.

(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]

Retrospective Appeals for Changes in Patient Status That Resulted in Denial of Part A Coverage for Hospital Services

Source: 89 FR 83283, Oct. 15, 2024, unless otherwise noted.

§ 405.931 Scope, basis, and definitions.

(a) *Scope and basis.* The provisions in §§ 405.931 through 405.938—

(1) Implement a federal district court order requiring appeal rights for hospital stays on or after January 1, 2009, for a specified class of beneficiaries under certain conditions (defined in § 405.931(b)) who were admitted to a hospital as inpatients, but were subsequently reclassified by the hospital as outpatients receiving observation services; and

(2) Apply to retrospective appeals, that is, appeals for hospital outpatient services, and as applicable, post-hospital extended care services in a skilled nursing facility (SNF services), furnished to eligible parties as defined in paragraph (b) of this section before the implementation of the prospective appeal process set forth in §§ 405.1210 through 405.1212.

(b) *Definitions.* For the purposes of the appeals conducted under §§ 405.931 through 405.938, the following definitions apply:

Eligible party means a beneficiary who, on or after January 1, 2009, meets the following criteria, and is, thus, eligible to request an appeal under §§ 405.931 through 405.938:

(i) Was formally admitted as a hospital inpatient.

(ii) While in the hospital was subsequently reclassified as an outpatient receiving observation services (as defined in § 405.931(h)).

(iii) Has received an initial determination (as defined in § 405.920) or a Medicare Outpatient Observation Notice (MOON) (as described in § 489.20(y)) indicating that the observation services are not covered under Medicare Part A.

(iv)(A) Was not enrolled in the Supplementary Medical Insurance program (that is, Medicare Part B coverage) at the time of beneficiary's hospitalization; or

(B) Stayed at the hospital for 3 or more consecutive days but was designated as an inpatient for fewer than 3 days, unless more than 30 calendar days has passed after the hospital stay without the beneficiary's having been admitted to a SNF.

(v) Medicare beneficiaries who meet the requirements of the paragraph (iv)(A) or (B) of this definition but who pursued an administrative appeal and received a final decision of the Secretary before September 4, 2011, are excluded from the definition of an eligible party.

Eligibility contractor means the contractor who meets all of the following:

(i) Is identified on the *Medicare.gov* website for accepting appeal requests.

(ii) Receives appeal requests and makes determinations regarding eligibility for the appeal under §§ 405.931 through 405.938.

(iii) Issues notices of eligibility.

(iv) Refers valid appeal requests to the processing contractor for a decision on the merits of the appeal.

Processing contractor means the contractor responsible for conducting the first-level appeal and issuing a decision on the merits of the appeal. Appeals under § 405.932 are conducted by the MAC who, at the time of the referral of the request for appeal under § 405.932(d)(2), has jurisdiction over claims submitted by the hospital where the eligible party received the services at issue.

(c) *Party to an appeal.* For the purposes of the appeals conducted under §§ 405.931 through 405.938, an eligible party is the only party to the appeal. The provisions of § 405.906 do not apply to appeals processed under these provisions, and the provider that furnished services to an eligible party may not file a request for an appeal and is not considered a party to any appeal decision or determination.

(d) *Authorized representatives, appointed representatives, or representatives of a deceased eligible party.* For the purposes of appeals conducted under §§ 405.931 through 405.938:

(1) The provisions of § 405.910 apply to an eligible party appointing a representative to assist in such appeal, as appropriate, except as follows:

(i) A provider of services who furnished items or services to a beneficiary whose claims are the subject of an appeal under the provisions of §§ 405.931 through 405.938 is prohibited from representing the beneficiary or eligible party in such appeal.

(ii) [Reserved]

(2) An authorized representative (as defined in § 405.902) may act on behalf of an eligible party and has all of the same rights and responsibilities of an eligible party throughout the appeals process.

(3) The provisions of § 405.906(a)(1) apply to a deceased eligible party in the same manner in which such provisions apply to a deceased beneficiary.

(4) The provisions of § 405.906(c) do not apply.

(5) A beneficiary who is an eligible party is considered unrepresented if

the beneficiary meets any of the following:

(i) Has not appointed a representative under § 405.910.

(ii) Has an authorized representative as defined in § 405.902.

(iii) Has appointed as its representative a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

(iv) Is deceased but met the conditions for an eligible party in paragraph (b)(1) of this section and the appeal is filed by an individual who meets the conditions set forth in § 405.906(a)(1).

(e) *Prohibition on assignment of appeal rights.* For the purposes of the appeals conducted under §§ 405.931 through 405.938, an eligible party may not assign appeal rights to a provider under the provisions of § 405.912.

(f) *Date of receipt of a notice or decision.* For the purposes of the appeals conducted under §§ 405.931 through 405.938, the date of receipt of a notice or decision sent by the eligibility contractor, processing contractor or other appeals adjudicator is presumed to be 5 calendar days following the date on the notice unless there is evidence to the contrary.

(g) *Three or more consecutive days.* For the purposes of the appeals conducted under §§ 405.931 through 405.938, when determining if a beneficiary is an eligible party and for the purposes of determining coverage of SNF services under section 1861 of the Act, inpatient hospital days are counted in accordance with § 409.30, that is, a patient must have a qualifying inpatient stay of at least 3 consecutive calendar days starting with the admission day but not counting the discharge day.

(h) *Outpatient receiving observation services.* For the purposes of appeals conducted under §§ 405.931 through 405.938 when determining if a beneficiary is an eligible party, a beneficiary is considered an outpatient receiving observation services when the hospital changes beneficiary's status from inpatient to outpatient while the beneficiary is in the hospital and the beneficiary subsequently receives observation services following a valid order for such services.

(i) *Conclusive effect of a Part A coverage determination.* For the purposes of appeals under §§ 405.931 through 405.938, the determination with respect to coverage under Part A is conclusive and binding with respect to the services furnished and must be applied to any existing appeals with respect to coverage and payment for hospital services under Part B and SNF services (as applicable).

§ 405.932 Right to appeal a denial of Part A coverage resulting from a change in patient status.

(a) *Filing an appeal request related to a change in patient status which resulted in the denial of Part A coverage.* (1) Only an eligible party, the party's appointed representative, or an authorized representative of an eligible party may request an appeal at any level of the appeals process under §§ 405.931 through 405.938.

(2) To initiate an appeal under §§ 405.931 through 405.938, an eligible party, the party's appointed representative, or an authorized representative of an eligible party must meet the following requirements:

(i) Submit a request for an appeal in writing to the eligibility contractor.

(ii) The request must be received by the eligibility contractor no later than 365 calendar days after the implementation date of the final rule. The eligibility contractor denies the written request if it is not received by the applicable filing timeframe under paragraph (d)(3) of this section, unless the eligible party established good cause for late submission as specified in § 405.942(b)(2) and (3).

(3) If an eligible party (or the party's representative) misfiles a request for appeal with a contractor or government entity other than the eligibility contractor, then for the purpose of determining timeliness of the request for appeal, the date the misfiled request was received by the contractor or government agency is considered the date of receipt. The misfiled request and all documentation must be forwarded to the eligibility contractor within 30 calendar days of receipt, or as soon as practicable.

(b) *Content of the appeal request.* (1) The written request filed by an eligible

party, the party's appointed representative, or an authorized representative of an eligible party may be made on a model CMS form. If the model form is not used, to be valid, the written request must include all of the following identifying information:

(i) Beneficiary name.

(ii) Beneficiary Medicare number (the number on the beneficiary's Medicare card).

(iii) Name of the hospital and dates of hospitalization.

(iv) Name of the SNF and the dates of stay (as applicable).

(2) If the appeal includes SNF services not covered by Medicare, the written request must also include an attestation to the out-of-pocket payment(s) made by the beneficiary for such SNF services and must include documentation of payments made to the SNF for such services.

(i) Payments for an eligible party's SNF services made by a third-party payer do not constitute out-of-pocket expenses or payment for an eligible party. If a third-party payer made payment for the eligible party's SNF services, then the services are excluded from consideration in the appeal.

(ii) Payments made for cost sharing (including, but not limited to, coinsurance and deductible) for SNF services covered by a third-party payer are not considered an out-of-pocket payment for the purposes of this provision.

(iii) Payments made by a family member (including payments made by an individual not biologically related to the beneficiary) for an eligible party's SNF services are considered an out-of-pocket payment for the eligible party.

(3) In the written request for an appeal, an eligible party (or their representative) may include an explanation of why the hospital admission satisfied the relevant criteria for Part A coverage and should have been covered under the Part A hospital insurance benefit instead of under the Part B supplementary medical insurance benefit.

(c) *Evidence and other information to be submitted with the appeal request.* (1) Eligible parties (or their representatives) are encouraged to submit all available information and documentation, including medical records related to the hospital stay and SNF services, as applicable, at issue in the appeal with the written request for an appeal.

(2) If the eligibility contractor determines there is information missing from the request that is needed to establish the beneficiary's eligibility as a party under § 405.931(b) or satisfy other conditions for eligibility for an appeal, the eligibility contractor works with the appropriate MAC and attempts to obtain the information from the provider or the eligible party (or the party's representative) or both, as applicable. The eligibility contractor allows up to 120 calendar days for submission of missing information.

(3) If the necessary information cannot be obtained from either the provider or the eligible party (or the party's representative), the eligibility contractor makes an eligibility determination based on the information available.

(d) *Determining eligibility for an appeal.* (1)(i) The eligibility contractor reviews the information submitted with the appeal request and any additional information it obtains to determine if the individual submitting the appeal request is an eligible party and that the services previously furnished are eligible for an appeal under § 405.931.

(ii) The eligibility contractor mails or otherwise transmits the notice of its determination to the eligible party (or the party's representative) within 60 calendar days of receipt of the appeal request.

(iii) The time between the eligibility contractor's request for missing information and receipt of such information (or in the case of information that is requested but is not received, the time allowed by the contractor to submit the information) does not count toward the timeframe for issuing a notice to the eligible party (or the party's representative).

(2) If the eligibility contractor determines that the individual is an eligible party and the services previously furnished are eligible for an appeal, the eligibility contractor—

(i) Issues a notice of acceptance to the eligible party (or the party's representative), explaining that the appeal has been accepted for processing; and

(ii) Refers the appeal to the processing contractor for adjudication under paragraph (f) of this section.

(3)(i) If the eligibility contractor determines that the request for appeal is untimely or incomplete, the individual does not satisfy the requirements for an eligible party, or the services previously furnished are not eligible for an appeal, the eligibility contractor issues a denial notice to the individual (or the party's representative) in writing.

(ii) The denial notice explains that the request is not eligible for an appeal, the reason(s) for the denial of the appeal request, the information needed to cure the denial, and the process for requesting a review of the eligibility denial under paragraph (e) of this section.

(4) Notices regarding eligibility for an appeal issued by the eligibility contractor are written in a manner to be understood by the eligible party or the party's representative.

(e) *Review of an eligibility contractor's denial of a request for an appeal.* (1)(i) An individual (or their representative) may request a review of the eligibility contractor's denial of a request for an appeal by filing a request in writing with the eligibility contractor.

(ii) The request for review should explain the reason(s) the denial of the request for an appeal was incorrect, and should include additional information, as applicable, to support the validity of the original appeal request.

(2) The request for review, with any additional information, must be received by the eligibility contractor no later than 60 calendar days from the date of receipt of the denial notice. If the request for review is received after this deadline, the individual (or the individual's representative) must establish good cause for untimely filing. In determining whether good cause for untimely filing exists, the eligibility contractor applies the provisions in § 405.942(b)(2) and (3).

(3) The review by the eligibility contractor must be conducted by individuals not involved in the initial denial of the request for an appeal.

(4) The eligibility contractor may issue a decision that affirms or reverses the denial of the request for an appeal or may dismiss the request for review. The notice of the eligibility contractor's decision must meet both of the following requirements:

(i) Be written in a manner to be understood by the individual or the individual's representative.

(ii) Be mailed or otherwise transmitted in writing within 60 calendar days of the date of receipt of the request for review.

(5) If the decision is to affirm the denial, or dismiss the request, the eligibility contractor must explain the rationale for the decision.

(6) A denial notice under paragraph (d)(3) of this section issued due to receipt of an untimely appeal request must be reversed if the eligible party (or the party's representative) establishes good cause for late filing under § 405.942(b)(2) and (3).

(7) If the eligibility contractor reverses the initial denial of the request for appeal, the eligibility contractor forwards the request for appeal to the processing contractor under paragraph (f) of this section.

(8) The eligibility contractor's decision that affirms the initial denial of a request for an appeal is binding and not subject to further review.

(9) If the eligibility contractor determines that the request for review of the eligibility denial under paragraph (e)(2) of this section was not submitted timely, and the eligibility contractor did not find good cause for the untimely submission, then the eligibility contractor dismisses the request for review, and such dismissal is binding and not subject to further review.

(f) *Processing eligible requests for appeal.* (1) If the processing contractor determines there is necessary information missing from the appeal case file, the processing contractor attempts to obtain the information from the provider or the eligible party (or the party's representative), as applicable.

(i) The processing contractor allows the provider or eligible party (or the party's representative), or both, up to

60 calendar days to submit missing information.

(ii) If the provider or eligible party (or the party's representative) does not submit the missing information within the allotted time, the processing contractor makes a decision on the request for appeal based on the information available.

(iii) The time between the processing contractor's request for information and receipt of such information (or in the case of information that is requested but is not received, the time allowed by the contractor to submit the information) does not count toward the timeframe for issuing the processing contractor's decision.

(2) The processing contractor reviews the information submitted with the appeal request and any additional information it obtains to determine if the inpatient admission satisfied the relevant criteria for Part A coverage at the time services were furnished. If the appeal request also includes a request to review denied SNF services that are eligible for an appeal, the processing contractor also determines if such eligible SNF services satisfied relevant criteria for Part A coverage at the time the services were furnished.

(3) Subject to the provisions in paragraph (f)(1) of this section, the processing contractor mails or otherwise transmits its written decision on the request for appeal within 60 calendar days of receipt of the request.

(g) *Notice and content of the decision.* (1) If the processing contractor determines that the inpatient admission, and as applicable, SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, then the processing contractor issues notice of the favorable decision to the eligible party (or the party's representative). The processing contractor also notifies the hospital and SNF, as applicable, in the case of a favorable determination for Part A coverage.

(2)(i) If the processing contractor determines that the inpatient admission, or as applicable, SNF services, did not satisfy the relevant criteria for Part A coverage at the time the services were furnished, then the processing contractor issues notice of the unfavorable or partially favorable decision to the eligible party (or the party's representative).

(ii) The processing contractor issues a notice of a partially favorable decision to the SNF if the inpatient admission satisfied the relevant criteria for Part A coverage, but the SNF services did not satisfy the relevant criteria for Part A coverage.

(3) The notice issued to the eligible party (or the party's representative) must be written in a manner calculated to be understood by the eligible party (or the party's representative) and include all of the following:

(i) A clear statement of the decision made by the processing contractor.

(ii) The reason the hospital admission, and as applicable, the SNF services, satisfied or did not satisfy the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) If a favorable decision, the effect of such decision, including, as applicable, a statement about the obligation of the SNF to refund any amounts collected for the covered SNF services, and that the SNF may then submit a new claim(s) for services covered under Part A in order to determine the amounts of benefits due.

(vi) If an unfavorable or partially favorable decision, a statement of any specific missing documentation that should be submitted with a request for reconsideration, if applicable.

(vii) The procedures for obtaining additional information concerning the decision, such as specific provisions of the policy, manual, regulations, or other rules used in making the decision.

(viii) If an unfavorable or partially favorable decision, information about the procedures for filing a request for reconsideration under § 405.934.

(ix) Any other requirements specified by CMS.

(4) As applicable, a notice of a favorable decision issued to the SNF (including a decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of beneficiary's hospitalization), includes all of the following:

(i) A clear statement of the decision made by the processing contractor.

(ii) The reason the SNF services satisfied the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the SNF must refund any payments collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) to determine the amount of benefits due for covered services.

(vi) Any other requirements specified by CMS.

(5) In the case of a favorable decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, notice is issued to the hospital that includes all of the following:

(i) A clear statement of the decision made by the processing contractor.

(ii) The reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the hospital must refund any payments collected for the outpatient hospital services, and that the hospital may then submit a new Part A inpatient claim in order to determine the amount of benefits due for covered services.

(vi) Any other requirements specified by CMS.

(6) In the case of a partially favorable decision issued to a SNF, the notice includes the following:

(i) A clear statement of the decision made by the processing contractor.

(ii) The reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, and the reason the SNF services did not satisfy the relevant criteria for Part A coverage.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the decision is being sent for informational purposes only, and that only the eligible party may appeal the decision to a QIC under § 405.934.

(vi) Any other requirements specified by CMS.

(h) *Effect of a favorable appeal decision.* (1)(i) If the processing contractor issues a decision that the beneficiary's inpatient admission satisfied the relevant criteria for Part A coverage and the hospital's decision to change the inpatient admission to outpatient receiving observation services was therefore erroneous, the beneficiary's reclassification as an outpatient is disregarded for the purposes of determining Part A benefits, including Part A SNF coverage, if applicable.

(ii) For the purposes of effectuating a favorable decision by the processing contractor, unless a Part A claim is submitted by a hospital, any claims previously submitted for outpatient hospital services and payments made for such services (including any applicable deductible and coinsurance amounts) are not reopened or revised by the MAC, and payment, as applicable, for covered SNF services may be made by the MAC to the SNF without regard to the hospital claim.

(2) In order to determine Part A benefits to be paid and to make payment

for covered services as a result of a favorable decision, as applicable:

(i) The SNF that furnished services to the beneficiary must refund payments previously collected from the beneficiary for the covered services and may then submit a Part A claim(s) for such services within 365 calendar days of receipt of the notice of a favorable decision.

(ii) In the case of a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services. After the refund is issued, the hospital may then submit a Part A inpatient claim for such services within 365 calendar days of receipt of the notice of a favorable decision.

(iii) In the case of a beneficiary enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services. The deadline for submitting a Part A claim for such services is 365 calendar days after receipt of the notice of a favorable decision, and the hospital must refund any payments collected for the outpatient services before submitting the Part A inpatient claim.

(3) The hospital, and as applicable, the SNF, must comply with all applicable provisions regarding charges to the beneficiary for covered services, including but not limited to relevant provisions in part 489 subparts B through D of this chapter.

(i) A favorable appeal decision is considered binding unless it is reopened and revised under the provisions of §§ 405.980 through 405.986.

(ii) The provisions regarding reopening of a redetermination in § 405.980(b) and (c) apply in the same manner to favorable decisions issued under this section.

(4) The notice of a favorable decision issued to a hospital and, as applicable, a SNF does not convey party status to such provider.

(i) *Effect of an unfavorable or partially favorable decision.* (1) An unfavorable or partially favorable appeal decision is considered binding unless—

(i) It is reopened and revised under the provisions of §§ 405.980 through 405.986; or

(ii) An eligible party (or the party's representative) files a request for reconsideration under § 405.934.

(2) The provisions regarding reopening of a redetermination in § 405.980(b) and (c) apply in the same manner to unfavorable or partially favorable decisions issued under this section.

[89 FR 83283, Oct. 15, 2024; 89 FR 106363, Dec. 30, 2024]

§ 405.934 Reconsideration.

(a) *Filing a request for reconsideration.* An eligible party, the party's appointed representative, or an authorized representative who is dissatisfied with the decision rendered by a processing contractor in § 405.932(g)(2) may request a reconsideration with a QIC within 180 calendar days of receipt of the processing contractor's notice. The request for reconsideration must include the elements specified in the processing contractor's notice.

(b) *Applicability of other provisions.* The provisions in §§ 405.960 through 405.978 that apply to reconsiderations of initial determinations apply to the extent they are appropriate/in the same manner to reconsiderations performed by a QIC under this section unless otherwise specified.

(c) *Notice and content of a reconsideration.* (1) If the QIC determines that the inpatient admission, and as applicable, eligible SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, then the QIC issues notice of the favorable reconsideration to the eligible party (or the party's representative). The QIC also notifies the hospital and SNF, as applicable, in the case of a favorable determination for Part A coverage.

(2)(i) If the QIC determines that the inpatient admission, or as applicable, SNF services, did not satisfy the relevant criteria for Part A coverage at the time the services were furnished,

then the QIC issues notice of the unfavorable or partially favorable reconsideration to the eligible party (or the party's representative).

(ii) The QIC issues a notice of a partially favorable reconsideration to the SNF if the inpatient admission satisfied the relevant criteria for Part A coverage, but the SNF services did not satisfy the relevant criteria for Part A coverage.

(3) The notice of reconsideration must be mailed or otherwise transmitted within 60 calendar days of the QIC's receipt of the request for reconsideration, subject to the exceptions specified in § 405.970.

(4) The notice of reconsideration issued to the eligible party (or the party's representative) must be written in a manner calculated to be understood by the eligible party (or the party's representative) and include all of the following:

(i) A clear statement of the decision made by the QIC.

(ii) The reason the hospital admission, and as applicable, the SNF services, satisfied or did not satisfy the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) If a favorable decision, the effect of such decision, including a statement about the obligation of the SNF to refund any amounts collected for the covered SNF services, and that the SNF may then submit a new claim(s) for services covered under Part A in order to determine the amounts of benefits due.

(vi) If the decision in § 405.932(f) indicated that specific documentation should be submitted with the reconsideration request, and the documentation was not submitted with the request for reconsideration, the summary must indicate how the missing documentation affected the reconsideration.

(vii) The procedures for obtaining additional information concerning the decision, such as specific provisions of the policy, manual, regulations, or other rules used in making the decision.

(viii) If an unfavorable or partially favorable decision, information concerning an eligible party's right to an ALJ hearing, including the applicable amount in controversy requirement and aggregation provisions and other procedures for filing a request for an ALJ hearing under § 405.936.

(ix) Any other requirements specified by CMS.

(5) As applicable, a notice of a favorable reconsideration issued to the SNF (including a decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization), includes all of the following:

(i) A clear statement of the decision made by the QIC.

(ii) The reason the SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining the SNF must refund any payments collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) to determine the amount of benefits due for the covered services.

(vi) Any other requirements specified by CMS.

(6) In the case of a favorable reconsideration for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, notice is issued to the hospital that includes all the following:

(i) A clear statement of the decision made by the QIC.

(ii) The reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the hospital must refund any payments collected for the outpatient hospital services, and that the hospital may then submit a new Part A inpatient claim in order to determine the amount of benefits due for covered services.

(vi) Any other requirements specified by CMS.

(7) In the case of a partially favorable reconsideration issued to a SNF the notice includes the following:

(i) A clear statement of the decision made by the QIC.

(ii) The reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, and the reason the SNF services did not satisfy the relevant criteria for Part A coverage.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the decision is being sent for informational purposes only, and that only the eligible party may appeal the decision to an ALJ under § 405.936.

(vi) Any other requirements specified by CMS.

(d) *Effect of a favorable reconsideration.* (1)(i) If the QIC issues a reconsideration decision that the beneficiary's inpatient admission satisfied the relevant criteria for Part A coverage and the hospital's decision to change the inpatient admission to outpatient receiving observation services was therefore erroneous, the beneficiary's reclassification as an outpatient is disregarded for the purposes of determining Part A benefits, including both Part A hospital coverage and Part A SNF coverage, if applicable.

(ii) For the purposes of effectuating a favorable reconsideration, unless a Part A claim is submitted by a hospital, any claims previously submitted for outpatient hospital services and payments made for such services (including any applicable deductible and coinsurance amounts) are not reopened or revised by the MAC, and payment, as applicable, for covered SNF services may be made by the MAC to the SNF without regard to the hospital claim.

(2) In order to determine Part A benefits to be paid and to make payment for covered services as a result of a favorable decision, as applicable—

(i) The SNF that furnished services to the beneficiary must refund payments previously collected from the beneficiary for the covered services and may then submit a Part A claim(s) for such services within 365 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services. After the refund is issued, the hospital may then submit a Part A inpatient claim for such services within 365 calendar days of receipt of the notice of a favorable decision;

(iii) In the case of a beneficiary enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services. The deadline for submitting a Part A claim for such services is 365 calendar days after receipt of the notice of a favorable decision, and the hospital must refund any payments collected for the outpatient services before submitting the Part A inpatient claim.

(3) The hospital, and as applicable, the SNF, must comply with all applicable provisions regarding charges to the

beneficiary for covered services, including but not limited to relevant provisions in part 489 subparts B through D of this chapter.

(4) A favorable reconsideration is considered binding unless it is reopened and revised under the provisions of §§ 405.980 through 405.986. The provisions regarding reopening of a reconsideration in § 405.980(d) and (e) apply in the same manner to favorable reconsiderations issued under this section.

(5) The notice of a favorable reconsideration sent to a hospital and, as applicable, a favorable or partially favorable reconsideration sent to a SNF does not convey party status.

(e) *Effect of an unfavorable or partially favorable reconsideration.* (1) An unfavorable or partially favorable reconsideration is considered binding unless—

(i) It is reopened and revised under the provisions of § 405.980(d) or (e); or

(ii) An eligible party (or the party's representative) files a request for a hearing by an ALJ under § 405.936.

(2) The provisions regarding reopening of a reconsideration in § 405.980(d) and (e) apply in the same manner to unfavorable and partially favorable decisions issued under this section.

[89 FR 83283, Oct. 15, 2024; 89 FR 106363, Dec. 30, 2024]

§ 405.936 Hearings before an ALJ and decisions by an ALJ or Attorney Adjudicator.

(a) *Filing a request for hearing.* An eligible party, the party's appointed representative, or an authorized representative who is dissatisfied with the reconsideration rendered by a QIC in § 405.934(c)(2), or a dismissal of a request for reconsideration, may request a hearing before an ALJ within 60 calendar days of receipt of the reconsideration. The request for hearing must include the elements specified in the QIC's reconsideration.

(b) *Applicability of other provisions.* The provisions in §§ 405.1000 through 405.1064 that apply to ALJ hearings and decisions by an ALJ or an attorney adjudicator apply to the extent they are appropriate/in the same manner to ALJ hearings and decisions by an ALJ or an attorney adjudicator under this section unless otherwise specified.

(c) *Calculating the amount remaining in controversy for an ALJ hearing or judicial review.* (1)(i) A request for ALJ hearing for an appeal under the provisions of §§ 405.931 through 405.938 must meet the amount in controversy requirement in § 405.1006(b).

(ii) A request for judicial review in federal district court for an appeal under the provisions of §§ 405.931 through 405.938 must meet the amount in controversy requirement in § 405.1006(c), subject to the calculation methodology set forth in this paragraph.

(2) For appeals under the provisions of §§ 405.931 through 405.938, the amount remaining in controversy for an ALJ hearing or for judicial review in federal district court under § 405.1136 is determined by the sum of the billed charges on the Part B outpatient hospital claim and, as applicable, any billed charges for the SNF claim at issue, if such claims were submitted to Medicare. If no SNF claim was submitted for services furnished to the beneficiary, then the billed charges to the beneficiary as indicated on an itemized statement or evidence of payment made by the beneficiary for such services are used in calculating the amount remaining in controversy.

(3) In the case of an appeal under the provisions of §§ 405.931 through 405.938 filed by an eligible party who was not enrolled in Part B at the time of hospitalization, and no Part B outpatient hospital claim was billed to Medicare, the amount remaining in controversy is determined by the charges billed to the beneficiary by the hospital for the outpatient hospital stay and billed charges for SNF services, if applicable. An itemized statement from the provider such services, or evidence of the payment made by the beneficiary to the provider is acceptable for the purpose of calculating the amount remaining in controversy.

(4) Any payments made, including coinsurance and deductible, for the Part B outpatient hospital claim, and as applicable, the SNF claim must not reduce the calculation of the amount in controversy for the purposes of a hearing or judicial review under this paragraph.

(d) *Notice and content of an ALJ or attorney adjudicator decision.* (1)(i) If the ALJ or attorney adjudicator determines that the inpatient admission, and as applicable, eligible SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, then the ALJ or attorney adjudicator issues notice of the favorable decision to the eligible party (or the party's representative).

(ii) The ALJ or attorney adjudicator also notifies the hospital and SNF, as applicable, in the case of a favorable determination for Part A coverage.

(2)(i) If the ALJ or attorney adjudicator determines that the inpatient admission, or as applicable, SNF services, did not satisfy the relevant criteria for Part A coverage at the time the services were furnished, then the ALJ or attorney adjudicator issues notice of the unfavorable or partially favorable decision to the eligible party (or the party's representative).

(ii) The ALJ or attorney adjudicator issues a notice of a partially favorable decision to the SNF if the inpatient admission satisfied the relevant criteria for Part A coverage, but the SNF services did not satisfy the relevant criteria for Part A coverage.

(3) The ALJ or attorney adjudicator decision issued to the eligible party (or the party's representative) must be written in a manner calculated to be understood by the eligible party (or the party's representative) and include all of the following:

(i) A clear statement of the decision made by the ALJ or attorney adjudicator.

(ii) The findings of fact.

(iii) The conclusions of law.

(iv) The reason for the determination that the hospital admission, and as applicable SNF services, satisfied or did not satisfy the relevant criteria for Part A coverage at the time the services were furnished, and, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(v) The procedures for obtaining additional information concerning the decision, such as specific provisions of the policy, manual, regulations, or other rules used in making the decision.

(vi) If a favorable decision, the effect of such decision, including, as applicable, a statement about the obligation of the SNF to refund any amounts collected for the covered SNF services, and that the SNF may then submit a new claim(s) for services covered under Part A in order to determine the amount of benefits due.

(vii) If an unfavorable decision or a partially favorable decision, information about the procedures for filing a request for review by the Appeals Council under § 405.938.

(4) As applicable, a notice of a favorable ALJ or attorney adjudicator decision (including a decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization) issued to the SNF, includes the following:

(i) A clear statement of the decision made by the ALJ or attorney adjudicator.

(ii) The findings of fact.

(iii) The conclusions of law.

(iv) The reason for the determination that the SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, and to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(v) The effect of such decision, including a statement explaining that the SNF must refund any payments collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) to determine the amount of benefits due for the covered services.

(5) In the case of a favorable ALJ or attorney adjudicator decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of beneficiary's hospitalization, notice is issued to the hospital that includes all of the following:

(i) A clear statement of the decision made by the ALJ or attorney adjudicator.

(ii) The findings of fact.

(iii) The conclusions of law.

(iv) The reason for the determination that the hospital admission satisfied

the relevant criteria for Part A coverage at the time the services were furnished, and to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(v) The effect of such decision, including a statement explaining that the hospital must refund any payments collected for the outpatient hospital services, and that the hospital may then submit a new Part A inpatient claim in order to determine the amount of benefits due for covered services.

(6) In the case of a partially favorable decision issued to a SNF, the notice includes the following:

(i) A clear statement of the decision made by the ALJ or attorney adjudicator.

(ii) The findings of fact.

(iii) The conclusions of law.

(iv) The reason for the determination that the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, and the reason the SNF services did not satisfy the relevant criteria for Part A coverage, and to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(v) The effect of such decision, including a statement explaining that the decision is being sent for informational purposes only, and that only the eligible party may appeal the decision to the Medicare Appeals Council under § 405.938.

(7) The timeframe within which notices must be issued under this paragraph are determined under the provisions in § 405.1016.

(e) *Effect of a favorable ALJ or attorney adjudicator decision.* (1)(i) If the ALJ or attorney adjudicator issues a decision that the beneficiary's inpatient admission satisfied the relevant criteria for Part A coverage and the hospital's decision to change the inpatient admission to outpatient receiving observation services was therefore erroneous, the beneficiary's reclassification as an outpatient is disregarded for the purposes of determining Part A benefits, including Part A SNF coverage, if applicable.

(ii) For the purposes of effectuating a favorable decision by an ALJ or attorney adjudicator, unless a Part A claim is submitted by a hospital, any claims previously submitted for outpatient hospital services and payments made for such services (including any applicable deductible and coinsurance amounts) are not reopened or revised by the MAC, and payment, as applicable, for covered SNF services may be made by the MAC to the SNF without regard to the hospital claim.

(2) In order to determine Part A benefits to be paid and to make payment for covered services as a result of a favorable decision, as applicable—

(i) The SNF that furnished services to the beneficiary must refund payments previously collected from the beneficiary for the covered services and may then submit a Part A claim(s) for such services within 365 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services. After the refund is issued, the hospital may then submit a Part A inpatient claim for such services within 365 calendar days of receipt of the notice of a favorable decision;

(iii) In the case of a beneficiary enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services. The deadline for submitting a Part A claim for such services is 365 calendar days after receipt of the notice of a favorable decision, and the hospital must refund any payments collected for the outpatient services before submitting the Part A inpatient claim.

(3) The hospital, and as applicable, the SNF, must comply with all applicable provisions regarding charges to the

beneficiary for covered services, including but not limited to relevant provisions in part 489 subparts B through D of this chapter.

(4) A favorable ALJ or attorney adjudicator decision is considered binding unless it is reopened and revised under the provisions of §§ 405.980 through 405.986. The provisions regarding reopening of an ALJ or attorney adjudicator decision in § 405.980(d) and (e) apply in the same manner to favorable ALJ or attorney adjudicator decisions issued under this section.

(5) The notice of a favorable decision issued to a hospital and, as applicable, notice of a favorable or partially favorable decision sent to a SNF does not convey party status to such provider.

(f) *Effect of an unfavorable or partially favorable ALJ or attorney adjudicator decision.* (1) An unfavorable or partially favorable ALJ or attorney adjudicator decision is considered binding unless—

(i) It is reopened and revised under the provisions of § 405.980(d) or (e); or

(ii) An eligible party (or the party's representative) files a request for Medicare Appeals Council review under § 405.938.

(2) The provisions regarding reopening of an ALJ or attorney adjudicator decision in § 405.980(d) and (e) apply in the same manner to unfavorable and partially favorable decisions issued under this section.

[89 FR 83283, Oct. 15, 2024; 89 FR 106363, Dec. 30, 2024]

§ 405.938 Review by the Medicare Appeals Council and judicial review.

(a) *Filing a request for Council review.* An eligible party, the party's appointed representative, or an authorized representative who is dissatisfied with the unfavorable decision of an ALJ or an attorney adjudicator in § 405.936(d)(2) may request the Council review the decision within 60 calendar days of receipt of the decision. The request for review must contain the elements specified in the ALJ or attorney adjudicator's decision notice.

(b) *Applicability of other provisions.* The provisions in §§ 405.1100 through 405.1130 that apply to Council review apply to the extent they are appropriate/in the same manner to Council review under this section unless otherwise specified.

(c) *Notice of the Council's action.* (1) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on consideration of additional evidence in § 405.1122, the Council makes a decision or remands the case to an ALJ or attorney adjudicator.

(2) The Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decision or recommended decision.

(3) Notice of the Council's decision or remand order is issued to the eligible party (or the party's representative).

(i) In the case of a modification or reversal of the ALJ's or attorney adjudicator's decision that is favorable to the eligible party, the Council's decision includes information regarding the effect of such decision, including, as applicable, a statement about the obligation of the SNF to refund any amounts collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) for services covered under Part A in order to determine the amount of benefits due.

(ii) If the appeal involves a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, a modification or reversal of the ALJ's or attorney adjudicator's decision that is favorable to the eligible party with respect to hospital services also includes a statement about the obligation of the hospital to refund any amounts collected for the outpatient hospital services, and that the hospital may then submit a new claim for covered inpatient hospital services in order to determine the amount of benefits due.

(iii)(A) If the Council adopts or modifies an ALJ or attorney adjudicator decision that is unfavorable or partially favorable to the eligible party, the decision includes information about the procedures for filing a request for judicial review under § 405.1136, including information regarding the amount in controversy requirement in § 405.936(c).

(B) A partially favorable decision issued by the Council refers to a determination that the inpatient admission satisfied the relevant criteria for Part A coverage but the SNF services did not satisfy the relevant criteria for Part A coverage.

(4) Notice of a Council decision, favorable or partially favorable to the eligible party, that modifies or reverses the decision or recommended decision by an ALJ or attorney adjudicator, or a remand order that is favorable to the eligible party, is issued to the SNF, as applicable, and to the hospital in the case of an appeal filed by, or on behalf of, a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of hospitalization.

(i)(A) Notice issued to the SNF includes information regarding the effect of such decision, including, as applicable, a statement explaining that the SNF must refund any payments collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) to determine the amount of benefits due for the covered services.

(B) A decision that is partially favorable to the eligible party is sent to the SNF and explains the reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, the reason the SNF services did not satisfy the relevant criteria for Part A coverage and explains that the decision is being sent for informational purposes only.

(ii) Notice issued to a hospital (in the case of an appeal filed by, or on behalf of, a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of hospitalization) includes information regarding the effect of such decision, including a statement explaining that the hospital must refund any payments collected for the outpatient hospital services, and that the hospital may then submit a new Part A inpatient claim in order to determine the amount of benefits due for covered services.

(5) The timeframe within which notices must be sent under this paragraph are determined under the provisions in § 405.1100.

(d) *Effect of a favorable Council decision.* (1)(i) If the Council issues a decision that the beneficiary's inpatient admission satisfied the relevant criteria for Part A coverage and the hospital's decision to change the inpatient admission to outpatient receiving observation services was therefore erroneous, the beneficiary's reclassification as an outpatient is disregarded for the purposes of determining Part A benefits, including both Part A hospital coverage and Part A SNF coverage, if applicable.

(ii) For the purposes of effectuating a favorable decision by the Council, unless a Part A claim is submitted by a hospital, any claims previously submitted for outpatient hospital services and payments made for such services (including any applicable deductible and coinsurance amounts) are not reopened or revised by the MAC, and payment, as applicable, for covered SNF services may be made by the MAC to the SNF without regard to the hospital claim.

(2) In order to determine Part A benefits to be paid and to make payment for covered services as a result of a favorable decision, as applicable—

(i) The SNF, that furnished services to the beneficiary must refund payments previously collected from the beneficiary for the covered services and may then submit a Part A claim(s) for such services within 365 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services. After the refund is issued, the hospital may then submit a Part A inpatient claim for such services within 365 calendar days of receipt of the notice of a favorable decision;

(iii) In the case of a beneficiary enrolled in the Supplementary Medical Insurance program (Medicare Part B)

at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services. The deadline for submitting a Part A claim for such services is 365 calendar days after receipt of the notice of a favorable decision, and the hospital must refund any payments collected for the outpatient services before submitting the Part A inpatient claim.

(3) The hospital, and as applicable, the SNF, must comply with all applicable provisions regarding charges to the beneficiary for covered services, including but not limited to relevant provisions in part 489 subparts B through D of this chapter.

(4) A favorable Council decision is considered final and binding unless it is reopened and revised under the provisions of §§ 405.980 through 405.986. The provisions regarding reopening of a Council decision in § 405.980(d) and (e) apply in the same manner to favorable Council decisions issued under this section.

(5) The notice of a favorable decision issued to a hospital and, as applicable, notice of a favorable or partially favorable decision issued to SNF does not convey party status to such provider.

(e) *Effect of an unfavorable or partially favorable Appeals Council decision.* (1) An unfavorable or partially favorable Appeals Council decision is considered final and binding unless it is reopened and revised under the provisions of § 405.980(d) or (e), or a Federal district court issues a decision modifying the Council's decision.

(2) The provisions regarding reopening of an Appeals Council decision in § 405.980(d) and (e) apply in the same manner to unfavorable and partially favorable decisions issued under this section.

(f) *Judicial review.* (1) An eligible party (or the party's representative) dissatisfied with a final and binding decision under paragraph (e) of this section who satisfies the amount in controversy requirement in § 405.936(c) may request judicial review in Federal district court under the procedures set forth in § 405.1136.

(2) An eligible party (or the party's representative) who satisfies the amount in controversy requirement in § 405.936(c) and the requirements to escalate a case from the Council in § 405.1132 may request judicial review in Federal district court under the procedures set forth in § 405.1136.

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.

(2) The request is considered as filed on the date it is received by the contractor.

(b) *Extending the time frame for filing a request. General rule.* If the 120 calendar day period in which to file a request for a redetermination has expired and a party shows good cause, the contractor may extend the time frame for filing a request for redetermination.

(1) *How to request an extension.* A party may file a request for an extension of time for filing a request for a redetermination with the contractor. The party should include any evidence supporting the request for extension. The request for redetermination extension must—

(i) Be in writing;

(ii) State why the request for redetermination was not filed within the required time frame; and

(iii) Meet the requirements of § 405.944.

(2) *How the contractor determines if good cause exists.* In determining if a party has good cause for missing a deadline to request a redetermination, the contractor considers—

(i) The circumstances that kept the party from making the request on time;

(ii) If the contractor's action(s) misled the party; and

(iii) If the party had or has any physical, mental, educational, or linguistic limitations, including any lack of facility with the English language, that prevented the party from filing a timely request or from understanding or knowing about the need to file a timely request.

(3) *Examples of good cause.* Examples of circumstances when good cause may be found to exist include, but are not limited to, the following situations:

(i) The party was prevented by serious illness from contacting the contractor in person, in writing, or through a friend, relative, or other person; or

(ii) The party had a death or serious illness in his or her immediate family; or

(iii) Important records of the party were destroyed or damaged by fire or other accidental cause; or

(iv) The contractor gave the party incorrect or incomplete information about when and how to request a redetermination; or

(v) The party did not receive notice of the determination or decision; or

(vi) The party sent the request to a Government agency in good faith within the time limit, and the request did not reach the appropriate contractor until after the time period to file a request expired.

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

§ 405.944 Place and method of filing a request for a redetermination.

(a) *Filing location.* The request for redetermination must be filed with the contractor indicated on the notice of initial determination.

(b) *Content of redetermination request.* The request for redetermination must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements as follows:

(1) The beneficiary's name;

(2) The Medicare number;

(3) Specific service(s) and/or item(s) for which the redetermination is being requested and the specific date(s) of the service;

(4) The name of the party or the representative of the party.

(c) *Requests for redetermination by more than one party.* If more than one party timely files a request for redetermination on the same claim before a redetermination is made on the first timely filed request, the contractor must consolidate the separate requests into one proceeding and issue one redetermination.

[70 FR 11472, Mar. 8, 2005, as amended at 84 FR 19869, May 7, 2019]

§ 405.946 Evidence to be submitted with the redetermination request.

(a) *Evidence submitted with the request.* When filing the request for redetermination, a party must explain why it disagrees with the contractor's determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination.

(b) *Evidence submitted after the request.* When a party submits additional evidence after filing the request for redetermination, the contractor's 60 calendar day decision-making time frame is automatically extended for up to 14 calendar days for each submission.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65333, Dec. 9, 2009]

§ 405.947 Notice to the beneficiary of applicable plan's request for a redetermination.

(a) A CMS contractor must send notice of the applicable plan's appeal to the beneficiary.

(b) Issuance and content of the notice must comply with CMS instructions.

[80 FR 10618, Feb. 27, 2015]

§ 405.948 Conduct of a redetermination.

A redetermination consists of an independent review of an initial determination. In conducting a redetermination, the contractor reviews the evidence and findings upon which the initial determination was based, and any additional evidence the parties submit or the contractor obtains on its own. An individual who was not involved in making the initial determination must make a redetermination. The contractor may raise and develop new issues that are relevant to the claims in the particular case.

§ 405.950 Time frame for making a redetermination.

(a) *General rule.* The contractor mails, or otherwise transmits, written notice of the redetermination or dismissal to the parties to the redetermination at their last known addresses within 60 calendar days of the date the contractor receives a timely filed request for redetermination.

(b) *Exceptions.* (1) If a contractor grants an appellant's request for an extension of the 120 calendar day filing deadline made in accordance with § 405.942(b), the 60 calendar day decision-making time frame begins on the date the contractor receives the late-filed request for redetermination, or when the request for an extension is granted, whichever is later.

(2) If a contractor receives from multiple parties timely requests for redetermination of a claim determination, consistent with § 405.944(c), the contractor must issue a redetermination or dismissal within 60 calendar days of the latest filed request.

(3) If a party submits additional evidence after the request for redetermination is filed, the contractor's 60 calendar day decision-making time frame is extended for up to 14 calendar days for each submission, consistent with § 405.946(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65333, Dec. 9, 2009]

§ 405.952 Withdrawal or dismissal of a request for a redetermination.

(a) *Withdrawing a request.* A party that files a request for redetermination may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must contain a clear statement that the appellant is withdrawing the request for a redetermination and does not intend to proceed further with the appeal. The request must be received in the contractor's mailroom before a redetermination is issued. The appeal will proceed with respect to any other parties that have filed a timely request for redetermination.

(b) *Dismissing a request.* A contractor dismisses a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 405.906(b) or does not otherwise have a right to a redetermination under section 1869(a) of the Act;

(2) When the contractor determines the party failed to make out a valid request for redetermination that substantially complies with § 405.944;

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with § 405.942;

(4) When a beneficiary or the beneficiary's representative files a request for redetermination, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the contractor considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party filed a valid and timely redetermination request under §§ 405.942 and 405.944;

(5) When a party filing the redetermination request submits a timely

written request for withdrawal with the contractor; or

(6) When the contractor has not issued an initial determination on the claim or the matter for which a redetermination is sought.

(c) *Notice of dismissal.* A contractor mails or otherwise transmits a written notice of the dismissal of the redetermination request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a contractor may vacate its dismissal of a request for redetermination within 180 calendar days from the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for redetermination is binding unless it is modified or reversed by a QIC under § 405.974(b) or vacated under paragraph (d) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009; 84 FR 19870, May 7, 2019]

§ 405.954 Redetermination.

Upon the basis of the evidence of record, the contractor adjudicates the claim(s), and renders a redetermination affirming or reversing, in whole or in part, the initial determination in question.

§ 405.956 Notice of a redetermination.

(a) *Notification to parties*—(1) *General rule.* Written notice of a redetermination affirming, in whole or in part, the initial determination must be mailed or otherwise transmitted to all parties at their last known addresses in accordance with the time frames established in § 405.950. Written notice of a redetermination fully reversing the initial determination must be mailed or otherwise transmitted to the appellant in accordance with the time frames established in § 405.950. If the redetermination results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.* In an overpayment case involving multiple beneficiaries who have no liability, the contractor may issue a written notice only to the appellant.

(b) *Content of the notice for affirmations, in whole or in part.* For decisions that are affirmations, in whole or in part, of the initial determination, the redetermination must be written in a manner calculated to be understood by a beneficiary, and contain—

(1) A clear statement indicating the extent to which the redetermination is favorable or unfavorable;

(2) A summary of the facts, including, as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case;

(4) A summary of the rationale for the redetermination in clear, understandable language;

(5) Notification to the parties of their right to a reconsideration and a description of the procedures that a party must follow in order to request a reconsideration, including the time frame within which a reconsideration must be requested;

(6) A statement of any specific missing documentation that must be submitted with a request for a reconsideration, if applicable;

(7) A statement that all evidence the appellant wishes to introduce during the claim appeals process should be submitted with the request for a reconsideration;

(8) Notification that evidence not submitted to the QIC as indicated in paragraph (b)(6) of this section, is not considered at the OMHA level or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously; and

(9) The procedures for obtaining additional information concerning the redetermination, such as specific provisions of the policy, manual, or regulation used in making the redetermination.

(10) Any other requirements specified by CMS.

(c) *Content of the notice for a full reversal.* For decisions that are full reversals

of the initial determination, the redetermination must be in writing and contain—

(1) A clear statement indicating that the redetermination is wholly favorable;

(2) Any other requirements specified by CMS.

(d) *Exception for beneficiary appeal requests.* (1) The notice must inform beneficiary appellants that the requirements of paragraph (b)(8) of this section are not applicable for purposes of beneficiary appeals.

(2) This exception does not apply for appeal requests from beneficiaries who are represented by providers or suppliers.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5107, Jan. 17, 2017]

§ 405.958 Effect of a redetermination.

In accordance with section 1869(a)(3)(D) of the Act, once a redetermination is issued, it becomes part of the initial determination. The redetermination is binding upon all parties unless—

(a) A reconsideration is completed in accordance with § 405.960 through § 405.978; or

(b) The redetermination is revised as a result of a reopening in accordance with § 405.980.

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

RECONSIDERATION

§ 405.960 Right to a reconsideration.

A person or entity that is a party to a redetermination made by a contractor as described under § 405.940 through § 405.958, and is dissatisfied with that determination, may request a reconsideration by a QIC in accordance with § 405.962 through § 405.966, regardless of the amount in controversy.

§ 405.962 Timeframe for filing a request for a reconsideration.

(a) *Timeframe for filing a request.* Except as provided in paragraph (b) of this section and in § 405.974(b)(1), regarding a request for QIC reconsideration of a contractor's dismissal of a redetermination request, any request for a reconsideration must be filed within 180 calendar days from the date the party receives the notice of the redetermination.

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

(2) For purposes of meeting the 180 calendar day filing deadline, the request is considered as filed on the date it is received by the QIC.

(b) *Extending the time for filing a request*—(1) *General rule.* A QIC may extend the 180 calendar day timeframe for filing a request for reconsideration for good cause.

(2) *How to request an extension.* A party to the redetermination must file its request for an extension of the time for filing the reconsideration request with its request for reconsideration. A party should include evidence to support the request for extension. The request for reconsideration and request for extension must—

(i) Be in writing;

(ii) State why the request for reconsideration was not filed within the required timeframe; and

(iii) Meet the requirements of § 405.964.

(3) *How the QIC determines whether good cause exists.* In determining whether a party has good cause for missing a deadline to request reconsideration, the QIC applies the good cause provisions contained in § 405.942(b)(2) and (b)(3).

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

§ 405.964 Place and method of filing a request for a reconsideration.

(a) *Filing location.* The request for reconsideration must be filed with the QIC indicated on the notice of redetermination.

(b) *Content of reconsideration request.* The request for reconsideration must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements, as follows:

(1) The beneficiary's name;

(2) Medicare number;

(3) Specific service(s) and item(s) for which the reconsideration is requested and the specific date(s) of service;

(4) The name of the party or the representative of the party; and

(5) The name of the contractor that made the redetermination.

(c) *Requests for reconsideration by more than one party.* If more than one party timely files a request for reconsideration on the same claim before a reconsideration is made on the first timely filed request, the QIC must consolidate the separate requests into one proceeding and issue one reconsideration.

[70 FR 11472, Mar. 8, 2005, as amended at 84 FR 19870, May 7, 2019]

§ 405.966 Evidence to be submitted with the reconsideration request.

(a) *Evidence submitted with the request.* When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination.

(1) This evidence must include any missing documentation identified in the notice of redetermination, consistent with § 405.956(b)(6).

(2) Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence.

(b) *Evidence submitted after the request.* Each time a party submits additional evidence after filing the request for reconsideration, the QIC's 60 calendar day decisionmaking timeframe is automatically extended by up to 14 calendar days for each submission. This extension does not apply to timely submissions of documentation specifically requested by a QIC, unless the documentation was originally requested in the notice of redetermination.

(c) *Exception for beneficiaries and State Medicaid Agencies that file reconsideration requests.* (1) Beneficiaries and State Medicaid Agencies that file requests for reconsideration are not required to comply with the requirements of paragraph (a) of this section. However, the automatic 14 calendar day extension described in paragraph (b) of this section applies to each evidence submission made after the request for reconsideration is filed.

(2) Beneficiaries who are represented by providers or suppliers must comply with the requirements of paragraph (a) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

§ 405.968 Conduct of a reconsideration.

(a) *General rules.* (1) A reconsideration consists of an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim. In conducting a reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own. If the initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), a QIC's reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable.

(b) *Authority of the QIC.* (1) National coverage determinations (NCDs), CMS Rulings, Council decisions designated by the Chair of the Departmental Appeals Board as having precedential effect under § 401.109 of this chapter, and applicable laws and regulations are binding on the QIC.

(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.

(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.

(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.

(5) A QIC may raise and develop new issues that are relevant to the claims in a particular case provided that the contractor rendered a redetermination with respect to the claims.

(c) *Qualifications of the QIC's panel members.* (1) Members of a QIC's panel who conduct reconsiderations must have sufficient medical, legal, and other expertise, including knowledge of the Medicare program.

(2) When a redetermination is made with respect to whether an item or service is reasonable and necessary (section 1862(a)(1)(A) of the Act), the QIC designates a panel of physicians or other appropriate health care professionals to consider the facts and circumstances of the redetermination.

(3) Where a claim pertains to the furnishing of treatment by a physician, or the provision of items or services by a physician, a reviewing professional must be a physician.

(d) *Disqualification of a QIC panel member.* No physician or health care professional employed by or otherwise working for a QIC may review determinations regarding—

(1) Health care services furnished to a patient if that physician or health care professional was directly responsible for furnishing those services; or

(2) Health care services provided in or by an institution, organization, or agency, if that physician or health care professional or any member of the physician's family or health care professional's family has, directly or indirectly, a significant financial interest in that institution, organization, or agency (see the term family member as defined in § 405.902).

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5107, Jan. 17, 2017]

§ 405.970 Timeframe for making a reconsideration following a contractor redetermination.

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration following a contractor redetermination or any additional time provided by paragraph (b) of this section, the QIC mails, or otherwise transmits to the parties at their last known addresses, written notice of—

(1) The reconsideration;

(2) Its inability to complete its review within 60 calendar days in accordance with paragraphs (c) through (e) of this section; or

(3) Dismissal.

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180 calendar day filing deadline made in accordance with § 405.962(b), the QIC's 60 calendar day decisionmaking timeframe begins on the date the QIC receives the late filed request for reconsideration following a contractor redetermination, or when the request for an extension that meets the requirements of § 405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration following a contractor redetermination from multiple parties, consistent with § 405.964(c), the QIC must issue a reconsideration, notice that it cannot complete its review, or dismissal within 60 calendar days for each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration following a contractor redetermination is filed, the QIC's 60 calendar day decisionmaking timeframe is extended by up to 14 calendar days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 calendar days of receiving a request for a reconsideration following a contractor redetermination, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

(1) Notify all parties of its reconsideration, consistent with § 405.976.

(2) Notify the parties that it cannot complete the reconsideration by the deadline specified in paragraph (b) of this section and offer the appellant the opportunity to escalate the appeal to OMHA. The QIC continues to process the reconsideration unless it receives a written request from the appellant to escalate the case to OMHA after the adjudication period has expired.

(d) *Responsibilities of the appellant.* If an appellant wishes to exercise the option of escalating the case to OMHA, the appellant must notify the QIC in writing.

(e) *Actions following appellant's notice.* (1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration following a contractor redetermination and notifies the appellant of its action consistent with § 405.972 or § 405.976.

(2) If the appellant notifies the QIC that the appellant wishes to escalate the case, the QIC must take one of the following actions within 5 calendar days of receipt of the notice or 5 calendar days from the end of the applicable adjudication period under paragraph (a) or (b) of this section:

(i) Complete its reconsideration following a contractor redetermination and notify all parties of its decision consistent with § 405.972 or § 405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to OMHA.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 82 FR 5107, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.972 Withdrawal or dismissal of a request for reconsideration or review of a contractor's dismissal of a request for redetermination.

(a) *Withdrawing a request.* An appellant that files a request for reconsideration may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must—

(1) Contain a clear statement that the appellant is withdrawing the request for reconsideration and does not intend to proceed further with the appeal.

(2) Be received in the QIC's mailroom before the reconsideration is issued.

(b) *Dismissing a request.* A QIC dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting reconsideration is not a proper party under § 405.906(b) or does not otherwise have a right to a reconsideration under section 1869(b) of the Act;

(2) When the QIC determines that the party failed to make out a valid request for reconsideration that substantially complies with § 405.964(a) and (b);

(3) When the party fails to file the reconsideration request in accordance with the timeframes established in § 405.962, or fails to file the request for review of a contractor's dismissal of a redetermination request in accordance with the timeframes established in § 405.974(b)(1);

(4) When a beneficiary or the beneficiary's representative files a request for reconsideration, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the QIC considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party to the redetermination filed a valid and timely request for reconsideration under §§ 405.962 and 405.964.

(5) When a party filing for the reconsideration submits a written request of withdrawal to the QIC and satisfies the criteria set forth in paragraph (a) of this section before the reconsideration has been issued; or

(6) When the contractor has not issued a redetermination on the initial determination for which a reconsideration is sought.

(c) *Notice of dismissal.* A QIC mails or otherwise transmits written notice of the dismissal of the reconsideration request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action. The appeal will proceed with respect to any other parties that have filed a timely request for reconsideration.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a QIC

may vacate its dismissal of a request for reconsideration within 180 calendar days of the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ or attorney adjudicator under § 405.1004 or vacated under paragraph (d) of this section. The dismissal of a request for review of a contractor's dismissal of a redetermination request is binding and not subject to further review unless vacated under paragraph (d) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009; 82 FR 5107, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.974 Reconsideration and review of a contractor's dismissal of a request for redetermination.

(a) *Reconsideration of a contractor determination.* Except as provided in § 405.972, upon the basis of the evidence of record, the QIC must issue a reconsideration affirming or reversing, in whole or in part, the initial determination, including the redetermination, in question.

(b) *Review of a contractor's dismissal of a redetermination request.* (1) A party to a contractor's dismissal of a request for redetermination has a right to have the dismissal reviewed by a QIC, if the party files a written request for review of the dismissal with the QIC within 60 calendar days after receipt of the contractor's notice of dismissal.

(i) For purposes of this section, the date of receipt of the contractor's notice of dismissal is presumed to be 5 calendar days after the date of the notice of dismissal, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the QIC indicated on the notice of dismissal.

(2) If the QIC determines that the contractor's dismissal was in error, it vacates the dismissal and remands the case to the contractor for a redetermination.

(3) A QIC's review of a contractor's dismissal of a redetermination request is binding and not subject to further review.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 82 FR 5108, Jan. 17, 2017]

§ 405.976 Notice of a reconsideration.

(a) *Notification to parties*—(1) *General rules.* (i) Written notice of the reconsideration must be mailed or otherwise transmitted to all parties at their last known addresses, in accordance with the timeframes established in § 405.970(a) or (b).

(ii) The notice must be written in a manner reasonably calculated to be understood by a beneficiary.

(iii) The QIC must promptly notify the entity responsible for payment of claims under Part A or Part B of its reconsideration. If the reconsideration results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.* In an overpayment case involving multiple beneficiaries who have no liability, the QIC may issue a written notice only to the appellant.

(b) *Content of the notice.* The reconsideration must be in writing and contain—

(1) A clear statement indicating whether the reconsideration is favorable or unfavorable;

(2) A summary of the facts, including as appropriate, a summary of the clinical or scientific evidence used in making the reconsideration;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies, apply to the facts of the case, including, where applicable, the rationale for declining to follow an LCD, LMRP, or CMS program guidance;

(4) In the case of a determination on whether an item or service is reasonable or necessary under section 1862(a)(1)(A) of the Act, an explanation of the medical and scientific rationale for the decision;

(5) A summary of the rationale for the reconsideration.

(i) If the notice of redetermination indicated that specific documentation

should be submitted with the reconsideration request, and the documentation was not submitted with the request for reconsideration, the summary must indicate how the missing documentation affected the reconsideration; and

(ii) The summary must also specify that, consistent with §§ 405.956(b)(8) and 405.966(b), all evidence, including evidence requested in the notice of redetermination, that is not submitted prior to the issuance of the reconsideration will not be considered at the OMHA level, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. This requirement does not apply to beneficiaries, unless the beneficiary is represented by a provider or supplier or to State Medicaid Agencies;

(6) Information concerning to the parties' right to an ALJ hearing, including the applicable amount in controversy requirement and aggregation provisions;

(7) A statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if—

(i) The request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency; and

(ii) The reconsideration decision is partially or fully unfavorable.

(8) A description of the procedures that a party must follow in order to obtain an ALJ hearing of an expedited reconsideration, including the time frame under which a request for an ALJ hearing must be filed;

(9) If appropriate, advice as to the requirements for use of the expedited access to judicial review process set forth in § 405.990;

(10) The procedures for obtaining additional information concerning the reconsideration, such as specific provisions of the policy, manual, or regulation used in making the reconsideration; and

(11) Any other requirements specified by CMS.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5108, Jan. 17, 2017]

§ 405.978 Effect of a reconsideration.

A reconsideration is binding on all parties, unless—

(a) An ALJ or attorney adjudicator decision is issued in accordance to a request for an ALJ hearing made in accordance with § 405.1014;

(b) A review entity issues a decision in accordance to a request for expedited access to judicial review under § 405.990; or

(c) The reconsideration is revised as a result of a reopening in accordance with § 405.980.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009; 82 FR 5108, Jan. 17, 2017]

REOPENINGS

§ 405.980 Reopening of initial determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a binding determination or decision that resulted in either an overpayment or underpayment, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. That action may be taken by—

(i) A contractor to revise the initial determination or redetermination;

(ii) A QIC to revise the reconsideration;

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

(2) If a contractor issues a denial of a claim because it did not receive requested documentation during medical review and the party subsequently requests a redetermination, the contractor must process the request as a reopening.

(3) Notwithstanding paragraph (a)(4) of this section, a contractor must process clerical errors (which includes minor errors and omissions) as reopenings, instead of as redeterminations as specified in § 405.940. If the contractor receives a request for reopening and disagrees that the issue is a clerical error, the contractor must dismiss the reopening request and advise the party of any appeal rights, provided

the timeframe to request an appeal on the original denial has not expired. For purposes of this section, clerical error includes human or mechanical errors on the part of the party or the contractor such as—

(i) Mathematical or computational mistakes;

(ii) Inaccurate data entry; or

(iii) Denials of claims as duplicates.

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(5) The contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

(6) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for services or items that were already reimbursed by the Medicare program is not a reopening, except where the recovery claim is based upon a provider's or supplier's failure to demonstrate that it filed a proper claim as defined in part 411 of this chapter.

(b) *Time frames and requirements for reopening initial determinations and redeterminations initiated by a contractor.* A contractor may reopen an initial determination or redetermination on its own motion—

(1) Within 1 year from the date of the initial determination or redetermination for any reason.

(2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in § 405.986.

(3) At any time if there exists reliable evidence as defined in § 405.902 that the initial determination was procured by fraud or similar fault as defined in § 405.902.

(4) At anytime if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.

(5) At any time to effectuate a decision issued under the coverage appeals process.

(c) *Time frame and requirements for reopening initial determinations and redeterminations requested by a party.* (1) A party may request that a contractor reopen its initial determination or redetermination within 1 year from the date of the initial determination or redetermination for any reason.

(2) A party may request that a contractor reopen its initial determination or redetermination within 4 years from the date of the initial determination or redetermination for good cause in accordance with § 405.986.

(3) A party may request that a contractor reopen its initial determination at any time if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based. Third party payer error does not constitute clerical error. See § 405.986(c).

(4) A party may request that a contractor reopen an initial determination for the purpose of reporting and returning an overpayment under § 401.305 of this chapter.

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by a QIC, ALJ or attorney adjudicator, or the Council.* (1) A QIC may reopen its reconsideration on its own motion within 180 calendar days from the date of the reconsideration for good cause in accordance with § 405.986. If the QIC's reconsideration was procured by fraud or similar fault, then the QIC may reopen at any time.

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 405.986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision, at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by a party.* (1) A party to a reconsideration may request that a QIC reopen its reconsideration within 180 calendar days from the date of the reconsideration for good cause in accordance with § 405.986.

(2) A party to an ALJ or attorney adjudicator decision may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 405.986.

(3) A party to a Council review may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 81 FR 7684, Feb. 12, 2016; 82 FR 5108, Jan. 17, 2017]

§ 405.982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings.* When any determination or decision is reopened and revised as provided in § 405.980, the contractor, QIC, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

(b) *Reopenings initiated at the request of a party.* The contractor, QIC, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5108, Jan. 17, 2017]

§ 405.984 Effect of a revised determination or decision.

(a) *Initial determinations.* The revision of an initial determination is binding upon all parties unless a party files a written request for a redetermination that is accepted and processed in accordance with § 405.940 through § 405.958.

(b) *Redeterminations.* The revision of a redetermination is binding upon all parties unless a party files a written request for a QIC reconsideration that is accepted and processed in accordance with § 405.960 through § 405.978.

(c) *Reconsiderations.* The revision of a reconsideration is binding upon all parties unless a party files a written request for an ALJ hearing that is accepted and processed in accordance with § 405.1000 through § 405.1063.

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding upon all parties unless a party files a written request for a Council review that is accepted and processed in accordance with § 405.1100 through § 405.1130.

(e) *Council review.* The revision of a Council review is binding upon all parties unless a party files a civil action in which a Federal district court accepts jurisdiction and issues a decision.

(f) *Appeal of only the portion of the determination or decision revised by the reopening.* Only the portion of the initial determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* A revised determination or decision is binding unless it is appealed or otherwise reopened.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5108, Jan. 17, 2017]

§ 405.986 Good cause for reopening.

(a) *Establishing good cause for reopening.* Good cause may be established when—

(1) There is new and material evidence that—

(i) Was not available or known at the time of the determination or decision; and

(ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

(b) *Change in substantive law or interpretative policy.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, or a change in legal interpretation or policy by SSA in a regulation, SSA ruling, or SSA general instruction in entitlement appeals, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision under this section. This provision does not preclude contractors from conducting reopenings to effectuate coverage decisions issued under the authority granted by section 1869(f) of the Act.

(c) *Third party payer error.* A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 86 FR 65660, Nov. 19, 2021]

EXPEDITED ACCESS TO JUDICIAL REVIEW

§ 405.990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.* (1) For purposes of this section, a ''review entity'' means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board (DAB), as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the Council does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) A party may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request.* (1) A party may request EAJR in place of an ALJ hearing or Council review if the following conditions are met:

(i) A QIC has made a reconsideration determination and the party has filed a request for—

(A) An ALJ hearing in accordance with § 405.1002 and a decision, dismissal order, or remand order of the ALJ or attorney adjudicator has not been issued;

(B) Council review in accordance with § 405.1102 and a final decision, dismissal order, or remand order of the Council has not been issued; or

(ii) The appeal has been escalated from the QIC to OMHA for an ALJ hearing after the period described in § 405.970(a) and § 405.970(b) has expired, and the QIC does not issue a decision or dismissal order within the timeframe described in § 405.970(e).

(2) The requestor is a party, as defined in paragraph (e) of this section.

(3) The amount remaining in controversy meets the requirements of § 405.1006(b) or (c).

(4) If there is more than one party to the reconsideration, hearing, or Council review, each party concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.

(c) *Content of the request for EAJR.* The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the requestor considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the requestor is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation or national coverage determination and specify the statutory provision that the requestor considers unconstitutional or the provision of a regulation or a national coverage determination that the requestor considers invalid, or

(ii) A CMS Ruling that the requester considers invalid;

(3) Include a copy of any QIC reconsideration and of any ALJ or attorney adjudicator decision that the requester has received;

(4) If any QIC reconsideration or ALJ or attorney adjudicator decision was based on facts that the requestor is disputing, state why the requestor considers those facts to be immaterial; and

(5) If any QIC reconsideration or ALJ or attorney adjudicator decision was based on a provision of a law, regulation, national coverage determination or CMS Ruling in addition to the one the requestor considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary.

(d) *Place and time for an EAJR request*—(1) *Method and place for filing request.* The requestor may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA, or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

(2) *Time of filing request.* The party may file a request for the EAJR—

(i) If the party has requested a hearing, at any time before receipt of the notice of the ALJ's or attorney adjudicator's decision; or

(ii) If the party has requested Council review, at any time before receipt of notice of the Council's decision.

(e) *Parties to the EAJR.* The parties to the EAJR are the persons or entities who were parties to the QIC's reconsideration determination and, if applicable, to the ALJ hearing.

(f) *Determination on EAJR request.* (1) The review entity described in paragraph (a) of this section will determine whether the request for EAJR meets all of the requirements of paragraphs (b), (c), and (d) of this section.

(2) Within 60 calendar days after the date the review entity receives a request and accompanying documents and materials meeting the conditions in paragraphs (b), (c), and (d) of this section, the review entity will issue either a certification in accordance to paragraph (g) of this section or a denial of the request.

(3) A determination by the review entity either certifying that the requirements for EAJR are met pursuant to paragraph (g) of this section or denying the request is not subject to review by the Secretary.

(4) If the review entity fails to make a determination within the time frame specified in paragraph (f)(2) of this section, then the requestor may bring a civil action in Federal district court within 60 calendar days of the end of the time frame.

(g) *Certification by the review entity.* If a party meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (g)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation, CMS Ruling, or national coverage determination;

(4) But for the provision challenged, the requestor would receive a favorable decision on the ultimate issue (such as whether a claim should be paid); and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(h) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (g) of this section—

(1) The party that requested the EAJR is considered to have waived any

right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The requestor has 60 calendar days, beginning on the date of the review entity's certification within which to bring a civil action in Federal district court.

(3) The requestor must satisfy the requirements for venue under section 1869(b)(2)(C)(iii) of the Act, as well as the requirements for filing a civil action in a Federal district court under § 405.1136(a) and § 405.1136(c) through § 405.1136(f).

(i) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises in writing all parties that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed, and if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

(j) *Interest on any amounts in controversy.* (1) If a provider or supplier is granted judicial review in accordance with this section, the amount in controversy, if any, is subject to annual interest beginning on the first day of the first month beginning after the 60 calendar day period as determined in accordance with paragraphs (f)(4) or (h)(2) of this section, as applicable.

(2) The interest is awarded by the reviewing court and payable to a prevailing party.

(3) The rate of interest is equal to the rate of interest applicable to obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this subpart is commenced.

(4) No interest awarded in accordance with this paragraph shall be income or cost for purposes of determining reimbursement due to providers or suppliers under Medicare.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 82 FR 5108, Jan. 17, 2017]

ALJ HEARINGS

§ 405.1000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If a party is dissatisfied with a QIC's reconsideration, or if the adjudication period specified in § 405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, CMS or its contractor may participate in the proceedings under § 405.1010, or join the hearing before an ALJ as a party under § 405.1012.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If all parties who are due a notice of hearing in accordance with § 405.1020(c) waive their right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties who are entitled to a notice of hearing in accordance with § 405.1020(c) have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold

the hearing even if none of the parties decide to appear.

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012.

(h) If more than one party timely files a request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued.

[82 FR 5109, Jan. 17, 2017]

§ 405.1002 Right to an ALJ hearing.

(a) A party to a QIC reconsideration has a right to a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 calendar days after receipt of the notice of the QIC's reconsideration.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the reconsideration, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the QIC's reconsideration.

(b) A party who files a timely appeal before a QIC and whose appeal continues to be pending before a QIC at the end of the period described in § 405.970 has a right to a hearing before an ALJ if—

(1) The party files a written request with the QIC to escalate the appeal for a hearing before an ALJ after the period described in § 405.970(a) and (b) has expired and the party files the request in accordance with § 405.970(d);

(2) The QIC does not issue a decision or dismissal order within 5 calendar days of receiving the request for escalation in accordance with § 405.970(e)(2); and

(3) The party has an amount remaining in controversy specified in § 405.1006.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017]

§ 405.1004 Right to a review of QIC notice of dismissal.

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ or attorney adjudicator if—

(1) The party files a written request for review within 60 calendar days after receipt of the notice of the QIC's dismissal.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the QIC's dismissal is presumed to be 5 calendar days after the date of the dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the QIC's dismissal.

(b) If the ALJ or attorney adjudicator determines that the QIC's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC for a reconsideration in accordance with § 405.1056.

(c) If the ALJ or attorney adjudicator affirms the QIC's dismissal of a reconsideration request, he or she issues a notice of decision affirming the QIC dismissal in accordance with § 405.1046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of a QIC's dismissal in accordance with § 405.1052(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017]

§ 405.1006 Amount in controversy required for an ALJ hearing and judicial review.

(a) *Definitions.* For the purposes of aggregating claims to meet the amount in controversy requirement for an ALJ hearing or judicial review:

(1) ''Common issues of law and fact'' means the claims sought to be aggregated are denied, or payment is reduced, for similar reasons and arise from a similar fact pattern material to the reason the claims are denied or payment is reduced.

(2) ''Delivery of similar or related services'' means like or coordinated services or items provided to one or more beneficiaries.

(b) *ALJ review.* To be entitled to a hearing before an ALJ, the party must meet the amount in controversy requirements of this section.

(1) For ALJ hearing requests, the required amount remaining in controversy must be $100 increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

(2) If the figure in paragraph (b)(1) of this section is not a multiple of $10, then it is rounded to the nearest multiple of $10. The Secretary will publish changes to the amount in controversy requirement in the FEDERAL REGISTER when necessary.

(c) *Judicial review.* To be entitled to judicial review, a party must meet the amount in controversy requirements of this subpart at the time it requests judicial review.

(1) For review requests, the required amount remaining in controversy must be $1,000 or more, adjusted as specified in paragraphs (b)(1) and (b)(2) of this section.

(2) [Reserved]

(d) *Calculating the amount remaining in controversy*—(1) *In general.* The amount remaining in controversy is computed as the actual amount charged the individual for the items and services in the disputed claim, reduced by—

(i) Any Medicare payments already made or awarded for the items or services; and

(ii) Any deductible and/or coinsurance amounts that may be collected for the items or services.

(2) *Limitation on liability.* Notwithstanding paragraph (d)(1) of this section, when payment is made for items or services under section 1879 of the Act or § 411.400 of this chapter, or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is computed as the amount the beneficiary would have been charged for the items or services in question if those expenses were not paid under § 411.400 of this chapter or if that liability was not limited under § 411.402 of this chapter, reduced by any deductible and/or coinsurance amounts that may be collected for the items or services.

(3) *Item or service terminations.* When a matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services, the amount in controversy is calculated in accordance with paragraph (d)(1) of this section, except that the amount charged to the individual and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services the beneficiary asserts should have been covered based on the beneficiary's current condition, and Medicare payment were not made for the items or services.

(4) *Overpayments.* Notwithstanding paragraph (d)(1) of this section, when an appeal involves an identified overpayment, the amount in controversy is the amount of the overpayment specified in the demand letter, or the amount of the revised overpayment if the amount originally demanded changes as a result of a subsequent determination or appeal, for the items or services in the disputed claim. When an appeal involves an estimated overpayment amount determined through the use of statistical sampling and extrapolation, the amount in controversy is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter, or as subsequently revised.

(5) *Coinsurance and deductible challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals filed by beneficiaries challenging only the computation of a coinsurance amount or the amount of a remaining deductible, the amount in controversy is the

difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct.

(6) *Fee schedule or contractor price challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected on the published fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services.

(e) *Aggregating claims to meet the amount in controversy*—(1) *Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were previously reconsidered by a QIC;

(ii) The appellant(s) requests aggregation of claims appealed in the same request for ALJ hearing, or in multiple requests for an ALJ hearing filed with the same request for aggregation, and the request is filed within 60 calendar days after receipt of all of the reconsiderations being appealed; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were pending before the QIC in conjunction with the same request for reconsideration;

(ii) The appellant(s) requests aggregation of the claims for an ALJ hearing in the same request for escalation; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(f) *Content of request for aggregation.* When an appellant(s) seeks to aggregate claims in a request for an ALJ hearing, the appellant(s) must—

(1) Specify all of the claims the appellant(s) seeks to aggregate; and

(2) State why the appellant(s) believes that the claims involve common issues of law and fact or delivery of similar or related services.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.1008 Parties to the proceedings on a request for an ALJ hearing.

The party who filed the request for hearing and all other parties to the reconsideration are parties to the proceedings on a request for an ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in § 405.1012.

[82 FR 5110, Jan. 17, 2017]

§ 405.1010 When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS or a contractor can participate.* (1) CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in any proceedings before the ALJ, including the hearing.

(b) *How an election is made*— (1) *No notice of hearing.* If CMS or a contractor elects to participate before receipt of a notice of hearing, or when a notice of hearing is not required, it must send written notice of its intent to participate to—

(i) The assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request for hearing is not yet assigned to an ALJ or attorney adjudicator; and

(ii) The parties who were sent a copy of the notice of reconsideration or, for escalated requests for reconsideration, any party that filed a request for reconsideration or was found liable for the services at issue subsequent to the initial determination.

(2) *Notice of hearing.* If CMS or a contractor elects to participate after receipt of a notice of hearing, it must send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

(3) *Timing of election.* CMS or a contractor must send its notice of intent to participate—

(i) If no hearing is scheduled, no later than 30 calendar days after notification that a request for hearing was filed; or

(ii) If a hearing is scheduled, no later than 10 calendar days after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing.

(c) *Roles and responsibilities of CMS or a contractor as a participant.* (1) Subject to paragraphs (d)(1) through (3) of this section, participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

(2) When CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in paragraph (d)(3) of this section. However, the parties may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS or contractor position papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit the position paper or written testimony, a position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing if a hearing is scheduled.

(ii) A copy of any position paper or written testimony it submits to OMHA must be sent within the same time frame specified in paragraph (c)(3)(i) of this section to—

(A) The parties that are required to be sent a copy of the notice of intent to participate in accordance with paragraph (b)(1) of this section, if the position paper or written testimony is being submitted before receipt of a notice of hearing for the appeal; or

(B) The parties who were sent a copy of the notice of hearing, if the position paper or written testimony is being submitted after receipt of a notice of hearing for the appeal.

(iii) If CMS or a contractor fails to send a copy of its position paper or written testimony to the parties or fails to submit its position paper or written testimony within the time frames described in this paragraph, the position paper or written testimony will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS or a contractor has

been made a party to a hearing in accordance with §405.1012, no entity that elected to be a participant in the proceedings in accordance with this section (or that elected to be a party to the hearing but was made a participant in accordance with §405.1012(d)(1)) may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(2) If CMS or a contractor did not elect to be a party to a hearing in accordance with §405.1012 and more than one entity elected to be a participant in the proceedings in accordance with this section, only the first entity to file a response to the notice of hearing as provided under §405.1020(c) may participate in the oral hearing. Entities that filed a subsequent response to the notice of hearing may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(3) If CMS or a contractor is precluded from participating in the oral hearing under paragraph (d)(1) or (2) of this section, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue. If the ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with §405.1012.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the election was not timely filed or the election was not sent to the correct parties.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election in accordance with this section.

(i) If no hearing is scheduled or the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a hearing is scheduled, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice must be sent as soon as possible after the oral notice is provided.

[82 FR 5110, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§405.1012 When CMS or its contractors may be a party to a hearing.

(a) *When CMS or a contractor can elect to be a party to a hearing.* (1) Unless the request for hearing is filed by an unrepresented beneficiary, and unless otherwise provided in this section, CMS or one of its contractors may elect to be a party to the hearing upon filing a notice of intent to be a party to the hearing in accordance with paragraph (b) of this section no later than 10 calendar days after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing.

(2) Unless the request for hearing is filed by an unrepresented beneficiary, an ALJ may request, but may not require, CMS and/or one or more of its contractors to be a party to the hearing. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to be a party to the hearing.

(b) *How an election is made.* If CMS or a contractor elects to be a party to the hearing, it must send written notice to the ALJ and the parties who were sent a copy of the notice of hearing of its intent to be a party to the hearing.

(c) *Roles and responsibilities of CMS or a contractor as a party.* (1) As a party, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties.

(2) CMS or contractor position papers, written testimony, and evidentiary submissions are subject to the following:

(i) Any position paper, written testimony, and/or evidence must be submitted no later than 5 calendar days prior to the hearing unless the ALJ grants additional time to submit the

position paper, written testimony, and/or evidence.

(ii) A copy of any position paper, written testimony, and/or evidence it submits to OMHA must be sent within the same time frame specified in paragraph (c)(2)(i) of this section to the parties who were sent a copy of the notice of hearing.

(iii) If CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit its position paper, written testimony, and/or evidence within the time frames described in this section, the position paper, written testimony, and/or evidence will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS and one or more contractors, or multiple contractors, file an election to be a party to the hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under § 405.1010, subject to § 405.1010(d)(1) and (3), unless the ALJ grants leave to an entity to also be a party to the hearing in accordance with paragraph (d)(2) of this section.

(2) If CMS or a contractor filed an election to be a party in accordance with this section but is precluded from being made a party under paragraph (d)(1) of this section, the ALJ may grant leave to be a party to the hearing if the ALJ determines that the entity's participation as a party is necessary for a full examination of the matters at issue.

(e) *Invalid election.* (1) An ALJ may determine that a CMS or contractor election is invalid under this section if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who were sent the notice of hearing.

(i) If the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the decision, dismissal, or remand notice is mailed.

(ii) If the election was submitted before the hearing occurs, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing must be sent as soon as possible after the oral notice is provided.

[82 FR 5111, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1014 Request for an ALJ hearing or a review of a QIC dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of a QIC dismissal must be made in writing. The request must include all of the following—

(i) The name, address, and Medicare number of the beneficiary whose claim is being appealed, and the beneficiary's telephone number if the beneficiary is the appealing party and not represented.

(ii) The name, address, and telephone number, of the appellant, when the appellant is not the beneficiary.

(iii) The name, address, and telephone number, of the designated representative, if any.

(iv) The Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed.

(v) The dates of service of the claim(s) being appealed, if applicable.

(vi) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(2) The appellant must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) Special rule for appealing statistical sample and/or extrapolation. If

the appellant disagrees with how a statistical sample and/or extrapolation was conducted, the appellant must—

(i) Include the information in paragraphs (a)(1) and (2) of this section for each sample claim that the appellant wishes to appeal;

(ii) File the request for hearing for all sampled claims that the appellant wishes to appeal within 60 calendar days of the date the party receives the last reconsideration for the sample claims, if they were not all addressed in a single reconsideration; and

(iii) Assert the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted in the request for hearing.

(b) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the appellant will be provided with an opportunity to complete the request, and if an adjudication time frame applies, it does not begin until the request is complete. If the appellant fails to provide the information necessary to complete the request within the time frame provided, the appellant's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(c) *When and where to file.* The request for an ALJ hearing or request for review of a QIC dismissal must be filed—

(1) Within 60 calendar days from the date the party receives notice of the QIC's reconsideration or dismissal, except as provided in paragraph (a)(3)(ii) of this section for appeals of extrapolations;

(2) With the office specified in the QIC's reconsideration or dismissal. If the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, the request is not treated as untimely, and any applicable time frame specified in §405.1016 for deciding the appeal begins on the date the office specified in the QIC's reconsideration or dismissal receives the request for hearing. If the request for hearing is filed with an office, other than the office specified in the QIC's reconsideration or dismissal, OMHA must notify the appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame.

(d) *Copy requirement.* (1) The appellant must send a copy of the request for hearing or request for review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. If additional materials submitted with the request are necessary to provide the information required for a complete request in accordance with paragraph (b) of this section, copies of the materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). If additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence, or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence).

(2) Evidence that a copy of the request for hearing or request for review of a QIC dismissal, or a copy of submitted evidence or a summary thereof, was sent in accordance with paragraph (d)(1) of this section includes—

(i) Certification on the standard form for requesting an ALJ hearing or requesting a review of a QIC dismissal that a copy of the request is being sent to the other parties;

(ii) An indication, such as a copy or ''cc'' line, on a request for hearing or request for review of a QIC dismissal that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipient;

(iii) An affidavit or certificate of service that identifies the name and address of the recipient, and what was sent to the recipient; or

(iv) A mailing or shipping receipt that identifies the name and address of the recipient, and what was sent to the recipient.

(3) If the appellant, other than an unrepresented beneficiary, fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of submitted evidence or a summary thereof, as described in paragraph (d)(1) of this section, the appellant will be provided with an additional opportunity to send the request, materials, and/or evidence or summary thereof, and if an adjudication time frame applies, it begins upon receipt of evidence that the request, materials, and/or evidence or summary thereof were sent. If the appellant, other than an unrepresented beneficiary, again fails to provide evidence that the request, materials, and/or evidence or summary thereof were sent within the additional time frame provided to send the request, materials, and/or evidence or summary thereof, the appellant's request for hearing or request for review of a QIC dismissal will be dismissed.

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review of a QIC dismissal is not filed within 60 calendar days of receipt of the QIC's reconsideration or dismissal, an appellant may request an extension for good cause (See § 405.942(b)(2) and (3)).

(2) Any request for an extension of time must be in writing, give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or request for review of a QIC dismissal, or upon notice that the request may be dismissed because it was not timely filed, with the office specified in the notice of reconsideration or dismissal.

(3) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of a QIC dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of a QIC dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or attorney adjudicator uses the standards set forth in § 405.942(b)(2) and (3).

(4) If a request for hearing is not timely filed, any applicable adjudication period in § 405.1016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(5) A determination granting a request to extend the filing deadline is not subject to further review.

[82 FR 5112, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019; 89 FR 106363, Dec. 30, 2024]

§ 405.1016 Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration.

(a) *Adjudication period for appeals of QIC reconsiderations.* When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *When the adjudication period begins.* (1) Unless otherwise specified in this subpart, the adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the office specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(2) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c) of this section, the remanded appeal will be subject to the adjudication time frame of paragraph (a) of this section beginning on the date that OMHA receives the Council remand.

(c) *Adjudication period for escalated requests for QIC reconsiderations.* When an appeal is escalated to OMHA because the QIC has not issued a reconsideration determination within the period

specified in §405.970, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180 calendar day period beginning on the date that the request for escalation is received by OMHA in accordance with §405.970, unless the 180 calendar day period is extended as provided in this subpart.

(d) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the appellant may waive the adjudication period specified in paragraphs (a) and (c) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the appellant.

(2) The adjudication periods specified in paragraphs (a) and (c) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction; or

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an appellant, provided no other party also filed a request for hearing on the same claim at issue.

(e) *Effect of exceeding adjudication period.* If an ALJ or attorney adjudicator fails to issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in this section, subject to paragraphs (b) and (d) of this section, the party that filed the request for hearing may escalate the appeal in accordance with paragraph (f) of this section. If the party that filed the request for hearing does not elect to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand.

(f) *Requesting escalation*—(1) *When and how to request escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending with OMHA at the end of the applicable adjudication period under paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, may exercise the option of escalating the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council and sending a copy of the request to escalate to the other parties who were sent a copy of the QIC reconsideration.

(2) *Escalation.* If the request for escalation meets the requirements of paragraph (f)(1) of this section and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation, or 5 calendar days from the end of the applicable adjudication period set forth in paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, OMHA will take the following actions—

(i) Send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of this section, the QIC reconsideration will be the decision that is subject to Council review consistent with §405.1102(a), and the appeal will be escalated to the Council for a review in accordance with §405.1108; and

(ii) Forward the case file to the Council.

(3) *Invalid escalation request.* If an ALJ or attorney adjudicator determines the request for escalation does not meet the requirements of paragraph (f)(1) of this section, OMHA will send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation.

[82 FR 5113, Jan. 17, 2017]

§405.1018 Submitting evidence.

(a) *When evidence may be submitted.* Except as provided in this section, parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with §405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(b) *Effect on adjudication period.* If a party submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified

in § 405.1016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(c) *New evidence.* (1) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see § 405.1028).

(2) If a statement explaining why the evidence was not previously submitted to the QIC or a prior decision-maker is not included with the evidence, the evidence will not be considered.

(d) *When this section does not apply.* (1) The requirements in paragraphs (a) and (b) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary.

(2) The requirements in paragraph (c) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier.

[82 FR 5113, Jan. 17, 2017]

§ 405.1020 Time and place for a hearing before an ALJ.

(a) *General.* The ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

(b) *Determining how appearances are made*—(1) *Appearances by unrepresented beneficiaries.* The ALJ will direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by video-teleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ find good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented beneficiary.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) VTC or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by individuals other than unrepresented beneficiaries.* The ALJ will direct that the appearance of an individual, other than an unrepresented beneficiary who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, also may find good cause that an in-person hearing should be conducted if—

(A) VTC and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to all parties that filed an appeal or participated in the reconsideration; any party who was found liable for the services at issue subsequent to the initial determination or may be found liable based on a review of the record; the QIC that issued the reconsideration or from which the request for reconsideration was escalated, or another contractor designated to receive the notice of hearing by CMS; and CMS or a contractor that elected to participate in the proceedings in accordance with § 405.1010(b) or that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the party or representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing.

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 405.1038(b). As provided in § 405.1000, an ALJ may require the parties to attend a hearing if it is necessary to decide the case. If an ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) *A party's objection to time and place of hearing.* (1) If a party objects to the time and place of the hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The party must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral requests for a rescheduled hearing in writing and maintain the documentation in the administrative record.

(4) The ALJ may change the time or place of the hearing if the party has good cause.

(5) If the party's objection to the place of the hearing includes a request for an in-person or VTC hearing, the objection and request are considered in paragraph (i) of this section.

(f) *Good cause for changing the time or place.* The ALJ can find good cause for changing the time or place of the scheduled hearing and reschedule the hearing if the information available to the ALJ supports the party's contention that—

(1) The party or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing; or

(3) Good cause exists as set forth in paragraph (g) of this section.

(g) *Good cause in other circumstances.* (1) In determining whether good cause exists in circumstances other than those set forth in paragraph (f) of this section, the ALJ considers the party's reason for requesting the change, the facts supporting the request, and the impact of the proposed change on the efficient administration of the hearing process.

(2) Factors evaluated to determine the impact of the change include, but are not limited to, the effect on processing other scheduled hearings, potential delays in rescheduling the hearing, and whether any prior changes were granted the party.

(3) Examples of other circumstances a party might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The party has attempted to obtain a representative but needs additional time.

(ii) The party's representative was appointed within 10 calendar days of the scheduled hearing and needs additional time to prepare for the hearing.

(iii) The party's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing.

(iv) A witness who will testify to facts material to a party's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for a party to travel to the hearing.

(vi) The party is unrepresented, and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) that he or she has.

(vii) The party or representative has a prior commitment that cannot be changed without significant expense.

(viii) The party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the appellant for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 405.1016.

(i) *A party's request for an in-person or VTC hearing.* (1) If an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or an in-person hearing.

(2) The party must state the reason for the objection and state the time and/or place he or she wants an in-person or VTC hearing to be held.

(3) The request must be in writing.

(4) When a party's request for an in-person or VTC hearing as specified under paragraph (i)(1) of this section is granted and an adjudication time frame applies in accordance with § 405.1016, the ALJ issues a decision, dismissal, or remand to the QIC within the adjudication time frame specified in § 405.1016 (including any applicable extensions provided in this subpart) unless the party requesting the hearing agrees to waive such adjudication time frame in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee if the request was for an in-person hearing, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person or by VTC before the ALJ. Good cause is not required for a request for VTC hearing made by an unrepresented beneficiary who filed the request for hearing and objects to an ALJ's offer to conduct a hearing by telephone.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing in accordance with § 405.1022(a).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5114, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the parties and other potential participants, as provided in § 405.1020(c) at their last known address, or given by personal service, except to a party or potential participant who indicates in writing that it does not wish to receive this notice. The notice is mailed, transmitted, or served at least 20 calendar days before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 405.1032.

(2) The notice will inform the parties that they may designate a person to represent them during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the appellant fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(5) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at § 405.1020(i) for notifying the ALJ of their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the party for an explanation.

(2) If the party states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the party and in accordance with OMHA procedures.

(3) The party may request that the ALJ reschedule the hearing in accordance with § 405.1020(e).

[82 FR 5115, Jan. 17, 2017]

§ 405.1024 Objections to the issues.

(a) If a party objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 calendar days before the hearing.

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing.

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009; 82 FR 5115, Jan. 17, 2017]

§ 405.1026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator cannot adjudicate an appeal if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator considers the party's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the party may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 405.1100 through § 405.1130. The Council will then consider whether the decision or dismissal should be revised or if applicable, a new hearing held before another ALJ. If the case is escalated to the Council after a hearing is held but before the ALJ issues a decision, the Council considers the reasons the party objected to the ALJ during its review of the case and, if the Council deems it necessary, may remand the case to another ALJ for a hearing and decision.

(d) If the party objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication time frame that applies to the appeal in accordance with § 405.1016 is extended by 14 calendar days.

[82 FR 5115, Jan. 17, 2017]

§ 405.1028 Review of evidence submitted by parties.

(a) *New evidence*—(1) *Examination of any new evidence.* After a hearing is requested but before a hearing is held by an ALJ or a decision is issued if no hearing is held, the ALJ or attorney adjudicator will examine any new evidence submitted in accordance with § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the OMHA level.

(2) *Determining if good cause exists.* An ALJ or attorney adjudicator finds good cause when—

(i) The new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration;

(ii) The new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with § 405.1032(b)(1);

(iii) The party was unable to obtain the evidence before the QIC issued its reconsideration and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration;

(iv) The party asserts that the evidence was submitted to the QIC or another contractor and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration; or

(v) In circumstances not addressed in paragraphs (a)(2)(i) through (iv) of this section, the ALJ or attorney adjudicator determines that the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration.

(3) *If good cause does not exist.* If the ALJ or attorney adjudicator determines that there was not good cause for submitting the evidence for the first time at the OMHA level, the ALJ or attorney adjudicator must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(4) *Notification to parties.* If a hearing is conducted, as soon as possible, but no later than the start of the hearing, the ALJ must notify all parties and participants who responded to the notice of hearing whether the evidence will be considered or is excluded from consideration.

(b) *Duplicative evidence.* The ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA.

[82 FR 5115, Jan. 17, 2017]

§ 405.1030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) At the hearing, the ALJ fully examines the issues, questions the parties and other witnesses, and may accept evidence that is material to the issues consistent with §§ 405.1018 and 405.1028.

(2) The ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter, in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that a party or party's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party

or representative to stop such behavior, the ALJ may excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with an opportunity to offer testimony and/or argument. If a party or representative was excused from the hearing, the ALJ will provide the party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the party or representative may request a recording of the hearing in accordance with § 405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause in accordance with § 405.1028 for not producing the evidence earlier.

(d) *Effect of new evidence on adjudication period.* If an appellant, other than an unrepresented beneficiary, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in § 405.1016 is extended in accordance with § 405.1018(b).

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with § 405.1022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the continuance and an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 405.1022, except that the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

[82 FR 5116, Jan. 17, 2017]

§ 405.1032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term ''party'' does not include a representative of CMS or one of its contractors that may be participating in the hearing.)

(b) *New issues*—(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS or its contractor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS or its contractor for the first time to the ALJ. The ALJ or any party may raise a new issue relating to a claim or appealed matter specified in the request for hearing; however, the ALJ may only consider a new issue, including a favorable portion of a determination on a claim or appealed

matter specified in the request for hearing, if its resolution could have a material impact on the claim or appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the parties that were or will be sent the notice of hearing about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the parties will have at least 10 calendar days after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding claims to a pending appeal.* (1) Claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims in accordance with § 405.1014(e).

(2) Before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates the information that constitutes a complete request for hearing in accordance with § 405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with § 405.1014(d).

(d) *Appeals involving statistical sampling and extrapolations*—(1) *Generally.* If the appellant does not assert the reasons the appellant disagrees with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), issues related to how the statistical sample and extrapolation were conducted shall not be considered or decided.

(2) *Consideration of sample claims.* If a party asserts a disagreement with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), paragraphs (a) through (c) of this section apply to the adjudication of the sample claims but, in deciding issues related to how a statistical sample and/or extrapolation was conducted the ALJ or attorney adjudicator must base his or her decision on a review of the entire sample to the extent appropriate to decide the issue.

[82 FR 5116, Jan. 17, 2017]

§ 405.1034 Requesting information from the QIC.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed claims, and official copies of dismissals of a request for redetermination or reconsideration, can be provided only by CMS or its contractors. Prior to issuing a request for information to the QIC, OMHA will confirm whether an electronic copy of the redetermination, reconsideration, or dismissal is available in the official system of record, and if so will accept the electronic copy as an official copy.

(2) ''Can be provided only by CMS or its contractors'' means the information is not publicly available, is not in the possession of, and cannot be requested and obtained by one of the parties. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS or contractor Web site or information in an official CMS or DHHS

publication (including, but not limited to, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions).

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The QIC has 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or another contractor.

(d) If an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever occurs first.

[82 FR 5117, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) Any party to a hearing has the right to appear before the ALJ to present evidence and to state his or her position. A party may appear by video-teleconferencing (VTC), telephone, or in person as determined under § 405.1020.

(2) A party may also make his or her appearance by means of a representative, who may make the appearance by VTC, telephone, or in person, as determined under § 405.1020.

(3) Witness testimony may be given and CMS participation may also be accomplished by VTC, telephone, or in person, as determined under § 405.1020.

(b) *Waiver of the right to appear.* (1) A party may submit to OMHA a written statement indicating that he or she does not wish to appear at the hearing.

(2) The appellant may subsequently withdraw his or her waiver at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the appellant agrees to an extension of the adjudication period as specified in § 405.1016 that may be necessary to schedule and hold the hearing.

(3) Other parties may withdraw their waiver up to the date of the scheduled hearing, if any. Even if all of the parties waive their right to appear at a hearing, the ALJ may require them to attend an oral hearing if he or she believes that a personal appearance and testimony by the appellant or any other party is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* A party or a person designated to act as a party's representative may appear before the ALJ to state the party's case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record. A copy of any written statements must be provided to the other parties to a hearing, if any, at the same time they are submitted to the ALJ.

(d) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the issues and allows the parties or their designated representatives to do so.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court.

(f) *Subpoenas.* (1) Except as provided in this section, when it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative or at the request of a party, issue subpoenas for the appearance and testimony of witnesses and for a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. An ALJ may not issue a subpoena to CMS or its contractors, on his or her own initiative or at the request of a party, to compel an appearance, testimony, or the production of evidence.

(2) A party's written request for a subpoena must—

(i) Give the names of the witnesses or documents to be produced;

(ii) Describe the address or location of the witnesses or documents with sufficient detail to find them;

(iii) State the important facts that the witness or document is expected to prove; and

(iv) Indicate why these facts cannot be proven without issuing a subpoena.

(3) Parties to a hearing who wish to subpoena documents or witnesses must file a written request for the issuance of a subpoena with the requirements set forth in paragraph (f)(2) of this section with the ALJ no later than the end of the discovery period established by the ALJ under § 405.1037(c).

(4) Where a party has requested a subpoena, a subpoena will be issued only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted by the ALJ; and

(iv) Nevertheless, has not received the requested discovery.

(5) Reviewability of subpoena rulings—

(i) *General rule.* An ALJ ruling on a subpoena request is not subject to immediate review by the Council. The ruling may be reviewed solely during the course of the Council's review specified in § 405.1016(e) and (f), § 405.1102, or § 405.1110, as applicable. *Exception.* To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the Council may review immediately the subpoena or that portion of the subpoena as applicable.

(ii) Where CMS objects to a subpoena ruling, the Council must take review and the subpoena ruling at issue is automatically stayed pending the Council's order.

(iii) Upon notice to the ALJ that a party or non-party, as applicable, intends to seek Council review of the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(iv) The ALJ determines the length of the stay under the circumstances of a given case, but in no event is the stay less than 15 calendar days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek Council review.

(v) If the Council grants a request for review of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until the Council issues a written decision that affirms, reverses, or modifies the ALJ's action on the subpoena.

(vi) If the Council does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ALJ's action stands.

(6) *Enforcement.* (i) If the ALJ determines, whether on his or her own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(iii) The ALJ must promptly mail a copy of the notice and related documents to the party subject to the subpoena, and to any other party and affected non-party to the appeal.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65336, Dec. 9, 2009; 82 FR 5117, Jan. 17, 2017]

§ 405.1037 Discovery.

(a) *General rules.* (1) Discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with § 405.1012.

(2) The ALJ may permit discovery of a matter that is relevant to the specific subject matter of the ALJ hearing, provided the matter is not privileged or otherwise protected from disclosure and the ALJ determines that the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

(3) Any discovery initiated by a party must comply with all requirements and limitations of this section, along with any further requirements or limitations ordered by the ALJ.

(b) *Limitations on discovery.* Any discovery before the ALJ is limited.

(1) A party may request of another party the reasonable production of documents for inspection and copying.

(2) A party may not take the deposition, upon oral or written examination, of another party unless the proposed deponent agrees to the deposition or the ALJ finds that the proposed deposition is necessary and appropriate in order to secure the deponent's testimony for an ALJ hearing.

(3) A party may not request admissions or send interrogatories or take any other form of discovery not permitted under this section.

(c) *Time limits.* (1) A party's discovery request is timely if the date of receipt of a request by another party is no later than the date specified by the ALJ.

(2) A party may not conduct discovery any later than the date specified by the ALJ.

(3) Before ruling on a request to extend the time for requesting discovery or for conducting discovery, the ALJ must give the other parties to the appeal a reasonable period to respond to the extension request.

(4) The ALJ may extend the time in which to request discovery or conduct discovery only if the requesting party establishes that it was not dilatory or otherwise at fault in not meeting the original discovery deadline.

(5) If the ALJ grants the extension request, it must impose a new discovery deadline and, if necessary, reschedule the hearing date so that all discoveries end no later than 45 calendar days before the hearing.

(d) *Motions to compel or for protective order.* (1) Each party is required to make a good faith effort to resolve or narrow any discovery dispute.

(2) A party may submit to the ALJ a motion to compel discovery that is permitted under this section or any ALJ order, and a party may submit a motion for a protective order regarding any discovery request to the ALJ.

(3) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute. The declaration must also be included with any response to a motion to compel or for protective order.

(4) The ALJ must decide any motion in accordance with this section and any prior discovery ruling in the appeal.

(5) The ALJ must issue and mail to each party a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part; if applicable, the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the ALJ finds necessary and appropriate.

(e) *Reviewability of discovery and disclosure rulings*—(1) *General rule.* An ALJ discovery ruling, or an ALJ disclosure ruling such as one issued at a hearing is not subject to immediate review by the Council. The ruling may be reviewed solely during the course of the Council's review specified in §405.1016(e) and (f), §405.1100, §405.1102, or §405.1110, as applicable.

(2) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the ALJ, the Council may review that portion of the discovery or disclosure ruling immediately.

(i) Where CMS objects to a discovery ruling, the Council must take review and the discovery ruling at issue is automatically stayed pending the Council's order.

(ii) Upon notice to the ALJ that a party intends to seek Council review of the ruling, the ALJ must stay all proceedings affected by the ruling.

(iii) The ALJ determines the length of the stay under the circumstances of a given case, but in no event must the length of the stay be less than 15 calendar days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek Council review.

(iv) Where CMS requests the Council to take review of a discovery ruling or where the Council grants a request, made by a party other than CMS, to review a discovery ruling, the ruling is stayed until the time the Council issues a written decision that affirms, reverses, modifies, or remands the ALJ's ruling.

(v) With respect to a request from a party, other than CMS, for review of a discovery ruling, if the Council does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling stands.

(f) *Adjudication period.* If an adjudication period applies to the appeal in accordance with § 405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65336, Dec. 9, 2009; 82 FR 5117, Jan. 17, 2017]

§ 405.1038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear.* (1) An ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) All the parties who would be sent a notice of hearing in accordance with § 405.1020(c) indicate in writing that they do not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ, and there are no other parties who would be sent a notice of hearing in accordance with § 405.1020(c) and who wish to appear.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made, and the written or oral statement agrees to the amount of payment the parties believe should be made if the amount of payment is an issue before the ALJ or attorney adjudicator, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

[82 FR 5117, Jan. 17, 2017]

§ 405.1040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties who will be or were sent a notice of hearing in accordance with § 405.1020(c), and CMS or a contractor that has elected to be a participant in the proceedings or party to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice if the parties consent to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(d) The ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. If a party does not object within 10 calendar days of receiving the

order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties.

[82 FR 5118, Jan. 17, 2017]

§ 405.1042 The administrative record.

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

(3) A party may request and review a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed or the case is escalated to the Council, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if a party seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, a party may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. The party may be asked to pay the costs of providing these items.

(2) If a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response.

(3) If a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the requesting party obtains consent from the individual.

[82 FR 5118, Jan. 17, 2017]

§ 405.1044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the appeals are consolidated for hearing. In considering the appellant's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an appellant to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an appellant to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§ 405.1020 and 405.1022.

(b) *Consolidated or separate decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the appellant or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement in accordance with § 405.1006 and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants.

[82 FR 5118, Jan. 17, 2017]

§ 405.1046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions. OMHA mails or otherwise transmits a copy of the decision to all the parties at their last known address and the QIC that issued the reconsideration or from which the appeal was escalated. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ or attorney adjudicator may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with the ALJ's or attorney adjudicator's decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to § 405.1028, a discussion of the new evidence and the good cause determination that was made;

(iii) The procedures for obtaining additional information concerning the decision; and

(iv) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the contractor for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's or attorney

adjudicator's decision is a new initial determination under § 405.924.

(b) *Decisions on requests for review of a QIC dismissal*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of a QIC dismissal, or the QIC's dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the QIC's dismissal. OMHA mails or otherwise transmits a copy of the decision to all the parties that received a copy of the QIC's dismissal.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to all the parties at their last known address.

[82 FR 5119, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1048 The effect of an ALJ's or attorney adjudicator's decision.

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding on all parties unless—

(1) A party requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 405.1110, and the Council issues a final decision or remand order or the appeal is escalated to Federal district court under the provisions at § 405.1132 and the Federal district court issues a decision.

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 405.980;

(3) The expedited access to judicial review process at § 405.990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 405.1138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures in § 405.980.

[82 FR 5119, Jan. 17, 2017]

§ 405.1050 Removal of a hearing request from OMHA to the Council.

If a request for hearing is pending before OMHA, the Council may assume responsibility for holding a hearing by requesting that OMHA send the hearing request to it. If the Council holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to all parties at their last known address informing them that the Council has assumed responsibility for the case.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5118, Jan. 17, 2017]

§ 405.1052 Dismissal of a request for a hearing before an ALJ or request for review of a QIC dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar days after the hearing, or does contact the ALJ but the

ALJ determines the party did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the party acknowledged the notice of hearing, the ALJ sends a notice to the party at the last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language), that the party may have.

(2) The person or entity requesting a hearing has no right to it under § 405.1002.

(3) The party did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 405.1014(e).

(4) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to § 405.1014.

(5) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The appellant abandons the request for hearing. An ALJ may conclude that an appellant has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(7) The appellant's request is not complete in accordance with § 405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(b) *Dismissal of request for review of a QIC dismissal.* An ALJ or attorney adjudicator dismisses a request for review of a QIC dismissal under any of the following conditions:

(1) The person or entity requesting a review of a dismissal has no right to it under § 405.1004.

(2) The party did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 405.1014(e).

(3) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(i) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1004.

(iii) No other individual or entity filed a valid and timely request for a review of the QIC dismissal in accordance to §405.1014.

(4) The appellant's request is not complete in accordance with §405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with §405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if only one party requested the hearing or review of the QIC dismissal and that party asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of a QIC dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing or review of the QIC dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the appellant, all parties who were sent a copy of the request for hearing or review at their last known address, and to CMS or a CMS contractor that is a party to the proceedings on a request for hearing. The notice states that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action. The appeal will proceed with respect to any other parties who filed a valid request for hearing or review regarding the same claim or disputed matter.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 180 calendar days of the date of the notice of dismissal.

[82 FR 5119, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§405.1054 Effect of dismissal of a request for a hearing or request for review of QIC dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under §405.1108(b), or vacated by the ALJ or attorney adjudicator under §405.1052(e).

(b) The dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under §405.1052(e).

[82 FR 5120, Jan. 17, 2017]

§405.1056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with §405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in §405.1034, the ALJ or attorney adjudicator may issue a remand directing the QIC or other contractor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the QIC does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the QIC to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the QIC or another contractor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with §405.1016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the QIC issued a reconsideration that addressed

coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required under this subpart) or the request for redetermination was dismissed, the reconsideration will be remanded to the QIC, or its successor to re-adjudicate the request for reconsideration.

(c) *Requested remand*—(1) *Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors may jointly request a remand of the appeal to the entity that conducted the reconsideration. The request must include the reasons why the appeal should be remanded and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding a QIC's dismissal of a request for reconsideration.* (1) Consistent with § 405.1004(b), an ALJ or attorney adjudicator will remand a case to the appropriate QIC if the ALJ or attorney adjudicator determines that a QIC's dismissal of a request for reconsideration was in error.

(2) If an official copy of the notice of dismissal or case file cannot be obtained from the QIC, an ALJ or attorney adjudicator may also remand a request for review of a dismissal in accordance with the procedures in paragraph (a) of this section.

(e) *Relationship to local and national coverage determination appeals process.* (1) An ALJ or attorney adjudicator remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to § 426.460(b)(1), § 426.488(b), or § 426.560(b)(1) of this chapter.

(2) Unless the appellant is entitled to relief pursuant to § 426.460(b)(1), § 426.488(b), or § 426.560(b)(1) of this chapter, the ALJ or attorney adjudicator applies the LCD or NCD in place on the date the item or service was provided.

(f) *Notice of remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the appellant, all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant in the proceedings or party to the hearing. The notice states that there is a right to request that the Chief ALJ or a designee review the remand, unless the remand was issued under paragraph (d)(1) of this section.

(g) *Review of remand.* Upon a request by a party or CMS or one of its contractors filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review. The review of remand procedures provided for in this paragraph are not available for and do not apply to remands that are issued under paragraph (d)(1) of this section.

[82 FR 5121, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with § 405.1056(g).

[82 FR 5121, Jan. 17, 2017]

APPLICABILITY OF MEDICARE COVERAGE POLICIES

§ 405.1060 Applicability of national coverage determinations (NCDs).

(a) *General rule.* (1) An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under Medicare or a determination of the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act as well as under other applicable provisions of the Act.

(4) An NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs and attorney adjudicators, and the Council.

(b) *Review by an ALJ or attorney adjudicator.* (1) An ALJ or attorney adjudicator may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ or attorney adjudicator may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

(c) *Review by the Council.* (1) The Council may not disregard, set aside, or otherwise review an NCD for purposes of a section 1869 claim appeal, except that the DAB may review NCDs as provided under part 426 of this title.

(2) The Council may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 82 FR 5121, Jan. 17, 2017]

§ 405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council.

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5121, Jan. 17, 2017]

§ 405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

[82 FR 5121, Jan. 17, 2017]

MEDICARE APPEALS COUNCIL REVIEW

§ 405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal.

(b) Under circumstances set forth in §§ 405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case.

(c) When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review. The Council issues a final decision or dismissal order or remands a case to the ALJ or attorney adjudicator within 90 calendar days of receipt of the appellant's request for review, unless the 90

calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the OMHA level to the Council, the Council will issue a final decision or dismissal order or remand the case to the OMHA Chief ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

[82 FR 5122, Jan. 17, 2017]

§ 405.1102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) A party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a Council review if the party files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

(2) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) A party requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the Council; and

(3) It explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at § 405.942(b)(2) and (3).

(c) A party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC, affirmation of a QIC's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC dismissal.

(d) For purposes of requesting Council review (§§ 405.1100 through 405.1140), unless specifically excepted, the term ''party'', includes CMS where CMS has entered into a case as a party according to § 405.1012. The term, ''appellant,'' does not include CMS, where CMS has entered into a case as a party according to § 405.1012.

[82 FR 5122, Jan. 17, 2017]

§ 405.1106 Where a request for review or escalation may be filed.

(a) When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The appellant must also send a copy of the request for review to the other parties to the ALJ or attorney adjudicator decision or dismissal who received notice of the decision or dismissal. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties to the ALJ or attorney adjudicator decision or dismissal receive notice of the request for Council review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under § 405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100

until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation. In a case that has been escalated from OMHA, the Council's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the Council.

[82 FR 5122, Jan. 17, 2017]

§ 405.1108 Council actions when request for review or escalation is filed.

(a) Except as specified in paragraphs (c) and (d) of this section, when a party requests that the Council review an ALJ's or attorney adjudicator's decision, the Council will review the ALJ's or attorney adjudicator's decision *de novo*. The party requesting review does not have a right to a hearing before the Council. The Council will consider all of the evidence in the administrative record. Upon completion of its review, the Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decision or remand the case to an ALJ or attorney adjudicator for further proceedings.

(b) When a party requests that the Council review an ALJ's or attorney adjudicator's dismissal of a request for a hearing, the Council may deny review or vacate the dismissal and remand the case to the ALJ or attorney adjudicator for further proceedings.

(c) The Council will dismiss a request for review when the party requesting review does not have a right to a review by the Council, or will dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request for hearing.

(d) When an appellant requests escalation of a case from the OMHA level to the Council, the Council may take any of the following actions:

(1) Issue a decision based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ or attorney adjudicator before the case was escalated.

(2) Conduct any additional proceedings, including a hearing, that the Council determines are necessary to issue a decision.

(3) Remand the case to OMHA for further proceedings, including a hearing.

(4) Dismiss the request for Council review because the appellant does not have the right to escalate the appeal.

(5) Dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5122, Jan. 17, 2017]

§ 405.1110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or any of its contractors may refer a case to the Council for it to consider reviewing under this authority anytime within 60 calendar days of receipt of an ALJ's or attorney adjudicator's decision or dismissal.

(b) *Referral of cases.* (1) CMS or any of its contractors may refer a case to the Council if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the Council take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the OMHA level; and

(ii) In CMS' view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's decision or dismissal is received. The written referral will state the reasons why CMS believes the Council must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d), and to the OMHA Chief ALJ. Parties to the ALJ's or attorney adjudicator's action may file

exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice. A party submitting comments to the Council must send such comments to CMS and all other parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d).

(c) *Standard of review*—(1) *Referral by CMS after participation at the OMHA level.* If CMS or its contractor participated in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the OMHA proceedings or appear as a party.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(d) *Council's action.* If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings or may dismiss a hearing request. The Council must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The Council may not, however, issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the Council does not act within the applicable adjudication deadline, the ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the ALJ's or attorney adjudicator's action.

(e) *Referral timeframe.* For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

[82 FR 5122, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1112 Content of request for review.

(a) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's or attorney adjudicator's decision or dismissal order, if any; and the name of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ's or attorney adjudicator's action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's or attorney adjudicator's decision, dismissal, or other determination being appealed. For example, if the party requesting review believes that the ALJ's or attorney adjudicator's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented

beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

[82 FR 5123, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1114 Dismissal of request for review.

The Council dismisses a request for review if the party requesting review did not file the request within the stated period of time and the time for filing has not been extended. The Council also dismisses the request for review if—

(a) The party asks to withdraw the request for review;

(b) The party does not have a right to request Council review; or

(c) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(1) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the Council considers whether the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue;

(2) No other individual or entity with a financial interest in the case wishes to pursue an appeal under § 405.1102;

(3) No other party to the ALJ's or attorney adjudicator's action filed a valid and timely review request under §§ 405.1102 and 405.1112.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017; 84 FR 19871, May 7, 2019]

§ 405.1116 Effect of dismissal of request for Council review or request for hearing.

The dismissal of a request for Council review or denial of a request for review of a dismissal issued by an ALJ or attorney adjudicator is binding and not subject to further review unless reopened and vacated by the Council. The Council's dismissal of a request for hearing is also binding and not subject to judicial review.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017]

§ 405.1118 Obtaining evidence from the Council.

A party may request and receive a copy of all or part of the record of the ALJ's or attorney adjudicator's action, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. However, the party may be asked to pay the costs of providing these items. If a party requests evidence from the Council and an opportunity to comment on that evidence, the time beginning with the Council's receipt of the request for evidence through the expiration of the time granted for the party's response will not be counted toward the 90 calendar day adjudication deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009; 82 FR 5123, Jan. 17, 2017]

§ 405.1120 Filing briefs with the Council.

Upon request, the Council will give the party requesting review, as well as all other parties, a reasonable opportunity to file briefs or other written statements about the facts and law relevant to the case. Any party who submits a brief or statement must send a copy to all of the other parties. Unless the party requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the Council will not be counted toward the adjudication timeframe set forth in § 405.1100. The Council may also request, but not require, CMS or its contractor to file a brief or position paper if the Council determines that it is necessary to resolve the issues in the case. The Council will not draw any adverse inference if CMS or a contractor either

participates, or decides not to participate in Council review.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017]

§ 405.1122 What evidence may be submitted to the Council.

(a) *Appeal before the Council on request for review of ALJ's or attorney adjudicator's decision.* (1) If the Council is reviewing an ALJ's or attorney adjudicator's decision, the Council limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ or attorney adjudicator. However, if the ALJ's or attorney adjudicator's decision decides a new issue that the parties were not afforded an opportunity to address at the OMHA level, the Council considers any evidence related to that issue that is submitted with the request for review.

(2) If the Council determines that additional evidence is needed to resolve the issues in the case and the administrative record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ or attorney adjudicator to obtain the evidence and issue a new decision.

(b) *Appeal before Council as a result of appellant's request for escalation.* (1) If the Council is reviewing a case that is escalated from the OMHA level to the Council, the Council will decide the case based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ or attorney adjudicator before the case was escalated.

(2) If the Council receives additional evidence with the request for escalation that is material to the question to be decided, or determines that additional evidence is needed to resolve the issues in the case, and the record provided to the Council indicates that the previous decision-makers did not attempt to obtain the evidence before escalation, the Council may remand the case to an ALJ or attorney adjudicator to consider or obtain the evidence and issue a new decision.

(c) *Evidence related to issues previously considered by the QIC.* (1) If new evidence related to issues previously considered by the QIC is submitted to the Council by a provider, supplier, or a beneficiary represented by a provider or supplier, the Council must determine if the provider, supplier, or the beneficiary represented by a provider or supplier had good cause for submitting it for the first time at the Council level.

(2) If the Council determines that good cause does not exist, the Council must exclude the evidence from the proceeding, may not consider it in reaching a decision, and may not remand the issue to an ALJ or attorney adjudicator.

(3) The Council must notify all parties if it excludes the evidence. The Council may remand to an ALJ or attorney adjudicator if—

(i) The ALJ or attorney adjudicator did not consider the new evidence submitted by the provider, supplier, or beneficiary represented by a provider or supplier because good cause did not exist; and

(ii) The Council finds that good cause existed under § 405.1028 and the ALJ or attorney adjudicator should have reviewed the evidence.

(iii) The new evidence is submitted by a party that is not a provider, supplier, or a beneficiary represented by a provider or supplier.

(d) *Subpoenas.* (1) Except as provided in this section, when it is reasonably necessary for the full presentation of a case, the Council may, on its own initiative or at the request of a party, issue subpoenas requiring a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. The Council may not issue a subpoena to CMS or its contractors, on its own initiative or at the request of a party, to compel the production of evidence.

(2) A party's request for a subpoena must—

(i) Give a sufficient description of the documents to be produced;

(ii) State the important facts that the documents are expected to prove; and

(iii) Indicate why these facts could not be proven without issuing a subpoena.

(3) A party to the Council review on escalation that wishes to subpoena documents must file a written request that complies with the requirements set out in paragraph (d)(2) of this section within 10 calendar days of the request for escalation.

(4) A subpoena will issue only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted; and

(iv) Nevertheless, has still not received the requested discovery.

(e) Reviewability of subpoena rulings—

(1) *General rule.* A Council ruling on a subpoena request is not subject to immediate review by the Secretary.

(2) *Exception.* To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the Council, the Secretary may review immediately that subpoena or portion of the subpoena.

(3) Upon notice to the Council that a party or non-party, as applicable, intends to seek Secretary review of the subpoena, the Council must stay all proceedings affected by the subpoena.

(4) The Council determines the length of the stay under the circumstances of a given case, but in no event is less than 15 calendar days after the day on which the Council received notice of the party or non-party's intent to seek Secretary review.

(5) If the Secretary grants a request for review, the subpoena or portion of the subpoena, as applicable, is stayed until the Secretary issues a written decision that affirms, reverses, modifies, or remands the Council's action for the subpoena.

(6) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the Council's action stands.

(f) *Enforcement.* (1) If the Council determines, whether on its own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the Council may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) Any enforcement request by the Council must consist of a written notice to the Secretary describing in detail the Council's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(3) The Council must promptly mail a copy of the notice and related documents to the party or non-party subject to the subpoena, and to any other party and affected non-party to the appeal.

(4) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the subpoena stands.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009; 82 FR 5123, Jan. 17, 2017]

§405.1124 Oral argument.

A party may request to appear before the Council to present oral argument.

(a) The Council grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The Council may decide on its own that oral argument is necessary to decide the issues in the case. If the Council decides to hear oral argument, it tells the parties of the time and place of the oral argument at least 10 calendar days before the scheduled date.

(c) In case of a previously unrepresented beneficiary, a newly hired representative may request an extension of time for preparation of the oral argument and the Council must consider whether the extension is reasonable.

(d) The Council may also request, but not require, CMS or its contractor to appear before it if the Council determines that it may be helpful in resolving the issues in the case.

(e) The Council will not draw any inference if CMS or a contractor decides

not to participate in the oral argument.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1126 Case remanded by the Council.

(a) *When the Council may remand a case.* Except as specified in § 405.1122(c), the Council may remand a case in which additional evidence is needed or additional action by the ALJ or attorney adjudicator is required. The Council will designate in its remand order whether the ALJ or attorney adjudicator will issue a decision or a recommended decision on remand.

(b) *Action by ALJ on remand.* The ALJ or attorney adjudicator will take any action that is ordered by the Council and may take any additional action that is not inconsistent with the Council's remand order.

(c) *Notice when case is returned with a recommended decision.* When the ALJ or attorney adjudicator sends a case to the Council with a recommended decision, a notice is mailed to the parties at their last known address. The notice tells them that the case was sent to the Council, explains the rules for filing briefs or other written statements with the Council, and includes a copy of the recommended decision.

(d) *Filing briefs with the Council when ALJ or attorney adjudicator issues recommended decision.* (1) Any party to the recommended decision may file with the Council briefs or other written statements about the facts and law relevant to the case within 20 calendar days of the date on the recommended decision. Any party may ask the Council for additional time to file briefs or statements. The Council will extend this period, as appropriate, if the party shows that it has good cause for requesting the extension.

(2) All other rules for filing briefs with and obtaining evidence from the Council follow the procedures explained in this subpart.

(e) *Procedures before the Council.* (1) The Council, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(2) If the Council determines that more evidence is required, it may again remand the case to an ALJ or attorney adjudicator for further inquiry into the issues, rehearing if applicable, receipt of evidence, and another decision or recommended decision. However, if the Council decides that it can get the additional evidence more quickly, it will take appropriate action.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1128 Action of the Council.

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on Council consideration of additional evidence in § 405.1122, the Council will make a decision or remand the case to an ALJ or attorney adjudicator.

(b) The Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decisionor recommended decision.

(c) The Council mails a copy of its decision to all the parties at their last known addresses. For overpayment cases involving multiple beneficiaries where there is no beneficiary liability the Council may choose to send written notice only to the appellant. In the event the decision will result in a payment to a provider or supplier, the Medicare contractor must issue any electronic or paper remittance advice notice to that provider or supplier.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1130 Effect of the Council's decision.

The Council's decision is final and binding on all parties unless a Federal district court issues a decision modifying the Council's decision or the decision is revised as the result of a reopening in accordance with § 405.980. A party may file an action in a Federal district court within 60 calendar days after the date it receives notice of the Council's decision.

[74 FR 65338, Dec. 9, 2009, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1132 Request for escalation to Federal court.

(a) If the Council does not issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator within the adjudication period specified in § 405.1100, or as extended as provided in this subpart, the appellant may request that the appeal, other than an appeal of an ALJ or attorney adjudicator dismissal, be escalated to Federal district court. Upon receipt of a request for escalation, the Council may—

(1) Issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator, if that action is issued within the latter of 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period set forth in § 405.1100; or

(2) If the Council is not able to issue a decision or dismissal or remand as set forth in paragraph (a)(1) of this section, it will send a notice to the appellant acknowledging receipt of the request for escalation and confirming that it is not able to issue a decision, dismissal or remand order within the statutory time frame.

(b) A party may file an action in a Federal district court within 60 calendar days after the date it receives the Council's notice that the Council is not able to issue a final decision, dismissal order, or remand order unless the party is appealing an ALJ or attorney adjudicator dismissal.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1134 Extension of time to file action in Federal district court.

(a) Any party to the Council's decision or to a request for EAJR that has been certified by the review entity other than CMS may request that the time for filing an action in a Federal district court be extended.

(b) The request must—

(1) Be in writing.

(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the Council.

(c) If the party shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards specified in § 405.942(b)(2) or (b)(3).

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1136 Judicial review.

(a) *General rules.* (1) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a Council decision, or an appellant who requests escalation to Federal district court if the Council does not complete its review of the ALJ's or attorney adjudicator's decision within the applicable adjudication period, may obtain a court review if the amount remaining in controversy satisfies the requirements of § 405.1006(c).

(2) If the Council's adjudication period set forth in § 405.1100 expires and the appellant does not request escalation to Federal district court, the case remains with the Council until a final decision, dismissal order, or remand order is issued.

(b) *Court in which to file civil action.* (1) Any civil action described in paragraph (a) of this section must be filed in the district court of the United States for the judicial district in which the party resides or where such individual, institution, or agency has its principal place of business.

(2) If the party does not reside within any judicial district, or if the individual, institution, or agency does not have its principal place of business within any such judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in § 405.1130, § 405.1132, or § 405.1134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the Council's decision or the Council's notice that it is not able to issue a decision within the statutory timeframe shall be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 405.990, the civil action must be filed within 60 calendar days after receipt of the review entity's certification, except where the time is extended by the ALJ or attorney adjudicator or Council, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff will be notified that he or she has named an incorrect defendant and is granted 60 calendar days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Prohibition against judicial review of certain Part B regulations or instructions.* Under section 1869(e)(1) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Medicare Part B if the regulation was published, or the instructions issued, before January 1, 1991.

(f) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

(2) When the Secretary's decision is adverse to a party due to a party's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof a party must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37705, June 30, 2005; 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1138 Case remanded by a Federal district court.

When a Federal district court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the Council, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ or attorney adjudicator with instructions to take action and either issue a decision, take other action, or return the case to the Council with a recommended decision. If the Council remands a case, the procedures specified in § 405.1140 will be followed.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1140 Council review of ALJ decision in a case remanded by a Federal district court.

(a) *General rules.* (1) In accordance with § 405.1138, when a case is remanded by a Federal district court for further consideration and the Council remands the case to an ALJ or attorney adjudicator, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the Council assumes jurisdiction.

(2) The Council may assume jurisdiction based on written exceptions to the decision of the ALJ or attorney adjudicator that a party files with the Council or based on its authority under paragraph (c) of this section.

(3) The Council either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ or attorney adjudicator for further proceedings.

(b) *A party files exceptions disagreeing with the decision of the ALJ or attorney adjudicator.* (1) If a party disagrees with an ALJ or attorney adjudicator decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the Council. Exceptions may be filed by submitting a written statement to the Council setting forth the reasons for disagreeing with the decision of the ALJ or attorney adjudicator. The party must file exceptions within 30 calendar days of the date the party receives the decision of the ALJ or attorney adjudicator or submit a

written request for an extension within the 30 calendar day period. The Council will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the party needs the additional time and may be granted if the Council finds good cause under the standard established in § 405.942(b)(2) or (b)(3).

(2) If written exceptions are timely filed, the Council considers the party's reasons for disagreeing with the decision of the ALJ or attorney adjudicator. If the Council concludes that there is no reason to change the decision of the ALJ or attorney adjudicator, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ or attorney adjudicator is warranted. In this instance, the decision of the ALJ or attorney adjudicator is the final decision of the Secretary after remand.

(3) When a party files written exceptions to the decision of the ALJ, the Council may assume jurisdiction at any time. If the Council assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or attorney adjudicator or remanding the case to an ALJ or attorney adjudicator for further proceedings, including a new decision. The new decision of the Council is the final decision of the Secretary after remand.

(c) *Council assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the decision of the ALJ or attorney adjudicator, the Council may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to all parties at their last known address.

(3) The parties will be provided with the opportunity to file briefs or other written statements with the Council about the facts and law relevant to the case.

(4) After the briefs or other written statements are received or the time allowed (usually 30 calendar days) for submitting them has expired, the Council will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ or attorney adjudicator for further proceedings, including a new decision.

(d) *Exceptions are not filed and the Council does not otherwise assume jurisdiction.* If no exceptions are filed and the Council does not assume jurisdiction of the cases within 60 calendar days after the date of the ALJ's or attorney adjudicator's decision, the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

Subpart J—Procedures and Beneficiary Rights for Expedited Determinations and Reconsiderations When Coverage is Changed or Terminated

SOURCE: 69 FR 69264, Nov. 26, 2004, unless otherwise noted.

§ 405.1200 Notifying beneficiaries of provider service terminations.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1200 through 405.1204, the term, provider, is defined as a home health agency (HHA), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), or hospice.

(2) For purposes of §§ 405.1200 through 405.1204, a termination of Medicare-covered service is a discharge of a beneficiary from a residential provider of services, or a complete cessation of coverage at the end of a course of treatment prescribed in a discrete increment, regardless of whether the beneficiary agrees that the services should end. A termination does not include a reduction in services. A termination also does not include the termination of one type of service by the provider if the beneficiary continues to receive other Medicare-covered services from the provider.

(b) *Advance written notice of service terminations.* Before any termination of services, the provider of the service must deliver valid written notice to

the beneficiary of the provider's decision to terminate services. The provider must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* A provider must notify the beneficiary of the decision to terminate covered services no later than 2 days before the proposed end of the services. If the beneficiary's services are expected to be fewer than 2 days in duration, the provider must notify the beneficiary at the time of admission to the provider. If, in a nonresidential setting, the span of time between services exceeds 2 days, the notice must be given no later than the next to last time services are furnished.

(2) *Content of the notice.* The standardized termination notice must include the following information:

(i) The date that coverage of services ends;

(ii) The date that the beneficiary's financial liability for continued services begins;

(iii) A description of the beneficiary's right to an expedited determination under §405.1202, including information about how to request an expedited determination and about a beneficiary's right to submit evidence showing that services must continue;

(iv) A beneficiary's right to receive the detailed information specified under §405.1202(f); and

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the termination notice is valid if—

(i) The beneficiary (or the beneficiary's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If a beneficiary refuses to sign the notice.* The provider may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(5) *Financial liability for failure to deliver valid notice.* A provider is financially liable for continued services until 2 days after the beneficiary receives valid notice as specified under paragraph (b)(3) of this section, or until the service termination date specified on the notice, whichever is later. A beneficiary may waive continuation of services if he or she agrees with being discharged sooner than the planned service termination date.

§ 405.1202 Expedited determination procedures.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to an expedited determination by a QIO under the following circumstances:

(1) For services furnished by a nonresidential provider, the beneficiary disagrees with the provider of those services that services should be terminated, and a physician certifies that failure to continue the provision of the service(s) may place the beneficiary's health at significant risk.

(2) For services furnished by a residential provider or a hospice, the beneficiary disagrees with the provider's decision to discharge the beneficiary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request for a determination to the QIO in the State in which the beneficiary is receiving those provider services, in writing or by telephone, by no later than noon of the calendar day following receipt of the provider's notice of termination. If the QIO is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIO is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or to supply information that the QIO may request to conduct its review.

(3) The beneficiary may, but is not required to, submit evidence to be considered by a QIO in making its decision.

(4) If a beneficiary makes an untimely request for an expedited determination by a QIO, the QIO will accept the request and make a determination as soon as possible, but the 72-hour

time frame under paragraph (e)(6) and the financial liability protection under paragraph (g) of this section do not apply.

(c) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the QIO reverses the provider's service termination decision. If the QIO's decision is delayed because the provider did not timely supply necessary information or records, the provider may be liable for the costs of any additional coverage, as determined by the QIO in accordance with paragraph (e)(7) of this section. If the QIO finds that the beneficiary did not receive valid notice, coverage of provider services continues until at least 2 days after valid notice has been received. Continuation of coverage is not required if the QIO determines that coverage could pose a threat to the beneficiary's health or safety.

(d) *Burden of proof.* When a beneficiary requests an expedited determination by a QIO, the burden of proof rests with the provider to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) In order for the QIO to determine whether the provider has met the burden of proof, the provider should supply any and all information that a QIO requires to sustain the provider's termination decision, consistent with paragraph (f) of this section.

(2) The beneficiary may submit evidence to be considered by a QIO in making its decision.

(e) *Procedures the QIO must follow.* (1) On the day the QIO receives the request for an expedited determination under paragraph (b) of this section, it must immediately notify the provider of those services that a request for an expedited determination has been made.

(2) The QIO determines whether the provider delivered valid notice of the termination decision consistent with § 405.1200(b) and paragraph (f) of this section.

(3) The QIO examines the medical and other records that pertain to the services in dispute. If applicable, the QIO determines whether a physician has certified that failure to continue the provision of services may place the beneficiary's health at significant risk.

(4) The QIO must solicit the views of the beneficiary who requested the expedited determination.

(5) The QIO must provide an opportunity for the provider/practitioner to explain why the termination or discharge is appropriate.

(6) No later than 72 hours after receipt of the request for an expedited determination, the QIO must notify the beneficiary, beneficiary's physician, and the provider of services of its determination whether termination of Medicare coverage is the correct decision, either on the basis of medical necessity or based on other Medicare coverage policies.

(7) If the QIO does not receive the information needed to sustain a provider's decision to terminate services, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's provider services, the provider may be held financially liable for these services, as determined by the QIO.

(8) The QIO's initial notification may be by telephone, followed by a written notice including the following information:

(i) The rationale for the determination;

(ii) An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for the services; and

(iii) Information about the beneficiary's right to a reconsideration of the QIO's determination, including how to request a reconsideration and the time period for doing so.

(f) *Responsibilities of providers.* (1) When a QIO notifies a provider that a beneficiary has requested an expedited determination, the provider must send a detailed notice to the beneficiary by close of business of the day of the QIO's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no

longer reasonable and necessary or are no longer covered;

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including citations to the applicable Medicare policy rules or information about how the beneficiary may obtain a copy of the Medicare policy;

(iii) Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case; and

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the provider must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required under § 405.1200(b) and under paragraph (f)(1) of this section. The provider must furnish this information as soon as possible, but no later than by close of business of the day the QIO notifies the provider of the request for an expedited determination. At the discretion of the QIO, the provider may make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(3) At a beneficiary's request, the provider must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO including records of any information provided by telephone. The provider may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The provider must accommodate such a request by no later than close of business of the first day after the material is requested.

(g) *Coverage during QIO review.* When a beneficiary requests an expedited determination in accordance with the procedures required by this section, the provider may not bill the beneficiary for any disputed services until the expedited determination process (and reconsideration process, if applicable) has been completed.

§ 405.1204 Expedited reconsiderations.

(a) *Beneficiary's right to an expedited reconsideration.* A beneficiary who is dissatisfied with a QIO's expedited determination may request an expedited reconsideration by the appropriate QIC.

(b) *Requesting an expedited reconsideration.* (1) A beneficiary who wishes to obtain an expedited reconsideration must submit a request for the reconsideration to the appropriate QIC, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone or in writing) receipt of the QIO's determination. If the QIC is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIC is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or supply information that the QIC may request to conduct its reconsideration.

(3) The beneficiary may, but is not required to, submit evidence to be considered by a QIC in making its decision.

(4) A beneficiary who does not file a timely request for an expedited QIC reconsideration subsequently may request a reconsideration under the standard claims appeal process, but the coverage protections described in paragraph (f) of this section would not extend through this reconsideration, nor would the timeframes or the escalation process described in paragraphs (c)(3) and (c)(5) of this section, respectively.

(c) *Procedures the QIC must follow.* (1) On the day the QIC receives the request for an expedited determination under paragraph (b) of this section, the QIC must immediately notify the QIO that made the expedited determination and the provider of services of the request for an expedited reconsideration.

(2) The QIC must offer the beneficiary and the provider an opportunity to provide further information.

(3) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, no later than 72 hours after receipt of the request for an expedited reconsideration, and any medical or other records needed for such reconsideration, the QIC

must notify the QIO, the beneficiary, the beneficiary's physician, and the provider of services, of its decision on the reconsideration request.

(4) The QIC's initial notification may be done by telephone, followed by a written notice including:

(i) The rationale for the reconsideration decision;

(ii) An explanation of the Medicare payment consequences of the determination and the beneficiary's date of liability; and

(iii) Information about the beneficiary's right to appeal the QIC's reconsideration decision to OMHA for an ALJ hearing in accordance with subpart I of this part, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to OMHA for an ALJ hearing in accordance with subpart I of this part, if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under § 405.1006.

(6) A beneficiary requesting an expedited reconsideration under this section may request (either in writing or orally) that the QIC grant such additional time as the beneficiary specifies (not to exceed 14 days) for the reconsideration. If an extension is granted, the deadlines in paragraph (c)(3) of this section do not apply.

(d) *Responsibilities of the QIO.* (1) When a QIC notifies a QIO that a beneficiary has requested an expedited reconsideration, the QIO must supply all information that the QIC needs to make its expedited reconsideration as soon as possible, but no later than by close of business of the day that the QIC notifies the QIO of the request for an expedited reconsideration.

(2) At a beneficiary's request, the QIO must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIC. The QIO may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The QIO must accommodate the request by no later than close of business of the first day after the material is requested.

(e) *Responsibilities of the provider.* A provider may, but is not required to, submit evidence to be considered by a QIC in making its decision. If a provider fails to comply with a QIC's request for additional information beyond that furnished to the QIO for purposes of the expedited determination, the QIC makes its reconsideration decision based on the information available.

(f) *Coverage during QIC reconsideration process.* When a beneficiary requests an expedited reconsideration in accordance with the deadline specified in (b)(1) of this section, the provider may not bill the beneficiary for any disputed services until the QIC makes its determination.

[69 FR 69624, Nov. 26, 2004, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1205 Notifying beneficiaries of hospital discharge appeal rights.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1204, 405.1205, 405.1206, and 405.1208, the term ''hospital'' is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition includes critical access hospitals.

(2) For purposes of §§ 405.1204, 405.1205, 405.1206, and 405.1208, a discharge is a formal release of a beneficiary from an inpatient hospital.

(b) *Advance written notice of hospital discharge rights.* For all Medicare beneficiaries, hospitals must deliver valid, written notice of a beneficiary's rights as a hospital inpatient, including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice at or near admission, but no later than 2 calendar days following the beneficiary's admission to the hospital.

(2) *Content of the notice.* The notice must include the following information:

(i) The beneficiary's rights as a hospital inpatient including the right to benefits for inpatient services and for post-hospital services in accordance with 1866(a)(1)(M) of the Act.

(ii) The beneficiary's right to request an expedited determination of the discharge decision including a description of the process under § 405.1206, and the availability of other appeals processes if the beneficiary fails to meet the deadline for an expedited determination.

(iii) The circumstances under which a beneficiary will or will not be liable for charges for continued stay in the hospital in accordance with 1866(a)(1)(M) of the Act.

(iv) A beneficiary's right to receive additional detailed information in accordance with § 405.1206(e).

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the written notice of rights described in this section is valid if—

(i) The beneficiary (or the beneficiary's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If a beneficiary refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Follow up notification.* (1) The hospital must present a copy of the signed notice described in paragraph (b)(2) of this section to the beneficiary (or beneficiary's representative) prior to discharge. The notice should be given as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

(2) Follow up notification is not required if the notice required under § 405.1205(b) is delivered within 2 calendar days of discharge.

[71 FR 68720, Nov. 27, 2006]

§ 405.1206 Expedited determination procedures for inpatient hospital care.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to request an expedited determination by the QIO when a hospital (acting directly or through its utilization review committee), with physician concurrence, determines that inpatient care is no longer necessary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request to the QIO that has an agreement with the hospital as specified in § 476.78 of this chapter. The request must be made no later than the day of discharge and may be in writing or by telephone.

(2) The beneficiary, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The beneficiary may, but is not required to, submit written evidence to be considered by a QIO in making its decision.

(4) A beneficiary who makes a timely request for an expedited QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraphs (f)(1) and (f)(2) of this section, as applicable.

(5) A beneficiary who fails to make a timely request for an expedited determination by a QIO, as described in paragraph (b)(1) of this section, and remains in the hospital without coverage, still may request an expedited QIO determination at any time during the hospitalization. The QIO will issue a decision in accordance with paragraph (d)(6)(ii) of this section, however, the financial liability protection under paragraphs (f)(1) and (f)(2) of this section does not apply.

(6) A beneficiary who fails to make a timely request for an expedited determination in accordance with paragraph (b)(1) of this section, and who is no longer an inpatient in the hospital, may request QIO review within 30 calendar days after the date of discharge, or at any time for good cause. The QIO

will issue a decision in accordance with paragraph (d)(6)(iii) of this section; however, the financial liability protection under paragraphs (f)(1) and (f)(2) of this section does not apply.

(c) *Burden of proof.* When a beneficiary (or his or her representative, if applicable) requests an expedited determination by a QIO, the burden of proof rests with the hospital to demonstrate that discharge is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies. Consistent with paragraph (e)(2) of this section, the hospital should supply any and all information that a QIO requires to sustain the hospital's discharge determination.

(d) *Procedures the QIO must follow.* (1) When the QIO receives the request for an expedited determination under paragraph (b)(1) of this section, it must immediately notify the hospital that a request for an expedited determination has been made.

(2) The QIO determines whether the hospital delivered valid notice consistent with § 405.1205(b)(3).

(3) The QIO examines the medical and other records that pertain to the services in dispute.

(4) The QIO must solicit the views of the beneficiary (or the beneficiary's representative) who requested the expedited determination.

(5) The QIO must provide an opportunity for the hospital to explain why the discharge is appropriate.

(6)(i) When the beneficiary requests an expedited determination in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the beneficiary, the hospital, and physician of its determination within one calendar day after it receives all requested pertinent information.

(ii) When the beneficiary makes an untimely request for an expedited determination, and remains in the hospital, consistent with paragraph (b)(5) of this section, the QIO will make a determination and notify the beneficiary, the hospital, and the physician of its determination within 2 calendar days following receipt of the request and pertinent information.

(iii) When the beneficiary makes an untimely request for an expedited determination, and is no longer an inpatient in the hospital, consistent with paragraph (b)(6) of this section, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 30 calendar days after receipt of the request and pertinent information.

(7) If the QIO does not receive the information needed to sustain a hospital's decision to discharge, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's hospital services, the hospital may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues an expedited determination, the QIO must notify the beneficiary, the physician, and hospital of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for the services.

(iv) Information about the beneficiary's right to a reconsideration of the QIO's determination as set forth in § 405.1204, including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of hospitals.* (1) When a QIO notifies a hospital that a beneficiary has requested an expedited determination, the hospital must deliver a detailed notice to the beneficiary as soon as possible but no later than noon of the day after the QIO's notification. The detailed notice must include the following information:

(i) A detailed explanation why services are either no longer reasonable and necessary or are otherwise no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including information about how the beneficiary may obtain a copy of the Medicare policy.

(iii) Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise

the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case.

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the hospital must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required as specified in §405.1205 (b) and (c) and paragraph (e)(1) of this section. The hospital must furnish this information as soon as possible, but no later than by noon of the day after the QIO notifies the hospital of the request for an expedited determination. At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(3) At a beneficiary's (or representative's) request, the hospital must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone. The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The hospital must accommodate such a request by no later than close of business of the first day after the material is requested.

(f) *Coverage during QIO expedited review*—(1) *General rule and liability while QIO review is pending.* If the beneficiary remains in the hospital past midnight of the discharge date ordered by the physician, and the hospital, the physician who concurred with the discharge determination, or the QIO subsequently finds that the beneficiary requires inpatient hospital care, the beneficiary is not financially responsible for continued care (other than applicable coinsurance and deductible) until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence from the physician responsible for the beneficiary's care or the QIO, and notifies the beneficiary with a notice consistent with 405.1205 (c).

(2) *Timely filing and limitation on liability.* If a beneficiary files a request for an expedited determination by the QIO in accordance with paragraph (b)(1) of this section, the beneficiary is not financially responsible for inpatient hospital services (other than applicable coinsurance and deductible) furnished before noon of the calendar day after the date the beneficiary (or his or her representative) receives notification (either orally or in writing) of the expedited determination by the QIO.

(3) *Untimely request and liability.* When a beneficiary does not file a request for an expedited determination by the QIO in accordance with paragraph (b) of this section, but remains in the hospital past the discharge date, that beneficiary may be held responsible for charges incurred after the date of discharge or as otherwise stated by the QIO.

(4) *Hospital requests an expedited review.* When the hospital requests a review in accordance with §405.1208, and the QIO concurs with the hospital's discharge determination, a hospital may not charge the beneficiary until the date specified by the QIO.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *Right to request a reconsideration.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in §405.1204.

(2) *Right to pursue the general claims appeal process.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, the determination is subject to the general claims appeal process.

[71 FR 68721, Nov. 27, 2006]

§ 405.1208 Hospital requests expedited QIO review.

(a) *General rule.* (1) If the hospital (acting directly or through its utilization review committee) believes that the beneficiary does not require further inpatient hospital care but is unable to obtain the agreement of the physician, it may request an expedited determination by the QIO.

(2) When the hospital requests review, and the QIO concurs with the hospital's discharge determination, a hospital may not charge a beneficiary until the date specified by the QIO in accordance with 405.1206(f)(4).

(b) *Procedures hospital must follow.* (1) The hospital must (acting directly or through its utilization review committee) notify the beneficiary (or his or her representative) that it has requested that review.

(2) The hospital must supply any pertinent information the QIO requires to conduct its review and must make it available by phone or in writing, by close of business of the first full working day immediately following the day the hospital submits the request for review.

(c) *Procedures the QIO must follow.* (1) The QIO must notify the hospital that it has received the request for review and must notify the hospital if it has not received all pertinent records.

(2) The QIO must examine the pertinent records pertaining to the services.

(3) The QIO must solicit the views of the beneficiary in question.

(4) The QIO must make a determination and notify the beneficiary, the hospital, and physician within 2 working days of the hospital's request and receipt of any pertinent information submitted by the hospital.

(d) *Notice of an expedited determination.* (1) When a QIO issues an expedited determination as stated in paragraph (c)(4) of this section, it must notify the beneficiary, physician, and hospital of its decision, by telephone and subsequently in writing.

(2) A written notice of the expedited initial determination must contain the following:

(i) The basis for the determination;.

(ii) A detailed rationale for the determination;

(iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any; and

(iv) A statement informing the beneficiary of his or her appeal rights and the timeframe for requesting an appeal.

(e) *Effect of an expedited determination.* The expedited determination under this section is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *When a beneficiary remains in the hospital.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with this determination, he or she may request a reconsideration according to the procedures described in § 405.1204. The procedures described in § 405.1204 will apply to reconsiderations requested under this section. If the beneficiary does not make a request in accordance with § 405.1204(b)(1), the timeframes described in § 405.1204(c)(3), the escalation procedures described in § 405.1204(c)(5), and the coverage rule described in § 405.1204(f) will not apply.

(2) *When a beneficiary is no longer an inpatient in the hospital.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, this determination is subject to the general claims appeal process.

[69 FR 69624, Nov. 26, 2004, as amended at 71 FR 68722, Nov. 27, 2006]

§ 405.1210 Notifying eligible beneficiaries of appeal rights when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

(a) *Applicability and scope.* (1) For purposes of this section and §§ 405.1211 and 405.1212, the term ''hospital'' is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non-acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition includes critical access hospitals (CAHs).

(2) For purposes of this section and §§ 405.1211 and 405.1212, the change in status occurs when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services (as defined in § 405.931(h)).

(3) For purposes of this section and §§ 405.1211 and 405.1212, a beneficiary is eligible to pursue an appeal regarding a change in status when the beneficiary meets all the following:

(i) Was formally admitted as a hospital inpatient in accordance with an order for inpatient admission by a physician or other qualified practitioner.

(ii) Was subsequently reclassified by the hospital as an outpatient receiving observation services after the admission.

(iii)(A) Was not enrolled in Part B coverage at the time of the beneficiary's hospitalization; or

(B) Stayed at the hospital for 3 or more consecutive days but was classified as an inpatient for fewer than 3 days.

(iv) The period ''3 or more consecutive days'' is counted using the rules for determining coverage of SNF services under section 1861 of the Act and § 409.30 of this chapter (that is, a beneficiary must have a qualifying inpatient stay of at least 3 consecutive calendar days starting with the admission day but not counting the discharge day).

(b) *Advance written notice of appeal rights.* For all eligible beneficiaries, hospitals must deliver valid, written notice of an eligible beneficiary's right to pursue an appeal regarding the decision to reclassify the beneficiary from an inpatient to an outpatient receiving observation services. The hospital must use a standardized notice specified by CMS in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice not later than 4 hours before release from the hospital and as soon as possible after the earliest of either of the following:

(i) The hospital reclassifies the beneficiary from an inpatient to an outpatient receiving observation services and the beneficiary is not enrolled in Part B.

(ii) The hospital reclassifies the beneficiary from an inpatient to an outpatient receiving observation services and the beneficiary has stayed in the hospital for 3 or more consecutive days but was an inpatient for fewer than 3 days.

(2) *Content of the notice.* The notice must include the following information:

(i) The eligible beneficiary's change in status and the appeal rights under § 405.1211 if the beneficiary wishes to pursue an appeal regarding that change.

(ii) An explanation of the implications of the change in status, including the potential change in beneficiary hospital charges resulting from a favorable decision, and subsequent eligibility for Medicare coverage for SNF services.

(iii) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the written notice of appeal rights described in this section is valid if—

(i) The eligible beneficiary (or the eligible beneficiary's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If an eligible beneficiary refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

[89 FR 83292, Oct. 15, 2024, as amended at 90 FR 20808, May 16, 2025]

EDITORIAL NOTES: 1. At 89 FR 83292, Oct. 15, 2024, § 405.1210 was added, with incorrect paragraph designations for the two subparagraphs in (b)(3).

2. At 89 FR 106364, Dec. 30, 2024, § 405.1210 was amended by adding paragraph (b)(3); however, the amendment could not be incorporated due to inaccurate amendatory instruction.

§ 405.1211 Expedited determination procedures when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

(a) *Beneficiary's right to an expedited determination by the QIO.* An eligible beneficiary has a right to request an expedited determination by the QIO when—

(1) A hospital changes a beneficiary's status from an inpatient to an outpatient receiving observation services; and

(2) The beneficiary meets other eligibility criteria as specified in § 405.1210(a)(3).

(b) *Requesting an expedited determination.* (1) An eligible beneficiary who

wishes to exercise the right to an expedited determination must submit a request to the QIO that has an agreement with the hospital as specified in §476.78 of this chapter. The request must be made in writing or by telephone before release from the hospital.

(2) The eligible beneficiary, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The eligible beneficiary may, but is not required to, submit written evidence to be considered by the QIO in making its decision.

(4) An eligible beneficiary who makes a timely request for an expedited QIO review in accordance with paragraph (b)(1) of this section is subject to the billing protection under paragraph (e) of this section, as applicable.

(5) An eligible beneficiary who fails to make a timely request for an expedited determination by a QIO, as described in paragraph (b)(1) of this section, may still request an untimely expedited QIO determination at any time. The QIO issues a decision in accordance with paragraph (c)(6)(ii) of this section, but the billing protection under paragraph (e) of this section does not apply.

(c) *Procedures the QIO must follow.* (1) When the QIO receives the request for an expedited determination under paragraph (b)(1) of this section, it must immediately notify the hospital that a request for an expedited determination has been made.

(2) The QIO determines whether the hospital delivered valid notice consistent with §405.1210(b)(3).

(3) The QIO examines the medical and other records that pertain to the change in status.

(4) The QIO must solicit the views of the eligible beneficiary (or the eligible beneficiary's representative) who requested the expedited determination.

(5) The QIO must provide an opportunity for the hospital to explain why the reclassification of the beneficiary from an inpatient to an outpatient receiving observation services is appropriate.

(6) The following timeframes apply for the QIO's decision when an eligible beneficiary requests—

(i) A timely expedited determination in accordance with paragraph (b)(1) of this section, the QIO must make a determination within 1 calendar day of receiving all requested pertinent information specified in paragraph (d)(1)(i) of this section; or

(ii) An untimely request for a QIO expedited determination, the QIO must make a determination within 2 calendar days after the QIO receives all requested information specified in paragraph (d)(1)(i) of this section.

(7) If the QIO does not receive the information specified in paragraph (d)(1)(i) of this section, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the requested information.

(8) When the QIO issues an expedited determination, the QIO must notify the eligible beneficiary, the hospital, and SNF (if applicable) of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination.

(iv) Information about the eligible beneficiary's right to an expedited reconsideration of the QIO's determination as set forth in §405.1212, including how to request a reconsideration and the time period for doing so.

(d) *Responsibilities of hospitals.* (1)(i) Upon notification by the QIO of the request for an expedited determination, the hospital must supply all information that the QIO needs to make its expedited determination, including a copy of the notice as required in §405.1210(b) of this section.

(ii) The hospital must furnish this information as soon as possible, but no later than by noon of the calendar day after the QIO notifies the hospital of the request for an expedited determination.

(iii) At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(2)(i) At an eligible beneficiary's (or representative's) request, the hospital must furnish the beneficiary with a

copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone.

(ii) The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and, if applicable, delivering it to the beneficiary.

(iii) The hospital must accommodate such a request by no later than close of business of the first calendar day after the material is requested.

(e) *Billing during QIO expedited review.* When an eligible beneficiary requests an expedited determination in accordance with paragraphs (b)(1) through (b)(4) of this section, the hospital may not bill the beneficiary for any disputed services until the expedited determination process (and reconsideration process, if applicable) has been completed.

(f) *Effect of an expedited QIO determination.* The QIO determination is binding for payment purposes upon the eligible beneficiary, hospital, and MAC, except if the eligible beneficiary is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 405.1212.

[89 FR 83292, Oct. 15, 2024]

§ 405.1212 Expedited reconsideration procedures regarding Part A coverage when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

(a) *Beneficiary's right to an expedited reconsideration.* An eligible beneficiary who is dissatisfied with a QIO's expedited determination per § 405.1211(c)(6) may request an expedited reconsideration by the QIO identified in the written notice specified in § 405.1211(c)(8)(iv).

(b) *Requesting an expedited reconsideration.* (1) An eligible beneficiary who wishes to obtain an expedited reconsideration must submit a request for the reconsideration to the appropriate QIO, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone or in writing) after receipt of the QIO's determination.

(2) The eligible beneficiary, or his or her representative, must be available to answer questions or supply information that the QIO may request to conduct its reconsideration.

(3) The eligible beneficiary may, but is not required to, submit evidence to be considered by the QIO in making the reconsideration.

(4) An eligible beneficiary who makes a timely request for an expedited reconsideration in accordance with paragraph (b)(1) of this section is subject to the billing protection under paragraph (e) of this section, as applicable.

(5) An eligible beneficiary who fails to make a timely request for an expedited reconsideration by a QIO, as described in paragraph (b)(1) of this section, may still request an expedited QIO reconsideration at any time. The QIO issues a reconsideration in accordance with paragraph (c)(3)(ii) of this section, but the billing protection under paragraph (e) of this section does not apply.

(c) *Procedures and responsibilities of the QIO.* (1) On the day the QIO receives the request for an expedited reconsideration under paragraph (b) of this section, the QIO must immediately notify the hospital of the request for an expedited reconsideration.

(2) The QIO must offer the eligible beneficiary and the hospital an opportunity to provide further information.

(3) When the eligible beneficiary makes—

(i) A timely request in accordance with paragraph (b)(1) of this section, the QIO must make a reconsideration determination within 2 calendar days of receiving all requested pertinent information; or

(ii) An untimely request, the QIO must make a reconsideration determination within 3 calendar days of receiving all requested pertinent information.

(4) When the QIO issues a reconsideration determination, the QIO must notify the eligible beneficiary, the hospital, and SNF, if applicable, of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination.

(iv) Information about the eligible beneficiary's right to appeal the QIO's reconsideration decision to OMHA for an ALJ hearing in accordance with subpart I of this part, including how to request an appeal and the time period for doing so.

(d) *Responsibilities of the hospital.* A hospital may, but is not required to, submit evidence to be considered by a QIO in making its reconsideration decision. If a hospital fails to comply with a QIO's request for additional information beyond that furnished to the QIO for purposes of the expedited determination, the QIO makes its reconsideration decision based on the information available.

(e) *Billing during QIO reconsideration.* When an eligible beneficiary requests an expedited reconsideration in accordance with the deadline specified in paragraph (b)(1) of this section, the hospital may not bill the beneficiary for any disputed services until the QIO makes its reconsideration decision.

(f) *Effect of an expedited QIO reconsideration.* The QIO expedited reconsideration is binding for payment purposes only, upon the eligible beneficiary, hospital, and MAC, except if a beneficiary elects to request a hearing by an ALJ in accordance with 42 CFR part 478 subpart B if he or she is dissatisfied with the expedited reconsideration decision.

[89 FR 83292, Oct. 15, 2024]

Subparts K–Q [Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

EDITORIAL NOTE: Nomenclature changes to subpart R of part 405 appear at 79 FR 55031, Aug. 22, 2014.

§ 405.1801 Introduction.

(a) *Definitions.* As used in this subpart:

Administrator means the Administrator or Deputy Administrator of CMS.

Administrator review means that review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and § 405.1875.

Board means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 1395oo) and § 405.1845.

Board hearing means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 1395oo(a)), and § 405.1835.

CMS reviewing official means the reviewing official provided for in § 405.1834.

CMS reviewing official procedure means the review provided for in § 405.1834.

Contractor determination means the following:

(1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24 of this chapter, the term means a final determination of the amount of total reimbursement due the provider, pursuant to § 405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a final determination of the total amount of payment due the hospital, pursuant to § 405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the final determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases ''intermediary's final determination,'' ''final determination of the organization serving as its fiscal intermediary,'' ''Secretary's final determination'' and ''final determination of the Secretary,'' as those phrases are used in section 1878(a) of the Act, and

with the phrases ''final contractor determination'' and ''final Secretary determination'' as those phrases are used in this subpart.

(4) For purposes of §405.376 concerning claims collection activities, the term does not include an action by CMS with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

Contractor hearing means that hearing provided for in §405.1809.

Contractor hearing officer(s) means the hearing officer or panel of hearing officers provided for in §405.1817.

Date of receipt means the date a document or other material is received by either of the following:

(1) *A party or an affected nonparty.* A party or an affected nonparty, such as CMS, involved in proceedings before a reviewing entity.

(i) As applied to a party or an affected nonparty, the phrase ''date of receipt'' in this definition is synonymous with the term ''notice,'' as that term is used in section 1878 of the Act and in this subpart.

(ii) For purposes of a contractor hearing, if no contractor hearing officer is appointed (or none is currently presiding), the date of receipt of materials sent to the contractor hearing officer (as permitted under paragraph (d) of this section) is presumed to be, as applicable, the date that the contractor stamps ''Received'' on the materials, or the date of electronic delivery.

(iii) The date of receipt by a party or affected nonparty of documents involved in proceedings before a reviewing entity is presumed to be 5 days after the date of issuance of a contractor notice or a reviewing entity document. This presumption, which is otherwise conclusive, may be overcome if it is established by a preponderance of the evidence that such materials were actually received on a later date.

(2) *A reviewing entity.* For purposes of this definition, a reviewing entity is deemed to include the Office of the Attorney Advisor. The determination as to the date of receipt by the reviewing entity to which the document or other material was submitted (as permitted under paragraph (d) of this section) is final and binding as to all parties to the appeal. The date of receipt of documents by a reviewing entity is presumed to be, as applicable, one of the following dates:

(i) Of delivery where the document or material is transmitted by a nationally-recognized next-day courier (such as the United States Postal Service's Express Mail, Federal Express, UPS, DHL, etc.).

(ii) Stamped ''Received'' by the reviewing entity on the document or other submitted material (where a nationally-recognized next-day courier is not employed). This presumption, which is otherwise conclusive, may be overcome if it is established by clear and convincing evidence that the document or other material was actually received on a different date.

(iii) Of electronic delivery. *In writing* or *written* means a hard copy or electronic submission (subject to the restrictions in paragraph (d) of this section), as applicable throughout this subpart.

Reviewing entity means the contractor hearing officer(s), a CMS reviewing official, the Board, or the Administrator.

(b) *General rules*—(1) *Providers.* In order to be paid for covered services furnished to Medicare beneficiaries, a provider must file a cost report with its contractor as specified in §413.24 of this chapter. For purposes of this subpart, the term ''provider'' includes a hospital (as described in part 482 of this chapter), hospice program (as described in §418.3 of this chapter), critical access hospital (CAH), comprehensive outpatient rehabilitation facility (CORF), renal dialysis facility, Federally qualified health center (FQHC), home health agency (HHA), rural health clinic (RHC), skilled nursing facility (SNF), and any other entity included under the Act. (FQHCs and RHCs are providers, for purposes of this subpart, effective with cost reporting periods beginning on or after October 1, 1991).

(2) *Other nonprovider entities participating in Medicare Part A.* (i) Providers of services, as well as, other entities (including, but not limited to health

maintenance organizations (HMOs) and competitive medical plans (CMPs) (as described in § 400.200 of this chapter)) may participate in the Medicare program, but do not qualify as providers under the Act or this subpart.

(ii) Some of these nonprovider entities are required to file periodic cost reports and are paid on the basis of information furnished in these reports. Except as provided at § 413.420(g) of this chapter, these nonprovider entities may not obtain a contractor hearing or a Board hearing under section 1878 of the Act or this subpart.

(iii) Some other hearing will be available to these nonprovider entities, if the amount in controversy is at least $1,000.

(iv) For any nonprovider hearing, the procedural rules for a Board hearing set forth in this subpart are applicable to the maximum extent possible.

(c) *Effective dates.* (1) Except as provided in paragraphs (c)(2) and (c)(3) of this section or in § 405.1885(e), this subpart applies to all cost reporting periods ending on or after December 31, 1971, for which reimbursement may be made on a reasonable cost basis.

(2) Sections 405.1835 to 405.1877 apply only to cost reporting periods ending on or after June 30, 1973, for which reimbursement may be made on a reasonable cost basis.

(3) With respect to hospitals under the prospective payment system (see part 412 of this chapter), the appeals procedures in §§ 405.1811 to 405.1877 that apply become applicable with the hospital's first cost reporting period beginning on or after October 1, 1983.

(d) *Method for submissions and calculating time periods and deadlines.* Except for subpoena requests being sent to a nonparty under § 405.1857(c), the reviewing entity may prescribe the method(s) by which a party must make a submission, including the requirement to use an electronic filing system for submission of documents. Such methods or instructions apply to any period of time or deadline prescribed or allowed under this subpart (for example, requests for appeal under §§ 405.1811(b), 405.1835(b), and 405.1837(c) and (e)) or authorized by a reviewing entity. In computing any period of time or deadline prescribed or allowed under this subpart or authorized by a reviewing entity the following principles are applicable:

(1) The day of the act, event, or default from which the designated time period begins to run is not included.

(2) Each succeeding calendar day, including the last day, is included in the designated time period, except that, in calculating a designated period of time for an act by a reviewing entity, a day is not included where the reviewing entity is unable to conduct business in the usual manner due to extraordinary circumstances beyond its control such as natural or other catastrophe, weather conditions, fire, or furlough. In that case, the designated time period resumes when the reviewing entity is again able to conduct business in the usual manner.

(3) If the last day of the designated time period is a Saturday, a Sunday, a Federal legal holiday (as enumerated in Rule 6(a) of the Federal Rules of Civil Procedure), or a day on which the reviewing entity is unable to conduct business in the usual manner, the deadline becomes the next day that is not one of the aforementioned days.

(4) For purposes of paragraph (d) of this section, the reviewing entity is deemed to also include—

(i) The contractor, if the contractor hearing officer(s) is not yet appointed (or none is currently presiding); and

(ii) The Office of the Attorney Advisor.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 39834, Sept. 1, 1983; 48 FR 45773, Oct. 7, 1983; 49 FR 322, Jan. 3, 1984; 49 FR 23013, June 1, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63749, Dec. 2, 1996; 73 FR 30243, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 80 FR 70597, Nov. 13, 2015; 85 FR 59018, Sept. 18, 2020; 87 FR 72284, Nov. 23, 2022]

§ 405.1803 Contractor determination and notice of amount of program reimbursement.

(a) *General requirement.* Upon receipt of a provider's cost report, or amended cost report where permitted or required, the contractor must within a reasonable period of time (as specified in § 405.1835(c)(1)), furnish the provider and other parties as appropriate (see § 405.1805) a written notice reflecting the contractor's final determination of the total amount of reimbursement due

the provider. The contractor must include the following information in the notice, as appropriate:

(1) *Reasonable cost.* The notice must—

(i) Explain the contractor's determination of total program reimbursement due the provider on the basis of reasonable cost for the reporting period covered by the cost report or amended cost report; and

(ii) Relate this determination to the provider's claimed total program reimbursement due the provider for this period.

(2) *Prospective payment.* With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (see part 412 of this chapter), the contractor must include in the notice its determination of the total amount of the payments due the hospital under that system for the cost reporting period covered by the notice. The notice must explain (with appropriate use of the applicable money amounts) any difference in the amount determined to be due, and the amounts received by the hospital during the cost reporting period covered by the notice.

(3) *Hospice caps.* With respect to a hospice, the reporting period for the cap calculation is the cap year; and the contractors' determination of program reimbursement letter, which provides the results of the inpatient and aggregate cap calculations, shall serve as a notice of program reimbursement. The time period for filing cap appeals begins with receipt of the determination of program reimbursement letter.

(b) *Requirements for contractor notices.* The contractor must include in each notice appropriate references to law, regulations, CMS Rulings, or program instructions to explain why the contractor's determination of the amount of program reimbursement for the period differs from the amount the provider claimed. The notice must also inform the provider of its right to contractor or Board hearing (see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843) and that the provider must request the hearing within 180 days after the date of receipt of the notice.

(c) *Use of notice as basis for recoupment of overpayments.* The contractor's determination contained in its notice is the basis for making the retroactive adjustment (required by § 413.64(f) of this chapter) to any program payments made to the provider during the period to which the determination applies, including recoupment under § 405.373 from ongoing payments to the provider of any overpayments to the provider identified in the determination. Recoupment is made notwithstanding any request for hearing on the determination the provider may make under § 405.1811 or § 405.1835.

(d) *Effect of certain final agency decisions and final court judgments; audits of self-disallowed and other items.* (1) This paragraph applies to the following administrative decisions and court judgments:

(i) A final hearing decision by the contractor (as described in § 405.1833 of this subpart) or the Board (as described in § 405.1871(b) of this subpart).

(ii) A final decision by a CMS reviewing official (as described in § 405.1834(f)(1) of this subpart) or the Administrator (as described in § 405.1875(e)(4) of this subpart) following review of a hearing decision by the contractor or the Board, respectively.

(iii) A final, non-appealable judgment by a court on a Medicare reimbursement issue that the court rendered in accordance with jurisdiction under section 1878 of the Act (as described in §§ 405.1842 and 405.1877 of this subpart).

(2) For any final agency decision or final court judgment specified in paragraph (d)(1) of this section, the contractor must promptly, upon notification from CMS—

(i) Determine the effect of the final decision or judgment on the contractor determination for the cost reporting period at issue in the decision or judgment; and

(ii) Issue any revised contractor determination, and make any additional program payment, or recoup or offset any program payment (as described in § 405.371 of this subpart), for the period that may be necessary to implement the final decision or judgment on the specific matters at issue in the decision or judgment.

(3) CMS may require the contractor to audit any item, including any self-disallowed item, at issue in an appeal or a civil action, before any revised

contractor determination or additional Medicare payment, recoupment, or offset may be determined for an item under paragraph (d)(2) of this section.

(4) For any final settlement agreement, whether for an appeal to the contractor hearing officer(s) or the Board or for a civil action before a court, the contractor must implement the settlement agreement in accordance with paragraphs (d)(2) and (d)(3) of this section, unless a particular administrative or judicial settlement agreement provides otherwise.

[48 FR 39834, Sept. 1, 1983, as amended at 49 FR 322, Jan. 3, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63748, Dec. 2, 1996; 73 FR 30244, May 23, 2008; 74 FR 39412, Aug. 6, 2009; 80 FR 70597, Nov. 13, 2015]

§ 405.1804 Matters not subject to administrative and judicial review under prospective payment.

Neither administrative nor judicial review is available for controversies about the following matters:

(a) The determination of the requirement, or the proportional amount, of the budget neutrality adjustment in the prospective payment rates required under section 1886(e)(1) of the Social Security Act.

(b) The establishment of—

(1) Diagnosis related groups (DRGs);

(2) The methodology for the classification of inpatient discharges within the DRGs; or

(3) Appropriate weighting factors that reflect the relative hospital resources used with respect to discharge within each DRG.

[49 FR 322, Jan. 1, 1984, as amended at 78 FR 75195, Dec. 10, 2013]

§ 405.1805 Parties to contractor determination.

The parties to the contractor's determination are the provider and any other entity found by the contractor to be a related organization of the provider under § 413.17 of this chapter.

[48 FR 39835, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§ 405.1807 Effect of contractor determination.

The determination shall be final and binding on the party or parties to such determination unless:

(a) A contractor hearing is requested in accordance with § 405.1811 and a contractor hearing decision rendered in accordance with § 405.1831; or

(b) The contractor determination is revised in accordance with § 405.1885; or

(c) A Board hearing is requested in accordance with § 405.1835 and a hearing decision rendered pursuant thereto.

§ 405.1809 Contractor hearing procedures.

(a) *Hearings.* Each contractor must establish and maintain written procedures for contractor hearings, in accordance with the regulations in this subpart, for resolving issues that may arise between the contractor and a provider concerning the amount of reasonable cost reimbursement, or prospective payment due the provider (except as provided in § 405.1804) under the Medicare program. The procedures must provide for a hearing on the contractor determination contained in the notice of program reimbursement (§ 405.1803), if the provider files a timely request for a hearing.

(b) *Amount in controversy.* In order for a contractor to grant a hearing, the following dates and amounts in controversy apply:

(1) For cost reporting periods ending prior to June 30, 1973, the amount of program reimbursement in controversy must be at least $1000.

(2) For cost reporting periods ending on or after June 30, 1973, the amount of program reimbursement in controversy must be at least $1000 but less than $10,000.

[48 FR 39835, Sept. 1, 1983, as amended at 49 FR 323, Jan. 1, 1984]

§ 405.1811 Right to contractor hearing; contents of, and adding issues to, hearing request.

(a) *Right to hearing on final contractor determination.* A provider (but no other individual, entity, or party) has a right to a contractor hearing, as a single provider appeal, with respect to a final contractor or Secretary determination for the provider's cost reporting period, if—

(1) The provider is dissatisfied with the contractor's final determination of the total amount of reimbursement due

the provider, as set forth in the contractor's written notice pursuant to § 405.1803. Exception: If a final contractor determination is reopened under § 405.1885, any review by the contractor hearing officer must be limited solely to those matters that are specifically revised in the contractor's revised final determination (§§ 405.1887(d), 405.1889(b), and the ''Exception'' in § 405.1832(c)(2)(i)).

(2) The amount in controversy (as determined in accordance with § 405.1839) must be at least $1,000 but less than $10,000.

(3) Unless the provider qualifies for a good cause extension under § 405.1813, the date of receipt by the contractor of the provider's hearing request must be no later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination.

(b) *Contents of request for a contractor hearing on final contractor determination.* The provider's request for a contractor hearing under paragraph (a) of this section must be submitted in writing to the contractor, and the request must include the elements described in paragraphs (b)(1) through (b)(3) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (b)(1), (b)(2), or (b)(3) of this section, the contractor hearing officer may dismiss with prejudice the appeal or take any other remedial action he or she considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a contractor hearing as specified in paragraph (a) of this section, including a specific identification of the final contractor or Secretary determination under appeal.

(2) For each specific item under appeal, a separate explanation of why, and a description of how, the provider is dissatisfied with the specific aspects of the final contractor or Secretary determination under appeal, including an account of all of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it allegedly does not have access to underlying information concerning the calculation of its payment); and

(ii) How and why the provider believes Medicare payment should be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of the final contractor or Secretary determination under appeal and any other documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (b)(1) and (b)(2) of this section.

(c) *Right to hearing based on untimely contractor determination.* Notwithstanding the provisions of paragraph (a) of this section, a provider (but no other individual, entity, or party) has a right to a contractor hearing, as a single provider appeal, for specific items for a cost reporting period if—

(1) A final contractor determination for the provider's cost reporting period is not issued (through no fault of the provider) within 12 months after the date of receipt by the contractor of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of this chapter). The date of receipt by the contractor of the provider's perfected cost report or amended cost report is presumed to be the date of electronic delivery, or the date the contractor stamped ''Received'' on such cost report unless it is shown by a preponderance of the evidence that the contractor received the cost report on an earlier date.

(2) Unless the provider qualifies for a good cause extension under § 405.1813, the date of receipt by the contractor of the provider's hearing request is no later than 180 days after the expiration of the 12 month period for issuance of the final contractor determination (as determined in accordance with paragraph (c)(1) of this section); and

(3) The amount in controversy (as determined in accordance with § 405.1839) is at least $1,000 but less than $10,000.

(d) *Contents of request for a contractor hearing based on untimely contractor determination.* The provider's request for a contractor hearing under paragraph (c) of this section must be submitted in writing to the contractor, and the request must include the elements described in paragraphs (d)(1) through (d)(3) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (d)(1), (d)(2), or (d)(3) of this section, the contractor hearing officer may dismiss with prejudice the appeal or take any other remedial action he or she considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a contractor hearing as specified in paragraph (c) of this section.

(2) An explanation (for each specific item at issue) of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it does not have access to underlying information concerning the calculation of Medicare payment).

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item, a description of the nature and amount of each self-disallowed item and the reimbursement or payment sought for the item.

(3) A copy of any documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (d)(1) and (d)(2) of this section.

(e) *Adding issues to the hearing request.* After filing a hearing request in accordance with paragraphs (a) and (b), or paragraphs (c) and (d), of this section, a provider may add specific Medicare payment issues to the original hearing request by submitting a written request to the contractor hearing officer, only if—

(1) The request to add issues complies with the requirements of paragraphs (a) and (b), or paragraphs (c) and (d), of this section as to each new specific item at issue.

(2) The specific items raised in the initial hearing request and the specific items identified in subsequent requests to add issues, when combined, satisfy the amount in controversy requirements of paragraph (a)(2) or paragraph (c)(3) of this section.

(3) The contractor hearing officer receives the provider's request to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(3) or paragraph (c)(2) of this section.

[73 FR 30244, May 23, 2008, as amended at 79 FR 50349, Aug. 22, 2014; 79 FR 59680, Oct. 3, 2014; 80 FR 70597, Nov. 13, 2015; 85 FR 59018, Sept. 18, 2020]

§ 405.1813 Good cause extension of time limit for requesting a contractor hearing.

(a) A request for a contractor hearing that is received by the contractor after the applicable 180-day time limit prescribed in § 405.1811(a)(3) or § 405.1811(c)(2) must be dismissed by the contractor hearing officer(s), except that the hearing officer(s) may extend the time limit upon a good cause showing by the provider.

(b) The contractor hearing officer(s) may find good cause to extend the time limit only if the provider demonstrates in writing it could not reasonably have been expected to file timely due to extraordinary circumstances beyond its control (such as a natural or other catastrophe, fire, or strike), and the provider's written request for an extension is received by the contractor hearing officer(s) within a reasonable time (as determined by the contractor hearing officer(s) under the circumstances) after the expiration of the applicable 180-day limit prescribed in § 405.1811(a)(3) or § 405.1811(c)(2).

(c) The contractor hearing officer(s) may not grant a request for an extension under this section if—

(1) The provider relies on a change in the law, regulations, CMS Rulings, or general CMS instructions (whether based on a court decision or otherwise) or a CMS administrative ruling or policy as the basis for the extension request; or

(2) The date of receipt by the contractor of the provider's extension request is later than 3 years after the

date of the contractor or other determination that the provider seeks to appeal.

(d) If an extension request is granted or denied under this section, the contractor hearing officer(s) must send prompt written notice to the provider, and send a copy to each party to the appeal. The notice must include an explanation of the reasons for the decision by the hearing officer(s) and the facts underlying the decision.

(e)(1) A decision denying an extension request under this section and dismissing the appeal is final and binding on the provider, unless the dismissal decision is reviewed by a CMS reviewing official in accordance with §405.1834(b)(2)(i) of this subpart or reopened and revised by the contractor hearing officer(s) in accordance with §405.1885 through §405.1889 of this subpart. The contractor hearing officer(s) promptly sends the decision to the appropriate component of CMS (currently the Center for Medicare Management) (as specified in §405.1834(b)(4) of this subpart).

(2) A decision granting an extension request under this section is not subject to immediate review by a CMS reviewing official (as described in §405.1834(b)(3) of this subpart). Any decision may be examined during the course of CMS review of a final jurisdictional dismissal decision or a final hearing decision by the contractor hearing officer(s) (as described in §§405.1834(b)(2)(i) and 405.1834(b)(2)(ii) of this subpart).

[73 FR 30245, May 23, 2008, as amended at 80 FR 70598, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§405.1814 Contractor hearing officer jurisdiction.

(a) *General rules.* (1) After a request for a contractor hearing is filed under §405.1811 of this subpart, the contractor hearing officer(s) must do the following:

(i) Determine in accordance with paragraph (b) of this section whether or not it has jurisdiction to grant a hearing on each of the specific matters at issue in the hearing request.

(ii) Make a preliminary determination of the scope of its jurisdiction (that is, whether the request for hearing was timely, and whether the amount in controversy requirement has been met), if any, over the matters at issue in the appeal before conducting any of the following proceedings:

(A) Determining its authority to decide a legal question relevant to a matter at issue (as described in §405.1829 of this subpart);

(B) Permitting discovery (as specified in §405.1821 of this subpart); or

(C) Conducting a hearing (as specified in §405.1819 of this subpart);

(2) The hearing officer(s) may revise a preliminary jurisdictional determination at any subsequent stage of the proceedings in an appeal, and it must promptly notify the parties of any revised determination.

(3) Under paragraph (c)(1) of this section, each contractor hearing decision (as described in §405.1831 of this subpart) must include a final jurisdictional finding for each specific matter at issue in the appeal.

(4) If the hearing officer(s) finally determines it lacks jurisdiction over every specific matter at issue in the appeal, it issues a jurisdictional dismissal decision under paragraph (c)(2) of this section.

(5) Final jurisdictional findings and jurisdictional dismissal decisions by the hearing officer(s) are subject to the CMS reviewing official procedure in accordance with paragraph (d) of this section and §405.1834(b)(2)(i) and (b)(2)(ii) of this subpart.

(b) *Criteria.* Except for the amount in controversy requirement, the jurisdiction of the contractor hearing officer(s) to grant a hearing is determined separately for each specific matter at issue in the contractor or Secretary determination for the cost reporting period under appeal. The hearing officer(s) has jurisdiction to grant a hearing over a specific matter at issue in an appeal only if the provider has a right to a contractor hearing under §405.1811. Certain matters at issue are removed from the jurisdiction of the contractor hearing officer(s); these matters include, but are not limited to, the following:

(1) A finding in a contractor determination that expenses incurred for certain items or services furnished by a

provider to an individual are not payable under title XVIII of the Act because those items and services are excluded from coverage under section 1862 of the Act and part 411 of the regulations. Review of these findings is limited to the applicable provisions of sections 1155, 1869, and 1879(d) of the Act, and of subpart I of part 405 and subpart B of part 478, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system, as provided in section 1886(d)(7) of the Act and §405.1804 of this subpart.

(c) *Final jurisdictional findings, and jurisdictional dismissal decisions by contractor hearing officer(s).* (1) In issuing a hearing decision under §405.1831 of this subpart, the contractor hearing officer(s) must make a final determination of its jurisdiction, or lack thereof, for each specific matter at issue in the hearing decision. Each contractor hearing decision must include specific findings of fact and conclusions of law as to the jurisdiction of the hearing officer(s), or lack thereof, to grant a hearing on each matter at issue in the appeal.

(2) If the hearing officer(s) finally determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a jurisdictional dismissal decision. Each jurisdictional dismissal decision by the hearing officer(s) must include specific findings of fact and conclusions of law explaining the determination that there is no jurisdiction to grant a hearing on each matter at issue in the appeal. A copy of the jurisdictional dismissal decision must be sent promptly to each party to the appeal.

(3) A jurisdictional dismissal decision by the contractor hearing officer(s) under paragraph (c)(2) of this section is final and binding on the parties, unless the decision is reviewed by a CMS reviewing official in accordance with §405.1834 of this subpart or reopened and revised by the contractor hearing officer(s) in accordance with §405.1885 through §405.1889 of this subpart.

(d) *CMS reviewing official review.* Any finding by the contractor hearing officer as to whether it has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative review, except as provided in this paragraph. The contractor hearing officer's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of CMS reviewing official review of one of the contractor hearing officer decisions specified in §405.1834(b)(2) of this subpart.

[73 FR 30245, May 23, 2008, as amended at 80 FR 70598, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§405.1815 Parties to proceedings before the contractor hearing officer(s).

When a provider files a request for a contractor hearing in accordance with §405.1811 of this subpart, the parties to all proceedings before the contractor hearing officer(s) are the provider and, if applicable, any other entity found by the contractor hearing officer(s) to be a related organization of the provider under the principles enunciated in §413.17 of this chapter. The parties must be given reasonable notice of the time, date, and place of any contractor hearing. Neither the contractor nor CMS may be made a party to proceedings before the contractor hearing officer(s).

[73 FR 30246, May 23, 2008]

§405.1817 Hearing officer or panel of hearing officers authorized to conduct contractor hearing; disqualification of officers.

The contractor hearing provided for in §405.1809 shall be conducted by a hearing officer or panel of hearing officers designated by the contractor. Such hearing officer or officers shall be persons knowledgeable in the field of health care reimbursement. The hearing officer or officers shall not have had any direct responsibility for the program reimbursement determination with respect to which a request for hearing is filed; no hearing officer (or officers) shall conduct a hearing in a case in which he is prejudiced or partial with respect to any party, or where he has any interest in the matter pending for determination before him. Notice of any objection which a party may have with respect to a hearing officer shall be presented in writing to such officer by the objecting party at

the party's earliest opportunity. The hearing officer shall consider the objection and shall, at his discretion, either proceed in the conduct of the hearing or withdraw. If the hearing officer does not withdraw, the objecting party may, after the hearing, present his objections to an executive official of the contractor, who shall rule promptly on the objection.

§ 405.1819 Conduct of contractor hearing.

The hearing shall be open to all parties thereto (see § 405.1815) and to representatives of the contractor and of the Centers for Medicare & Medicaid Services (see § 405.1815). The hearing officer(s) shall inquire fully into all of the matters at issue and shall receive into evidence the testimony and any documents which are relevant and material to such matters. If the hearing officer(s) believes that there is relevant and material evidence available which has not been presented at the hearing, he (they) may, at any time prior to the sending of notice of the decision, reopen the hearing record for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the hearing officer(s).

[39 FR 34515, Sept. 26, 1974, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1821 Prehearing discovery and other proceedings prior to the contractor hearing.

(a) *Discovery rule: Time limits.* (1) Limited prehearing discovery may be permitted by the contractor hearing officer(s) upon request of a party, provided the request is timely and the hearing officer(s) makes a preliminary finding of its jurisdiction over the matters at issue in accordance with § 405.1814(a) of this subpart.

(2) A prehearing discovery request is timely if the request by a party is served no later than 120 days before the initially scheduled starting date of the contractor hearing, unless the contractor hearing officer(s) extends the time for requesting discovery.

(3) In the absence of a specific schedule for responses set by the contractor hearing officer(s), responses to interrogatories and requests for production of documents are due according to the schedule agreed upon by the party serving discovery and the party to which the discovery is directed. Responses by a party to interrogatories or requests for production of documents must be served no later than 45 days before the initially scheduled start of the contractor hearing, unless the contractor hearing officer(s) orders otherwise. Responses by a nonparty to requests for production of documents must be served no later than 75 days after the date the requests were served on the nonparty, unless the party requesting the documents and the nonparty to which the requests are directed agree on a different time for responding, or unless the contractor hearing officer(s) extends the time for responding.

(4) Before ruling on a request to extend the time for requesting discovery or for responding to discovery, the hearing officer(s) must give the other parties to the appeal and any nonparty subject to a discovery request a reasonable period to respond to the extension request.

(5) If the extension request is granted, the hearing officer(s) sets a new deadline and has the discretion to reschedule the hearing date.

(b) *Discovery criteria*—(1) *General rule.* The contractor hearing officer(s) may permit discovery of a matter that is relevant to the specific subject matter of the contractor hearing, provided the matter is not privileged or otherwise protected from disclosure and the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate. In determining whether to permit discovery, and in fixing the scope and limits of any discovery, the hearing officer(s) uses the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence for guidance.

(2) *Limitations on discovery.* Any discovery before the contractor hearing officer(s) is limited as follows:

(i) A party may request of another party, or of a nonparty other than CMS, HHS or any Federal agency, the reasonable production of documents for inspection and copying.

(ii) A party may request another party to respond to a reasonable number of written interrogatories.

(iii) A party may not request admissions, take oral or written depositions, or take any other form of discovery not permitted under this section.

(c) *Discovery procedures. Rights of nonparties: Motions to compel or for protective order.* (1) A party may request discovery of another party to the proceedings before the contractor hearing officer(s) or of a nonparty other than CMS, HHS or other Federal agency. Any discovery request filed with the contractor hearing officer(s) must be sent promptly to the party or nonparty from which the discovery is requested, and to any other party to the contractor hearing (as described in §405.1815 of this subpart).

(2) If a discovery request is made of a nonparty to the contractor hearing, the nonparty has the rights any party has in responding to a discovery request. The rights of the nonparty include, but are not limited to, the right to select and use any attorney or other representative, and to submit discovery responses, objections, or motions to the hearing officer(s).

(3) Each party and nonparty is required to make a good faith effort to resolve or narrow any discovery dispute, regardless of whether the dispute is with another party or a nonparty.

(i) A party may submit to the contractor hearing officer(s) a motion to compel discovery that is permitted under this section, and a motion for a protective order regarding any discovery request may be submitted to the hearing officer(s) by a party or nonparty.

(ii) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute. A self-sworn declaration describing efforts to resolve or narrow a discovery dispute also must be included with any response to a motion to compel or for a protective order.

(iii) The hearing officer(s) must—

(A) Decide the motion in accordance with this section and any prior discovery ruling; and

(B) Issue and send to each party and any affected nonparty a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part; if applicable the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the hearing officer(s) finds necessary and appropriate. Nothing in this section authorizes the contractor hearing officer to compel any action from the Secretary or CMS.

(d) *Reviewability of discovery or disclosure rulings*—(1) *General rule.* A discovery ruling issued in accordance with paragraph (c)(3) of this section, or a disclosure ruling (such as one issued at a hearing), is not subject to immediate review by a CMS official (as described in §405.1834(b)(3) of this subpart). A discovery ruling may be examined solely during the course of CMS review under §405.1834 of this subpart of a jurisdictional dismissal decision (as described in §405.1814(c)(2) of this subpart) or a hearing decision (as described in §405.1831 of this subpart) by the contractor hearing officer(s).

(2) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the contractor hearing officer(s), that portion of the discovery or disclosure ruling may immediately be reviewed by a CMS reviewing official in accordance with §405.1834(b)(3).

(i) Upon notice to the contractor hearing officer that the provider intends to seek immediate review of a ruling, or that the contractor or other affected nonparty intends to suggest that the Administrator through the CMS reviewing official, take own motion review of the ruling, the contractor hearing officer stays all proceedings affected by the ruling.

(ii) The contractor hearing officer must determine, under the circumstances of a given case, the length of any stay, but in no event may the stay be less than 15 days.

(iii) If the Administrator through the CMS reviewing official—

(A) Grants a request for review, or takes own motion review, of a ruling, the ruling is stayed until such time as

the CMS reviewing official issues a written decision that affirms, reverses, modifies, or remands the contractor hearing officer's ruling.

(B) Does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling is not subject to immediate review.

(e) *Prehearing conference.* The contractor hearing officer(s) has discretion to schedule a prehearing conference. A prehearing conference may be conducted in person or telephonically, at the discretion of the contractor hearing officer(s). When a panel of contractor hearing officers is designated, the panel may appoint one or more hearing officers to act for the panel for any prehearing conference or any matter addressed at the conference.

[73 FR 30246, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1823 Evidence at contractor hearing.

Evidence may be received at the contractor hearing even though inadmissible under the rules of evidence applicable to court procedure. The hearing officer(s) shall give the parties opportunity for submission and consideration of facts and arguments, and during the course of the hearing, should in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The hearing officer(s) shall render a final ruling on the admissibility of evidence.

§ 405.1825 Witnesses at contractor hearing.

The hearing officer(s) may examine the witnesses and shall allow the parties and their representatives to do so. Parties to the proceedings may also cross-examine witnesses.

§ 405.1827 Record of proceedings before the contractor hearing officer(s).

(a) The contractor hearing officer(s) must maintain a complete record of all proceedings in an appeal.

(b) The record consists of all documents and any other tangible materials timely submitted to the hearing officer(s) by the parties to the appeal and by any nonparty (as described in § 405.1821(c) of this subpart), along with all correspondence, rulings, orders, and decisions (including the final decision) issued by the hearing officer(s).

(c) The record must include a complete transcription of the proceedings at any contractor hearing.

(d) A copy of the transcription must be made available to any party upon request.

[73 FR 30247, May 23, 2008]

§ 405.1829 Scope of authority of contractor hearing officer(s).

(a) The hearing officer(s) in exercising his authority must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with CMS Rulings issued under the authority of the Administrator of the Centers for Medicare & Medicaid Services (as described in § 401.108 of this chapter), and with the general instructions issued by the Centers for Medicare & Medicaid Services in accordance with the Secretary's agreement with the contractor.

(b)(1) If the contractor hearing officer(s) has jurisdiction to conduct a hearing on the specific matters at issue under § 405.1811, and the legal authority to fully resolve the matters in a hearing decision (as described in § 405.1831 of this subpart), the hearing officer(s) must affirm, modify, or reverse the contractor's findings on each specific matter at issue in the contractor or Secretary determination for the cost year under appeal.

(2) The contractor hearing officer(s) also may make additional revisions on specific matters regardless of whether the contractor considered the matters in issuing the contractor determination for the cost year, provided the hearing officer(s) does not consider or decide any specific matter for which it lacks jurisdiction (as described in § 405.1814(b) of this subpart) or which was not timely raised in the provider's hearing request.

(3) The authority of the contractor hearing officer(s) under this paragraph to make the additional revisions is limited to those revisions necessary to fully resolve a specific matter at issue if—

(i) The hearing officer(s) has jurisdiction to grant a hearing on the specific

matter under §§405.1811 and 405.1814 of this subpart; and

(ii) The specific matter was timely raised in an initial request for a contractor hearing filed in accordance with §405.1811(b) of this subpart or in a timely request to add issues to an appeal submitted in accordance with §405.1811(c) of this subpart.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 73 FR 30247, May 23, 2008]

§405.1831 Contractor hearing decision.

(a) If the contractor hearing officer(s) finds jurisdiction (as described in §405.1814(a) of this subpart) and conducts a hearing, the contractor hearing officer(s) must promptly issue a written hearing decision.

(b) The contractor hearing decision must be based on the evidence from the contractor hearing (as described in §405.1823 of this subpart) and other evidence as may be included in the record (as described in §405.1827 of this subpart).

(c) The decision must include findings of fact and conclusions of law on jurisdictional issues (as described in §405.1814(c)(1) of this subpart) and on the merits of the provider's reimbursement claims, and include appropriate citations to the record evidence and to the applicable law, regulations, CMS Rulings, and other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(d) A copy of the decision must be sent promptly to the contractor, to each party and to the appropriate component of CMS (which currently is the Center for Medicare Management).

(e) When the contractor's denial of the relief that the provider seeks before the contractor hearing officer(s) was based on procedural grounds (for example, the alleged failure of the provider to satisfy a time limit), or was based on the alleged failure to supply adequate documentation to support the provider's claim, and the contractor hearing officer(s) rule(s) that the basis of the contractor's denial is invalid, the contractor hearing officer(s) remands to the contractor for the contractor to make a determination on the merits of the provider's claim.

[73 FR 30248, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§405.1832 Contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim.

(a) *General.* In order to receive or potentially qualify for reimbursement for a specific item, the provider must include in its cost report an appropriate claim for the specific item (as prescribed in §413.24(j) of this chapter). If the provider files an appeal to the contractor seeking reimbursement for a specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item, the contractor hearing officer(s) must address such questions in accordance with the procedures set forth in this section.

(b) *Summary of procedures*—(1) *Preliminary steps.* The contractor hearing officer(s) must give each party to the appeal an adequate opportunity to submit factual evidence and legal argument regarding the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. Upon receipt of timely submitted factual evidence and legal argument (if any), the contractor hearing officer(s) must review such evidence and argument, and prepare written specific findings of fact and conclusions of law on the question of whether the provider's cost report complied with, for the specific item under appeal, the cost report claim requirements prescribed in §413.24(j) of this chapter. In reaching such specific factual findings and legal conclusions, the contractor hearing officer(s) must follow the procedures set forth in §413.24(j)(3) of this chapter for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The contractor hearing officer(s) must promptly give a copy of such written specific factual findings and legal conclusions to each party to the appeal, and such factual findings and legal conclusions must be included in the record

of administrative proceedings for the appeal (as prescribed in § 405.1827).

(2) *Limits on contractor hearing officer(s) actions.* The contractor hearing officer(s)'s specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section) must not be invoked or relied on by the contractor hearing officer(s) as a basis to deny, or decline to exercise, jurisdiction over a specific item or take any other of the actions specified in paragraph (c) of this section. Upon giving the parties to the appeal the contractor hearing officer(s)'s written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate cost report claim for the specific item under appeal, the contractor hearing officer(s) must proceed to issue one of the two types of overall decisions specified in paragraphs (d) and (e) of this section with respect to the specific item. If the contractor hearing officer(s) issues an overall contractor hearing decision (as specified in paragraph (d) of this section) regarding the specific item under appeal, the contractor hearing officer(s)'s written specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) must be included in such overall contractor hearing decision regarding the specific item, along with the other matters that are required by the regulations for an overall contractor hearing decision. However, if the contractor hearing officer(s) issues an overall jurisdictional dismissal decision (as specified in paragraph (e) of this section) regarding the specific item under appeal, the contractor hearing officer(s)'s written specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) must not be included in the overall jurisdictional dismissal decision regarding the specific item. The contractor hearing officer(s) may permit reimbursement for the specific item under appeal, as part of an overall contractor hearing decision, but such reimbursement may be permitted only to the extent authorized by paragraph (f) of this section.

(c) *Prohibition of certain types of decisions, orders, and other actions.* (1) If the contractor hearing officer(s) determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section);

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section); or

(iii) Impose any sanction or take any other action against the interests of any party to the appeal except as provided in paragraph (f) of this section, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section).

(2) Regardless of whether the contractor hearing officer(s) determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did or did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item. *Exception:* If the provider's appeal of the specific item is based on a reopening of such item (pursuant to § 405.1885) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor or Secretary determination, the contractor must deny jurisdiction over the specific item under appeal (as prescribed in §§ 405.1887(d) and 405.1889(b));

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item; or

(iii) Impose any sanction or take any other action against the interests of any party to the appeal except as provided in paragraph (f) of this section, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item.

(d) *Contractor hearing decision must include any factual findings and legal conclusions under paragraph (b)(1) of this section.* If the contractor hearing officer(s) issues a hearing decision regarding the specific item under appeal (pursuant to §405.1831), any specific findings of fact and conclusions of law by the contractor hearing officer(s) (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such hearing decision along with the other matters prescribed by §405.1831. The contractor hearing officer(s)'s factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) about whether there was an appropriate cost report claim for the specific item under appeal are subject to the provisions of §405.1833 just as those provisions apply to the other parts of the contractor hearing decision. If the contractor hearing officer(s) determines that the provider's cost report—

(1) Included an appropriate claim for the specific item under appeal (as prescribed in §413.24(j) of this chapter), the contractor hearing decision also must address whether the other substantive reimbursement requirements for the specific item are also satisfied; or

(2) Did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) has discretion whether or not to address in the contractor hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

(e) *Contractor jurisdictional dismissal decision must not include factual findings and legal conclusions under paragraph (b)(1) of this section.* If the contractor hearing officer(s) issues a jurisdictional dismissal decision regarding the specific item under appeal (in accordance with §405.1814(c)), the contractor hearing officer(s)'s specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate claim for the specific item must not be included in such jurisdictional dismissal decision.

(f) Effects of the contractor hearing officer(s)'s factual findings and legal conclusions under paragraph (b)(1) of this section when part of a final contractor hearing decision. If the contractor hearing officer(s) determines, as part of a final and binding contractor hearing decision (pursuant to §405.1833 and paragraphs (b)(1) and (d) of this section), that the provider's cost report—

(1) Included an appropriate claim for the specific item under appeal (as prescribed in §413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only if the contractor hearing officer(s) further determines in such final contractor hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied; or

(2) Did not include an appropriate cost report claim for the specific item under appeal, the specific item is not reimbursable, regardless of whether the contractor hearing officer(s) further determines in such final contractor hearing decision that the other substantive reimbursement requirements for the specific item are or are not satisfied.

[80 FR 70598, Nov. 13, 2015]

§ 405.1833 Effect of contractor hearing decision.

A contractor hearing decision issued in accordance with § 405.1831 of this subpart is final and binding on all parties to the contractor hearing and on the contractor, unless the hearing decision is reviewed by a CMS reviewing official in accordance with § 405.1834 of this subpart or reopened and revised by the contractor hearing officer(s) in accordance with § 405.1885 through § 405.1889 of this subpart. Final contractor hearing decisions are subject to the provisions of § 405.1803(d) of this subpart.

[73 FR 30248, May 23, 2008; 73 FR 49356, Aug. 21, 2008]

§ 405.1834 CMS reviewing official procedure.

(a) *Scope.* A provider that is a party to, and dissatisfied with, a final decision by the contractor hearing officer(s), upon submitting a request that meets the requirements of paragraph (c) of this section, is entitled to further administrative review of the decision, or the decision may be reviewed at the discretion of the Administrator. No other individual, entity, or party has the right to the review. The review is conducted on behalf of the Administrator by a designated CMS reviewing official who considers whether the decision of the contractor hearing officer(s) is consistent with the controlling legal authority (as described in § 405.1834(e)(1) of this subpart) and the evidence in the record. Based on the review, the CMS reviewing official issues a decision on behalf of the Administrator.

(b) *General rules.* (1) A CMS reviewing official may immediately review any final decision of the contractor hearing officer(s) as specified in paragraph (b)(2) of this section.

(i) Nonfinal decisions and other nonfinal actions by the contractor hearing officer(s) are not immediately reviewable, except as provided in paragraph (b)(3) of this section.

(ii) The CMS reviewing official exercises this review authority in response to a request from a provider party to the appeal that meets the requirements of paragraph (c) of this section or may exercise his or her discretion to take own motion review.

(2) A CMS reviewing official may immediately review the following:

(i) Any final jurisdictional dismissal decision by the contractor hearing officer(s), including any finding that the provider failed to demonstrate good cause for extending the time in which to request a hearing (as described in §§ 405.1813(e)(1) and 405.1814(c)(3) of this subpart).

(ii) Any final contractor hearing decision (as described in § 405.1831 of this subpart).

(iii) If the CMS reviewing official reviews a contractor hearing decision regarding a specific item, then the CMS reviewing official's review of such a contractor hearing decision will include, and any decision issued by the CMS reviewing official (under paragraph (e) of this section) will address, the contractor hearing officer(s)'s specific findings of fact and conclusions of law in such contractor hearing decision (as specified in § 405.1832(b)(1) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as specified in § 413.24(j) of this chapter).

(3) Nonfinal decisions and other nonfinal actions by the contractor hearing officer(s) are not subject to the CMS reviewing official procedure until the contractor hearing officer(s) issues a final decision as specified in paragraph (b)(2) of this section (as described in §§ 405.1813(e)(2), 405.1814(c) and (d), and 405.1821(d)(1) of this subpart), except that the CMS reviewing official may immediately review a ruling, authorizing discovery or disclosure of a matter, where there is a claim of privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden.

(4) In order to facilitate the Administrator's exercise of this review authority, the contractor hearing officer(s) must promptly send copies of any decision specified in paragraph (b)(2) of this section or in § 405.1821(d)(2) of this subpart to the appropriate component of CMS (currently the Center for Medicare Management).

(i) All requests for review by a CMS reviewing official and all written submissions to a CMS reviewing official under paragraphs (c) and (d) of this section also must be sent to the appropriate component of CMS.

(ii) The appropriate CMS component examines each contractor hearing officer decision that is reviewable under paragraph (b)(2) of this section or § 405.1821(d)(2) of this subpart, along with any review requests and any other submissions made by a party in accordance with the provisions of this section, in order to assist the Administrator's exercise of this review authority.

(c) *Request for review.* (1) A provider's request for review by a CMS reviewing official is granted if—

(i) The date of receipt by the appropriate CMS component of the review request is no later than 60 days after the date of receipt by the provider of the contractor hearing officer decision; or

(ii) The request seeks review of a decision listed in paragraph (b)(2) of this section, and the provider complies with the requirements of paragraph (c)(2) of this section.

(2) The provider must submit its request for review in writing, attach a copy of the contractor decision for which it seeks review and include a brief description of all of the following:

(i) Those aspects of the contractor hearing officer decision with which the provider is dissatisfied.

(ii) The reasons for the provider's dissatisfaction.

(iii) Any argument or record evidence the provider believes supports its position.

(iv) Any additional, extra-record evidence relied on by the provider, along with a demonstration that such evidence was improperly excluded from the contractor hearing (as described in § 405.1823 of this subpart).

(3) A provider request for immediate review of a contractor hearing officer ruling authorizing discovery or disclosure in accordance with paragraph (b)(3) of this section must—

(i) Be made as soon as practicable after the ruling is made, but in no event later than 5 business days after the date it received notice of the ruling; and

(ii) State the reason(s) why the ruling is in error and the potential harm that may be caused if immediate review is not granted.

(d) *Own motion review.* (1) The Administrator has discretion to take own motion review of a contractor hearing officer decision (regardless of whether the decision was favorable or unfavorable to the provider) or other reviewable action.

(2) In order to exercise this authority, the CMS reviewing official must, no later than 60 days after the date of the contractor hearing officer's decision, notify the parties and the contractor that he or she intends to review the contractor hearing officer decision or other reviewable action.

(3) In the notice, the CMS reviewing official identifies with particularity the issues that are to be reviewed, and gives each party (as described in § 405.1815 of this subpart) and affected nonparty a reasonable period to comment on the issues through a written submission complying with paragraph (c)(2) of this section.

(e) *Review procedure.* (1) In reviewing a contractor hearing officer decision specified in paragraph (b)(2) of this section, the CMS reviewing official must—

(i) Comply with all applicable law, regulations, and CMS Rulings (as described in § 401.108 of this chapter), and afford great weight to other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS;

(ii) Subject to paragraph (e)(1)(iii) of this section, limit the review to the record of the proceedings before the contractor hearing officer(s) (as described in § 405.1827 of this subpart) and any written submissions by the parties under paragraphs (c)(2) or (d) of this section; and

(iii) Consider additional, extra-record evidence only if he or she determines that the evidence was improperly excluded from the contractor hearing (as described in § 405.1823 of this subpart).

(2) Review of a contractor decision specified in paragraph (b)(2) of this section is limited to a hearing on the written record in accordance with paragraph (e)(1)(ii) of this section, unless

the CMS reviewing official determines that—

(i) Additional, extra-record evidence may be considered in accordance with paragraph (e)(1)(iii) of this section;

(ii) An oral hearing is necessary for consideration of the extra-record evidence; and

(iii) It is not necessary or appropriate to remand the matter to the contractor hearing officer(s).

(3) Upon completion of the review of a contractor hearing decision specified in paragraph (b)(2) of this section, the CMS reviewing official issues a written decision that affirms, reverses, modifies, or remands the contractor hearing decision. A copy of the decision must be sent promptly to each party, to the contractor, and to the appropriate component of CMS (currently the Center for Medicare Management).

(f) *Effect of a decision: Remand.* (1) A decision of affirmation, reversal, or modification by the CMS reviewing official is final and binding on each party and the contractor. No further review or appeal of a decision is available, but the decision may be reopened and revised by a CMS reviewing official in accordance with §405.1885 through §405.1889 of this subpart. Decisions of a CMS reviewing official are subject to the provisions of §405.1803(d) of this subpart. A decision by a CMS reviewing official remanding an appeal to the contractor hearing officer(s) for further proceedings under paragraph (f)(2) of this section is not a final decision.

(2) A remand to the contractor hearing officer(s) by the CMS reviewing official must—

(i) Vacate the contractor hearing officer decision;

(ii) Be governed by the same criteria that apply to remands by the Administrator to the Board under §405.1875(f)(2) of this subpart, and require the contractor hearing officer(s) to take specific actions on remand; and

(iii) Result in the contractor hearing officer(s) taking the actions required on remand and issuing a new contractor hearing decision in accordance with §§405.1831 and 405.1833 of this subpart.

[73 FR 30248, May 23, 2008; 73 FR 49356 Aug. 21, 2008, as amended at 80 FR 70599, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§405.1835 Right to Board hearing; contents of, and adding issues to, hearing request.

(a) Right to hearing on final contractor determination. A provider (but no other individual, entity, or party) has a right to a Board hearing, as a single provider appeal, with respect to a final contractor or Secretary determination for the provider's cost reporting period, if—

(1) The provider is dissatisfied with the contractor's final determination of the total amount of reimbursement due the provider, as set forth in the contractor's written notice specified under §405.1803. *Exception:* If a final contractor determination is reopened under §405.1885, any review by the Board must be limited solely to those matters that are specifically revised in the contractor's revised final determination (§§405.1887(d), 405.1889(b), and the ''Exception'' in §405.1873(c)(2)(i)).

(2) The amount in controversy (as determined in accordance with §405.1839) must be $10,000 or more.

(3) Unless the provider qualifies for a good cause extension under §405.1836, the date of receipt by the Board of the provider's hearing request must be no later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination.

(b) *Contents of request for a Board hearing on final contractor determination.* The provider's request for a Board hearing under paragraph (a) of this section must be submitted in writing in the manner prescribed by the Board, and the request must include the elements described in paragraphs (b)(1) through (4) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (b)(1), (2), or (3) of this section, the Board may dismiss with prejudice the appeal or take any other remedial action it considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a Board hearing as specified in paragraph (a) of this section, including a specific identification of the final contractor or Secretary determination under appeal.

(2) For each specific item under appeal, a separate explanation of why, and a description of how, the provider is dissatisfied with the specific aspects

of the final contractor or Secretary determination under appeal, including an account of all of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it does not have access to underlying information concerning the calculation of its payment).

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of the final contractor or Secretary determination under appeal and any other documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (b)(1) and (b)(2) of this section.

(4) With respect to a provider under common ownership or control, the name and address of its parent corporation, and a statement that—

(i) To the best of the provider's knowledge, no other provider to which it is related by common ownership or control, has pending a request for a Board hearing pursuant to this section or pursuant to § 405.1837(b)(1) on any of the same issues contained in the provider's hearing request for a cost reporting period that ends within the same calendar year as the calendar year covered by the provider's hearing request; or

(ii) Such a pending appeal(s) exist(s), and the provider name(s), provider number(s), and the case number(s) (if assigned), for such appeal(s).

(c) *Right to hearing based on untimely contractor determination.* Notwithstanding the provisions of paragraph (a) of this section, a provider (but no other individual, entity, or party) has a right to a Board hearing, as a single provider appeal, for specific items for a cost reporting period if—

(1) A final contractor determination for the provider's cost reporting period is not issued (through no fault of the provider) within 12 months after the date of receipt by the contractor of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of this chapter). The date of receipt by the contractor of the provider's perfected cost report or amended cost report is presumed to be the date the contractor stamped ''Received'' on such cost report unless it is shown by a preponderance of the evidence that the contractor received the cost report on an earlier date.

(2) Unless the provider qualifies for a good cause extension under § 405.1836, the date of receipt by the Board of the provider's hearing request is no later than 180 days after the expiration of the 12 month period for issuance of the final contractor determination (as determined in accordance with paragraph (c)(1) of this section); and

(3) The amount in controversy (as determined in accordance with § 405.1839) is $10,000 or more.

(d) *Contents of request for a Board hearing based on untimely contractor determination.* The provider's request for a Board hearing under paragraph (c) of this section must be submitted in writing in the manner prescribed by the Board, and the request must include the elements described in paragraphs (d)(1) through (4) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (d)(1), (2), or (3) of this section, the Board may dismiss with prejudice the appeal or take any other remedial action it considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a Board hearing as specified in paragraph (c) of this section.

(2) An explanation (for each specific item at issue) of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it does not have access to underlying information concerning the calculation of Medicare payment).

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item, a description of the nature and amount of each self-disallowed item and the reimbursement or payment sought for the item.

(3) A copy of any documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (d)(1) and (d)(2) of this section.

(4) With respect to a provider under common ownership or control, the name and address of its parent corporation, and a statement that meets all of the requirements of paragraphs (b)(4)(i) and (b)(4)(ii) of this section.

(e) *Adding issues to the hearing request.* After filing a hearing request in accordance with paragraphs (a) and (b), or paragraphs (c) and (d), of this section, a provider may add specific Medicare payment issues to the original hearing request by submitting a written request to the Board only if—

(1) The request to add issues complies with the requirements of paragraphs (a) and (b), or paragraphs (c) and (d), of this section as to each new specific item at issue.

(2) The specific items raised in the initial hearing request and the specific items identified in subsequent requests to add issues, when combined, satisfy the amount in controversy requirements of paragraph (a)(2) or paragraph (c)(3) of this section.

(3) The Board receives the provider's request to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(3) or paragraph (c)(2), of this section.

[73 FR 30249, May 23, 2008; 73 FR 49356, Aug. 21, 2008, as amended at 79 FR 50350, Aug. 22, 2014; 79 FR 59680, Oct. 3, 2014; 80 FR 70599, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1836 Good cause extension of time limit for requesting a Board hearing.

(a) A request for a Board hearing that the Board receives after the applicable 180-day time limit prescribed in § 405.1835(a)(3) or § 405.1835(c)(2) must be dismissed by the Board, except that the Board may extend the time limit upon a good cause showing by the provider.

(b) The Board may find good cause to extend the time limit only if the provider demonstrates in writing it could not reasonably be expected to file timely due to extraordinary circumstances beyond its control (such as a natural or other catastrophe, fire, or strike), and the provider's written request for an extension is received by the Board within a reasonable time (as determined by the Board under the circumstances) after the expiration of the applicable 180-day limit specified in § 405.1835(a)(3) or § 405.1835(c)(2).

(c) The Board may not grant a request for an extension under this section if—

(1) The provider relies on a change in the law, regulations, CMS Rulings, or general CMS instructions (whether based on a court decision or otherwise) or a CMS administrative ruling or policy as the basis for the extension request; or

(2) The date of receipt by the Board of the provider's extension request is later than 3 years after the date of the contractor or other determination that the provider seeks to appeal.

(d) If an extension request is granted or denied under this section, the Board must give prompt written notice to the provider, and send a copy of the notice to each party to the appeal. The notice must include a detailed explanation of the reasons for the decision by the Board and the facts underlying the decision.

(e)(1) If the Board denies an extension request and determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a Board dismissal decision dismissing the appeal for lack of Board jurisdiction. This decision by the Board must be in writing and include the explanation of the extension request denial required under paragraph (d) of this section, in addition to specific findings of fact and conclusions of law explaining the Board's determination that it lacks jurisdiction to grant a hearing on each matter at issue in the appeal (as described in § 405.1840(c)). A copy of the Board's dismissal decision must be sent promptly to each party to the appeal (as described in § 405.1843).

(2) A Board dismissal decision under paragraph (e)(1) of this section is final and binding on the parties, unless the decision is reversed, affirmed, modified, or remanded by the Administrator under §§ 405.1875(a)(2)(ii) and 405.1875(e) or § 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision.

(i) This Board decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision, within the period.

(ii) A Board decision under paragraph (e)(1) of this section that is otherwise final and binding may be reopened and revised by the Board in accordance with §§ 405.1885 through 405.1889 of this subpart.

(3) The Administrator may review a Board decision granting an extension request solely during the course of an Administrator review of one of the Board decisions specified as final, or deemed final by the Administrator, under § 405.1875(a)(2) of this subpart.

(4) A finding by the Board or the Administrator that the provider did or did not demonstrate good cause for extending the time for requesting a Board hearing is not subject to judicial review.

[73 FR 30250, May 23, 2008; 73 FR 49356, Aug. 21, 2008, as amended at 80 FR 70600, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1837 Group appeals.

(a) *Right to Board hearing as part of a group appeal: Criteria.* A provider (but no other individual, entity, or party) has a right to a Board hearing, as part of a group appeal with other providers, with respect to a final contractor or Secretary determination for the provider's cost reporting period, only if—

(1) The provider satisfies individually the requirements for a Board hearing under § 405.1835(a) or § 405.1835(c), except for the $10,000 amount in controversy requirement in § 405.1835(a)(2) or § 405.1835(c)(3).

(2) The matter at issue in the group appeal involves a single question of fact or interpretation of law, regulations, or CMS Rulings that is common to each provider in the group; and

(3) The amount in controversy is, in the aggregate, $50,000 or more, as determined in accordance with § 405.1839 of this subpart.

(b) *Usage and filing of group appeals—* (1) *Mandatory use of group appeals.* (i) Two or more providers under common ownership or control that wish to appeal to the Board a specific matter at issue that involves a question of fact or interpretation of law, regulations, or CMS Rulings that is common to the providers, and that arises in cost reporting periods that end in the same calendar year, and for which the amount in controversy is $50,000 or more in the aggregate, must bring the appeal as a group appeal.

(ii) One or more of the providers under common ownership or control may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for purposes of meeting the $50,000 amount in controversy requirement, and, subject to the Board's discretion, may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for other purposes, such as convenience.

(iii) A group appeal involving two or more providers under common ownership or control must consist entirely of providers under common (to all) ownership or control.

(iv)(A) Example 1: A, B, C and D are commonly owned providers that wish to appeal issue X. This issue was adjusted on A, B and C's CY 2004 cost reports, and on D's CY 2005 cost report. The amount in controversy is more than $50,000 in the aggregate for providers A, B and C, and more than $10,000 for provider D. Providers A, B and C must appeal issue X as a group appeal. Provider D may pursue an individual appeal to the Board under the procedures set forth in § 405.1835 of this subpart, or if the Board agrees, Provider D may join the group appeal. (If Provider D joins the group appeal, the calendar years in the group appeal would then be 2004 and 2005, and any provider related to Providers A through D by common ownership or control would be required to appeal issue X for its cost reporting period

ending in 2004 or 2005 through the group appeal.)

(B) Example 2: A, B and C are commonly owned providers that wish to appeal issue X. This issue was adjusted on A, B and C's CY 2004 cost reports. The amount in controversy is less than $50,000 in the aggregate for providers A, B and C ($10,000 for A, $10,000 for B and $7,000 for C). Providers A, B and C cannot appeal issue X as a group appeal. Provider A, if it wishes, and provider B, if it wishes, may pursue an individual appeal to the Board under the procedures set forth in § 405.1835 of this subpart. Provider C may not pursue an individual appeal to the Board, because the amount in controversy is less than $10,000; however, it may pursue an appeal to the contractor under the procedures set forth in § 405.1811 of this subpart.

(2) *Optional group appeals.* (i) Two or more providers not under common ownership or control may bring a group appeal before the Board under this section, if the providers wish to appeal to the Board a specific matter at issue that involves a question of fact or interpretation of law, regulations, or CMS Rulings that is common to the providers. Alternatively, any provider may appeal to the Board any issues in a single provider appeal brought under § 405.1835 of this subpart.

(ii) One or more of the providers bringing a group appeal under this paragraph may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for purposes of meeting the $50,000 amount in controversy requirement, and, subject to the Board's discretion, may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for other purposes, such as convenience.

(3) *Initiating a group appeal.* With respect to group appeals brought under paragraph (b)(1) of this section, one or more commonly owned or operated providers must make a written request for a Board hearing as a group appeal in accordance with paragraph (c) of this section. Any group appeal filed by a single provider must be joined by related providers on common issues in accordance with paragraphs (b)(1) and (e) of this section. With respect to group appeals brought under paragraph (b)(2) of this section, two or more providers may submit—

(i) A written request for a Board hearing as a group appeal in accordance with paragraph (c) of this section; or

(ii) A request to the Board in accordance with paragraph (e)(4) of this section that a specific matter at issue in a single provider appeal, filed previously under § 405.1835 of this subpart, be transferred from the single appeal to a group appeal.

(c) *Contents of request for a group appeal.* The request for a Board hearing as a group appeal must be submitted in writing to the Board, and the request must include all of the following:

(1) A demonstration that the request satisfies the requirements for a Board hearing as a group appeal, as specified in paragraph (a) of this section.

(2) An explanation (for each specific item at issue) of each provider's dissatisfaction with the final contractor or Secretary determination under appeal, including an account of—

(i) Why the provider believes Medicare payment is incorrect for each disputed item;

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item; and

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of each final contractor or Secretary determination under appeal, and any other documentary evidence the providers consider to satisfy the hearing request requirements of paragraphs (c)(1) and (c)(2) of this section, and a precise description of the one question of fact or interpretation of law, regulations, or CMS Rulings that is common to the particular matter at issue in the group appeal.

(4) A statement that—

(i) The providers believe they have satisfied all of the requirements for a

group appeal hearing request under paragraph (a) of this section and requesting the Board to proceed to make jurisdictional findings in accordance with §405.1840; or

(ii) The Board is requested to defer making jurisdictional findings until the providers request the findings in accordance with paragraph (e)(2) of this section.

(d) *Board's preliminary response to group appeal hearing requests.* (1) Upon receipt of a group appeal hearing request, the Board must take any necessary ministerial steps.

(2) The steps, include, for example—

(i) Acknowledging the request;

(ii) Assigning a case number to the appeal; or

(iii) If applicable, transferring a specific matter at issue from a single provider appeal filed under §405.1835 of this subpart to a group appeal filed under this section.

(e) *Group appeal procedures pending full formation of the group and issuance of a Board decision.* (1) A provider (or providers) may file a group appeal hearing request with the Board under this section before each provider member of the group identifies or complies with paragraphs (a)(1) and (a)(2) of this section, or before the group satisfies the $50,000 amount in controversy requirement under paragraph (a)(3) of this section. Proceedings before the Board in any partially formed group appeal are subject to the provisions of paragraphs (e)(2), (e)(3), and (e)(4) of this section. The Board will determine that a group appeal brought under paragraph (b)(1) of this section is fully formed upon a notice in writing from the group that it is fully formed. Absent such a notice from the group, the Board may issue an order, requiring the group to demonstrate (within a period of not less than 15 days) that at least one commonly owned or controlled provider has preserved the issue for appeal by claiming the relevant item on its cost report or by self-disallowing the item, but has not yet received its final determination with respect to the item for a cost year that is within the same calendar year as that covered by the group appeal (or that it has received its final determination with respect to the item for that period, and is still within the time to request a hearing on the issue). The Board determines that a group appeal brought under paragraph (b)(2) of this section is fully formed upon a notice in writing from the group that it is fully formed, or following an order from the Board that in its judgment, that the group is fully formed, or through general instructions that set forth a schedule for the closing of group appeals brought under paragraph (b)(2) of this section. When the Board has determined that a group appeal brought under paragraph (b)(1) of this section is fully formed, absent an order from the Board modifying its determination, no other provider under common ownership or control may appeal to the Board the issue that is the subject of the group appeal with respect to a cost reporting period that falls within the calendar year(s) covered by the group appeal.

(2) The Board may make jurisdictional findings under §405.1840 at any time, including, but not limited to, following a request by the providers for the jurisdictional findings. The providers may request jurisdictional findings by notifying the Board in writing that the group appeal is fully formed, or that the providers believe they have satisfied all of the requirements for a group appeal hearing request, and the Board may proceed to make jurisdictional findings. The providers must include with the notice any additional information or documentary evidence that is required for group appeal hearing requests. The Board does not dismiss a group appeal hearing request for failure to meet the $50,000 amount in controversy requirement until the Board has determined, in accordance with paragraph (e)(1) of this section, that the group is fully formed.

(3) If the Board makes a preliminary determination of jurisdiction to conduct a hearing as a group appeal under this section, the Board then takes any further actions in the appeal it finds to be appropriate under this subpart (as described in §405.1840(a) of this subpart). The Board may take further actions, even though the providers in the appeal may wish to add other providers to the group in accordance with paragraph (e)(4) of this section. The Board

must make separate jurisdictional findings for each cost reporting period added subsequently to the group appeal (as described in §§ 405.1837(a) and 405.1839(b) of this subpart).

(4) A provider may submit a request to the Board to join a group appeal any time before the Board issues one of the decisions specified in § 405.1875(a)(2). By submitting a request, the provider agrees that, if the request is granted, the provider is bound by the Board's actions and decision in the appeal. If the Board denies a request, the Board's action is without prejudice to any separate appeal the provider may bring in accordance with § 405.1811, § 405.1835, or this section. For purposes of determining timeliness for the filing of any separate appeal and for the adding of issues to such appeal, the date of receipt of the provider's request to form or join the group appeal is considered the date of receipt for purposes of meeting the applicable 180-day period prescribed in § 405.1835(a)(3) or § 405.1835(c)(2).

(5)(i) Except as specified in paragraph (ii) of this paragraph, when a provider has appealed an issue through electing to form, or joining, a group appeal under the procedures set forth in this section, it may not subsequently request that the Board transfer that issue to a single provider appeal brought in accordance with § 405.1811 or § 405.1835 of this subpart.

(ii) *Exception.* When the Board determines that the requirements for a group appeal are not met (that is, when there has been a failure to meet the amount in controversy or the common issue requirement), it transfers the issue that was the subject of the group appeal to a single provider appeal (or appeals) for the provider (or providers) that meets (or meet) the requirements for a single provider appeal.

(f) *Limitations on group appeals.* (1) After the date of receipt by the Board of a group appeal hearing request under paragraph (c) of this section, a provider may not add other questions of fact or law to the appeal, regardless of whether the question is common to other members of the appeal (as described in § 405.1837(a)(2) and (g) of this subpart).

(2) The Board may not consider, in one group appeal, more than one question of fact, interpretation of law, regulations, or CMS Rulings that is common to each provider in the appeal. If the Board finds jurisdiction over a group appeal hearing request under § 405.1840 of this subpart—

(i) The Board must determine whether the appeal involves specific matters at issue that raise more than one factual or legal question common to each provider; and

(ii) When the appeal is found to involve more than one factual or legal question common to each provider, the Board must assign a separate case number to the appeal of each common factual or legal question and conduct further proceedings in the various appeals separately for each case.

(g) *Issues not common to the group appeal.* A provider involved in a group appeal that also wishes to appeal a specific matter that does not raise a factual or legal question common to each of the other providers in the group must file a separate request for a single provider hearing in accordance with § 405.1811 or § 405.1835 of this subpart, or file a separate request for a hearing as part of a different group appeal under this section, as applicable.

[73 FR 30250, May 23, 2008, as amended at 80 FR 70600, Nov. 13, 2015]

§ 405.1839 Amount in controversy.

(a) *Single provider appeals.* (1) In order to satisfy the amount in controversy requirement under § 405.1811(a)(2) or § 405.1811(c)(3) for a contractor hearing or the amount in controversy requirement under § 405.1835(a)(2) or § 405.1835(c)(3) for a Board hearing for a single provider, the provider must demonstrate that if its appeal were successful, the provider's total program reimbursement for each cost reporting period under appeal would increase by at least $1,000 but by less than $10,000 for a contractor hearing, or by at least $10,000 for a Board hearing, as applicable.

(2) *Aggregation of claims.* For purposes of satisfying the applicable amount in controversy requirement for a single provider appeal to the contractor or the Board, the provider may aggregate claims for additional program payment for more than one specific matter at issue, provided each specific claim and

issue is for the same cost reporting period. Aggregation of claims from more than one cost reporting period to meet the applicable amount in controversy requirement is prohibited, even if a specific claim or issue in the appeal recurs for multiple cost years.

(b) *Group appeals.* (1) In order to satisfy the amount in controversy requirement under § 405.1837(a)(3) of this subpart for a Board hearing as a group appeal, the group must demonstrate that if its appeal were successful, the total program reimbursement for the cost reporting periods under appeal would increase, in the aggregate, by at least $50,000.

(2) *Aggregation of claims.* (i) For purposes of satisfying the amount in controversy requirement, group members are not allowed to aggregate claims involving different issues.

(A) A group appeal must involve a single question of fact or interpretation of law, regulations, or CMS Ruling that is common to each provider (as described in § 405.1837(a)(2) of this subpart).

(B) The single issue that is common to each provider may exist over different cost reporting periods.

(ii) For purposes of satisfying the amount in controversy requirement, a provider may appeal multiple cost reporting periods and different providers in the group may appeal different cost reporting periods.

(c) *Limitations on change in Medicare reimbursement.* (1) In order to satisfy the applicable amount in controversy requirement for a single provider appeal or a group appeal, an appeal favorable to the provider(s) on all specific matters at issue in the appeal increases program reimbursement for the provider(s) in the cost reporting period(s) at issue by an amount that equals or exceeds the applicable amount in controversy threshold.

(2) The applicable amount in controversy requirement is not satisfied if the result of a favorable appeal decreases program reimbursement for the provider(s) in the cost reporting year(s) at issue in the appeal.

(3) Any effects that a favorable appeal might have on program reimbursement for the provider(s) in cost reporting period(s) not at issue in the appeal have no bearing on whether the amount in controversy requirement is satisfied for the cost year(s) at issue in the appeal.

(4) When a provider (or group of providers) has requested a hearing before a contractor under § 405.1811 of this subpart, and the amount in controversy is subsequently determined to be at least $10,000 (for example, due to a reassessment of the amount in controversy by the contractor hearing office or due to adding an issue), the appeal is transferred to the Board. The Board is not bound by any jurisdictional finding of the contractor hearing officer(s).

(5) When a provider or group of providers has requested a hearing before the Board under § 405.1835 or § 405.1837 of this subpart, and the amount in controversy changes to an amount less than the minimum for a Board appeal due to—

(A) The settlement or partial settlement of an issue, transfer of an issue to a group appeal, or the abandonment of an issue in an individual appeal, the change in the amount in controversy does not deprive the Board of jurisdiction.

(B) A more accurate assessment of the amount in controversy, the Board does not retain jurisdiction.

[73 FR 30252, May 23, 2008; 73 FR 49356, Aug. 21, 2008, as amended at 80 FR 70600, Nov. 13, 2015]

§ 405.1840 Board jurisdiction.

(a) *General rules.* (1) After a request for a Board hearing is filed under § 405.1835 or § 405.1837 of this part, the Board must determine in accordance with paragraph (b) of this section, whether or not it has jurisdiction to grant a hearing on each of the specific matters at issue in the hearing request.

(2) The Board must make a preliminary determination of the scope of its jurisdiction (that is, whether the request for hearing was timely, and whether the amount in controversy requirement has been met), if any, over the matters at issue in the appeal before conducting any of the following proceedings:

(i) Determining its authority to decide a legal question relevant to a matter at issue (as described in § 405.1842 of this subpart).

(ii) Permitting discovery (as described in § 405.1853 of this subpart).

(iii) Issuing a subpoena (as described in § 405.1857 of this subpart).

(iv) Conducting a hearing (as described in § 405.1845 of this subpart).

(3) The Board may revise a preliminary determination of jurisdiction at any subsequent stage of the proceedings in a Board appeal, and must promptly notify the parties of any revised determination. Under paragraph (c)(1) of this section, each expedited judicial review (EJR) decision (as described in § 405.1842 of this subpart) and hearing decision (as described in § 405.1871 of this subpart) by the Board must include a jurisdictional finding for each specific matter at issue in the appeal.

(4) If the Board finally determines it lacks jurisdiction over every specific matter at issue in the appeal, the Board must issue a dismissal decision under paragraph (c)(2) of this section.

(5) Final jurisdictional findings and dismissal decisions by the Board under paragraphs (c)(1) and (c)(2) of this section are subject to Administrator and judicial review in accordance with paragraph (d) of this section.

(b) *Criteria.* Except with respect to the amount in controversy requirement, the jurisdiction of the Board to grant a hearing must be determined separately for each specific matter at issue in each contractor or Secretary determination for each cost reporting period under appeal. The Board has jurisdiction to grant a hearing over a specific matter at issue in an appeal only if the provider has a right to a Board hearing as a single provider appeal under § 405.1835 of this subpart or as part of a group appeal under § 405.1837 of this subpart, as applicable. Certain matters at issue are removed from jurisdiction of the Board. These matters include, but are not necessarily limited to, the following:

(1) A finding in a contractor determination that expenses incurred for certain items or services furnished by a provider to an individual are not payable under title XVIII of the Act because those items or services are excluded from coverage under section 1862 of the Act and part 411 of the regulations. Review of these findings is limited to the applicable provisions of sections 1155, 1869, and 1879(d) of the Act and of subpart I of part 405 and subpart B of part 478 of the regulations, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system, as provided in section 1886(d)(7) of the Act and § 405.1804 of this subpart.

(c) *Board's jurisdictional findings and jurisdictional dismissal decisions.* (1) In issuing an EJR decision under § 405.1842 of this subpart or a hearing decision under § 405.1871 of this subpart, as applicable, the Board must make a separate determination of whether it has jurisdiction for each specific matter at issue in each contractor or Secretary determination under appeal. A decision by the Board must include specific findings of fact and conclusions of law as to whether the Board has jurisdiction to grant a hearing on each matter at issue in the appeal.

(2) Except as provided in §§ 405.1836(e)(1) and 405.1842(f)(2)(i), where the Board determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a dismissal decision dismissing the appeal for lack of Board jurisdiction. The decision by the Board must include specific findings of fact and conclusions of law explaining the Board's determination that it lacks jurisdiction to grant a hearing on each matter at issue in the appeal. A copy of the Board's decision must be sent promptly to each party to the appeal (as described in § 405.1843).

(3) A dismissal decision by the Board under paragraph (c)(2) of this section is final and binding on the parties unless the decision is reversed, affirmed, modified or remanded by the Administrator under § 405.1875(a)(2)(ii) and § 405.1875(e) or § 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision. The Board decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies or remands that decision within that period. A final Board decision under paragraphs (c)(2) and (c)(3) of this section may be reopened and revised by the

Board in accordance with §§ 405.1885 through 405.1889 of this subpart.

(d) *Administrator and judicial review.* Any finding by the Board as to whether it has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative and judicial review, except as provided in this paragraph. The Board's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final, or deemed to be final by the Administrator, under § 405.1875(a)(2) of this subpart, or during the course of judicial review of a final agency decision as described in § 405.1877(a) of this subpart, as applicable.

[73 FR 30253, May 23, 2008, as amended at 80 FR 70600, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1842 Expedited judicial review.

(a) *Basis and scope.* (1) This section implements provisions in section 1878(f)(1) of the Act that give a provider the right to seek EJR of a legal question relevant to a specific matter at issue in a Board appeal if there is Board jurisdiction to conduct a hearing on the matter (as described in § 405.1840 of this subpart), and the Board determines it lacks the authority to decide the legal question (as described in § 405.1867 of this subpart, which explains the scope of the Board's legal authority).

(2) A provider may request a Board decision that the provider is entitled to seek EJR or the Board may consider issuing a decision on its own motion. Each EJR decision by the Board must include a specific jurisdictional finding on the matter(s) at issue, and, where the Board determines that it does have jurisdiction on the matter(s) at issue, a separate determination of the Board's authority to decide the legal question(s).

(3) The Administrator may review the Board's jurisdictional finding, but not the Board's authority determination.

(4) The provider has a right to seek EJR of the legal question under section 1878(f)(1) of the Act only if—

(i) The final EJR decision of the Board or the Administrator, as applicable, includes a finding of Board jurisdiction over the specific matter at issue and a determination by the Board that it has no authority to decide the relevant legal question; or

(ii) The Board fails to make a determination of its authority to decide the legal question no later than 30 days after finding jurisdiction over the matter at issue and notifying the provider that the provider's EJR request is complete.

(b) *General*—(1) *Prerequisite of Board jurisdiction.* The Board (or the Administrator) must find that the Board has jurisdiction over the specific matter at issue before the Board may determine its authority to decide the legal question.

(2) *Initiating EJR procedures.* A provider or group of providers may request the Board to grant EJR of a specific matter or matters under appeal, or the Board on its own motion may consider whether to grant EJR of a specific matter or matters under appeal. Under paragraph (c) of this section, the Board may initiate own motion consideration of its authority to decide a legal question only if the Board makes a preliminary finding that it has jurisdiction over the specific matter at issue to which the legal question is relevant. Under paragraphs (d) and (e) of this section, a provider may request a determination of the Board's authority to decide a legal question, but the 30-day period for the Board to make a determination under section 1878(f)(1) of the Act does not begin to run until the Board finds jurisdiction to conduct a hearing on the specific matter at issue in the EJR request and notifies the provider that the provider's request is complete.

(c) *Board's own motion consideration.* (1) If the Board makes a finding that it has jurisdiction to conduct a hearing on a specific matter at issue in accordance with § 405.1840(a) of this part, it may then consider on its own motion whether it lacks the authority to decide a legal question relevant to the matter at issue.

(2) The Board must initiate its own motion consideration by issuing a written notice to each of the parties to the

appeal (as described in § 405.1843 of this subpart). The notice must—

(i) Identify each specific matter at issue for which the Board has made a finding that it has jurisdiction under § 405.1840(a) of this part, and for each specific matter, identify each relevant statutory provision, regulation, or CMS Ruling; and

(ii) Specify a reasonable period of time for the parties to respond in writing.

(3) After considering any written responses made by the parties to its notice of own motion consideration, the Board must determine whether it has sufficient information to issue an EJR decision for each specific matter and legal question included in the notice. If necessary, the Board may request additional information regarding its jurisdiction or authority from a party (or parties), and the Board must give any other party a reasonable opportunity to comment on any additional submission. Once the Board determines it needs no further information from the parties (or that any information has not been rendered timely), it must issue an EJR decision in accordance with paragraph (f) of this section.

(d) *Provider requests.* A provider (or, in the case of a group appeal, a group of providers) may request a determination by the Board that it lacks the authority to decide a legal question relevant to a specific matter at issue in an appeal. A provider must submit a request in writing to the Board and to each party to the appeal (as described in § 405.1843 of this subpart), and the request must include—

(1) For each specific matter and question included in the request, an explanation of why the provider believes the Board has jurisdiction under § 405.1840 of this subpart over each matter at issue and no authority to decide each relevant legal question; and

(2) Any documentary evidence the provider believes supports the request.

(e) *Board action on provider requests.* (1) If the Board makes a finding that it has jurisdiction to conduct a hearing on a specific matter at issue in accordance with § 405.1840(a) of this part, then (and only then) it must consider whether it lacks the authority to decide a legal question relevant to the matter at issue. The Board is required to make a determination of its authority to decide the legal question raised in a review request under paragraph (d)(1) of this section by issuing an EJR decision no later than 30 days after receiving a complete provider request as defined in paragraph (e)(2) of this section.

(2) *Requirements of a complete provider request.* A complete provider request for EJR consists of the following:

(i) A request for an EJR decision by the provider(s).

(ii) All of the information and documents found necessary by the Board for issuing a decision in accordance with paragraph (f) of this section.

(3) *Board's response to provider requests.* After receiving a provider request for an EJR decision, the Board must review the request, along with any responses to the request submitted by other parties to the appeal (as described in § 405.1843 of this subpart). The Board must respond to the provider(s) as follows:

(i) Upon receiving a complete provider request, issue an EJR decision in accordance with paragraph (f) of this section no later than 30 days after receipt of the complete provider request. If the Board does not issue a decision within that 30-day period, the provider has a right to file a complaint in Federal district court in order to obtain EJR over the specific matter(s) at issue.

(ii) If the provider has not submitted a complete request, issue no later than 30 days after receipt of the incomplete request a written notice to the provider describing in detail the further information that the provider must submit in order to complete the request.

(f) *Board's decision on EJR: Criteria for granting EJR.* Subject to paragraph (h)(3) of this section, the Board is required to issue an EJR decision following either the completion of the Board's own motion consideration under paragraph (c) of this section, or a notice issued by the Board in accordance with paragraph (e)(3)(i) of this section.

(1) The Board's decision must grant EJR for a legal question relevant to a

specific matter at issue in a Board appeal if the Board determines the following conditions are satisfied:

(i) The Board has jurisdiction to conduct a hearing on the specific matter at issue in accordance with §405.1840 of this subpart.

(ii) The Board lacks the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is a challenge either to the constitutionality of a provision of a statute, or to the substantive or procedural validity of a regulation or CMS Ruling.

(2) The Board's decision must deny EJR for a legal question relevant to a specific matter at issue in a Board appeal if any of the following conditions are satisfied:

(i) The Board determines that it does not have jurisdiction to conduct a hearing on the specific matter at issue in accordance with §405.1840 of this subpart.

(ii) The Board determines it has the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is neither a challenge to the constitutionality of a provision of a statute, nor a challenge to the substantive or procedural validity of a regulation or CMS Ruling.

(iii) The Board does not have sufficient information to determine whether the criteria specified in paragraph (f)(1)(i) or (f)(1)(ii) of this section are met.

(3) A copy of the Board's decision must be sent promptly to—

(i) Each party to the Board appeal (as described in §405.1843 of this subpart) and

(ii) The Office of the Attorney Advisor.

(g) *Further review after the Board issues an EJR decision*—(1) *General rules.* (i) Under §405.1875(a)(2)(iii) of this subpart, the Administrator may review, on his or her own motion, or at the request of a party, the jurisdictional component only of the Board's EJR decision.

(ii) Any review by the Administrator is limited to the question of whether there is Board jurisdiction over the specific matter at issue; the Administrator may not review the Board's determination of its authority to decide the legal question.

(iii) An EJR decision by the Board becomes final and binding on the parties unless the decision is reversed, affirmed, modified, or remanded by the Administrator under §§405.1875(a)(2)(iii), 405.1875(e), and 405.1875(f) of this subpart no later than 60 days after the date of receipt by the provider of the Board's decision.

(iv) A Board decision is inoperative during the 60-day period for review by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision within that period.

(v) Any right of the provider to obtain EJR from a Federal district court is specified at paragraphs (g)(2) and (g)(3) of this section (when the Board issues a timely EJR decision) and paragraph (g)(4) of this section (in the absence of a timely Board decision).

(vi) A final Board decision under paragraph (f) of this section, and a final Administrator decision made upon review of a final Board decision (as described in §405.1875(a)(2) and (e) of this subpart) may be reopened and revised in accordance with §§405.1885 through 405.1889 of this subpart.

(2) *Board grants EJR.* If the Board grants EJR, the provider may file a complaint in a Federal district court in order to obtain EJR of the legal question. If the Administrator renders, no later than 60 days after the date of receipt by the provider of the Board's decision granting EJR, a decision finding that the Board has no jurisdiction over the matter at issue, the Board's decision is nonfinal and the provider has no right to obtain judicial review based on the Board's decision (as described in §405.1877(a)(3) and (b)(3) of this subpart).

(3) *Board denies EJR.* If the Board's decision denies EJR because the Board finds that it has the authority to decide the legal question relevant to the matter at issue, the Administrator may not review the Board's authority determination, and the provider has no right to obtain EJR. If the Board denies EJR based on a finding that it lacks jurisdiction over the specific matter, the provider has no right to obtain EJR unless—

(i) The Administrator renders timely a final decision reversing the Board, finding the Board has jurisdiction over the matter at issue, and remanding to the Board; or

(ii) A court reverses the Board's or Administrator's decision as to jurisdiction, the Administrator remands to the Board, and the Board subsequently issues on remand from the Administrator an EJR decision granting EJR on the basis that it lacks the authority to decide the legal question.

(4) *No timely EJR decision.* The Board must issue an EJR decision no later than 30 days after the date of a written notice under paragraph (e)(3)(i) of this section, when the provider submits a complete request for EJR. If the Board does not issue an EJR decision within a 30-day period, the provider(s) has a right to seek EJR under section 1878(f)(1) of the Act.

(h) *Effect of final EJR decisions and lawsuits on further Board proceedings—* (1) *Final decisions granting EJR.* If the final decision of the Board or the Administrator, as applicable (as described in §§ 405.1842(g)(1) and 405.1875(e)(4) of this subpart), grants EJR, the Board may not conduct any further proceedings on the legal question. The Board must dismiss—

(i) The specific matter at issue from the appeal.

(ii) The entire appeal if there are no other matters at issue that are within the Board's jurisdiction and can be fully decided by the Board.

(2) *Final decisions denying EJR.* If the final decision:

(i) Of the Board denies EJR solely on the basis that the Board determines it has the authority to decide the legal question relevant to the specific matter at issue, the Board must conduct further proceedings on the legal question and issue a decision on the matter at issue in accordance with this subpart.

Exception: If the provider(s) file(s) a lawsuit pertaining to the legal question, and for a period that is covered by the Board's decision denying EJR, the Board may not conduct any further proceedings under this subpart on the legal question or the matter at issue before the lawsuit is finally resolved.

(ii) Of the Board (or the Administrator) denies EJR on the basis that the Board lacks jurisdiction over the specific matter at issue, the Board (or the Administrator) must, as applicable, dismiss the specific matter at issue from the appeal, or dismiss the appeal entirely if there are no other matters at issue that are within the Board's jurisdiction and can be fully decided by the Board. If only the specific matter(s) is dismissed from the appeal, judicial review may be had only after a final decision on the appeal is made by the Board or Administrator, as applicable (as described in §§ 405.1840(d) and 405.1877(a) of this subpart). If the Board or the Administrator, as applicable, dismisses the appeal entirely, the decision is subject to judicial review under § 405.1877(a) of this subpart.

(3) *Provider lawsuits.* (i) If the provider files a lawsuit seeking judicial review (whether on the basis of the EJR provisions of section 1878(f)(1) of the Act or on some other basis) pertaining to a legal question that is allegedly relevant to a specific matter at issue in a Board appeal to which the provider is a party and that is allegedly not within the Board's authority to decide, the Office of the Attorney Advisor must promptly provide the Board with written notice of the lawsuit and a copy of the complaint.

(ii) If the lawsuit is filed after a final EJR decision by the Board or the Administrator, as applicable (as described in §§ 405.1842(g)(1) and 405.1875(e)(4) of this subpart), on the legal question, the Board must carry out the applicable provisions of paragraphs (h)(1) and (h)(2) of this section in any pending Board appeal on the specific matter at issue.

(iii) If the lawsuit is filed before a final EJR decision is issued on the legal question, the Board may not conduct any further proceedings on the legal question or the matter at issue until the lawsuit is resolved.

[73 FR 30254, May 23, 2008; 73 FR 49356, Aug. 21, 2008]

§ 405.1843 Parties to proceedings in a Board appeal.

(a)(1) When a provider files a request for a hearing before the Board in accordance with § 405.1835 or § 405.1837, the

parties to all proceedings in the Board appeal include the provider, a contractor, and, where applicable, any other entity found by the Board to be a related organization of the provider under the principles enunciated in §413.17 of this chapter.

(2) All parties to a Board appeal are to familiarize themselves with the instructions for handling a Provider Reimbursement Review Board (PRRB) appeal, including any and all requirements related to the electronic/online filing of documents.

(b) Neither the Secretary nor CMS may be made a party to proceedings in a Board appeal.

(1) The Board may call as a witness any employee or officer of the Department of Health and Human Services or CMS having personal knowledge of the facts and the issues in controversy in an appeal.

(2) The regulations at 45 CFR Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) apply as to whether such employee or officer will appear.

(c) A contractor may designate a representative from the Secretary or CMS, who may be an attorney, to represent the contractor in proceedings before the Board.

(d) Although CMS is not a party to proceedings in a Board appeal, there may be instances where CMS determines that the administrative policy implications of a case are substantial enough to warrant comment from CMS (as described in §405.1863 of this subpart). CMS—

(1) May file *amicus curiae* (friend of the court) briefing papers with the Board in accordance with a schedule to be determined by the Board.

(2) Must promptly send copies of any documents filed with the Board to each party to the appeal.

(e) A nonparty other than CMS may seek leave from the Board to file *amicus curiae* briefing papers with the Board.

(f) The Board may exclude from the record all or part of an amicus curiae briefing paper. When the Board excludes from the record all or part of an amicus curiae briefing paper submitted by CMS, it states for the record its reason(s) in writing.

[73 FR 30256, May 23, 2008, as amended at 85 FR 59019, Sept. 18, 2020]

§405.1845 Composition of Board; hearings, decisions, and remands.

(a) *Composition of the Board.* The Board consists of five members appointed by the Secretary.

(1) All members must be knowledgeable in the field of payment of providers under Medicare Part A.

(2) At least one member must be a certified public accountant.

(3) At least two Board members must be representative of providers of services.

(b) *Terms of office.* The term of office for Board members must be 3 years, except that initial appointments may be for such shorter terms as the Secretary may designate to permit staggered terms of office.

(1) No member may serve more than three consecutive terms of office.

(2) The Secretary has the authority to terminate a Board member's term of office for good cause.

(c) *Role of the Chairperson.* The Secretary designates one member of the Board as Chairperson. The Chairperson coordinates and directs the administrative activities of the Board and the conduct of proceedings before the Board. CMS provides administrative support for the Board. Under the direction of the Chairperson, the Board is solely responsible for the content of its decisions.

(d) *Quorum.* (1) The Board must have a quorum in order to issue one of the decisions specified as final, or deemed final by the Administrator, under §405.1875(a)(2)(i), (a)(2)(iii), and (a)(2)(iv), but a quorum is not required for other Board actions.

(2) Three Board members, at least one of whom is representative of providers, are required in order to constitute a quorum.

(3) The opinion of the majority of those Board members issuing a decision specified as final, or deemed as final by the Administrator, under §405.1875(a)(2), constitutes the Board's decision.

(e) *Hearings.* The Board may conduct a hearing and issue a hearing decision

(as described in § 405.1871 of this subpart) on a specific matter at issue in an appeal, provided it finds jurisdiction over the matter at issue in accordance with § 405.1840 of this part and determines it has the legal authority to fully resolve the issue (as described in § 405.1867 of this subpart).

(f) *Oral hearings.* (1) In accordance with paragraph (d) of this section, the Board does not need a quorum in order to hold an oral hearing (as described in § 405.1851 of this subpart). The Chairperson of the Board may designate one or more Board members to conduct an oral hearing (where less than a quorum conducts the hearing). Because the presence of all Board members is not required at an oral hearing, the Board, at its discretion, may hold more than one oral hearing at a time.

(2) *Waiver of oral hearings.* With the contractor's agreement and the Board's approval, the provider (or, in the case of group appeals, the group of providers) and any related organizations (as described in § 405.1843(a) of this subpart) may waive any right to an oral hearing and stipulate that the Board may issue a hearing decision on the written record. An on-the-written-record hearing consists of all the evidence and written argument or comments submitted to the Board and included in the record (as described in § 405.1865 of this subpart).

(g) *Hearing decisions.* The Board's hearing decision must be based on the transcript of any oral hearing before the Board, any matter admitted into evidence at a hearing or deemed admissible evidence for the record (as described in § 405.1855 of this subpart), and any written argument or comments timely submitted to the Board (as described in § 405.1865 of this subpart).

(h) *Remands.* (1) Except as provided in paragraph (h)(3) of this section, a Board remand order may be reviewed solely during the course of Administrator review of one of the Board decisions specified in § 405.1875(a)(2) of this subpart), or of judicial review of a final agency decision as described in § 405.1877(a) and (c)(3) of this part, as applicable.

(2) The Board may order a remand requiring specific actions of a party to the appeal. In ordering a remand, the Board must—

(i) Specify any actions required of the party and explain the factual and legal basis for ordering a remand;

(ii) Issue the remand order in writing; and

(iii) Send the remand order promptly to the parties and any affected nonparty, such as CMS, to the appeal.

(3) A Board remand order is not subject to immediate Administrator review unless the Administrator determines that the remand order might otherwise evade his or her review (as described in § 405.1875(a)(2)(iv) of this subpart).

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 73 FR 30256, May 23, 2008; 85 FR 59019, Sept. 18, 2020; 89 FR 69909, Aug. 28, 2024]

§ 405.1847 Disqualification of Board members.

No Board member shall join in the conduct of a hearing in a case in which he is prejudiced or partial with respect to any party or in which he has any interest in the matter pending for decision before him. Notice of any objection which a party may have with respect to a Board member shall be presented in writing to such Board member by the objecting party at its earliest opportunity. The Board member shall consider the objection and shall, in his discretion, either proceed to join in the conduct of the hearing or withdraw. If he does not withdraw, the objecting party may petition the Board, presenting its objection and reasons therefor, and be entitled to a ruling thereon before the hearing can proceed.

§ 405.1849 Establishment of time and place of hearing by the Board.

The Board shall fix the time and place for the hearing and shall send notice thereof to the parties' contact information on file, not less than 30 days prior to the scheduled time. Either on its own motion or for good cause shown by a party, the Board may, as appropriate, reschedule, adjourn, postpone, or reopen the hearing, provided that

reasonable written notice is given to the parties.

[39 FR 34515, Sept. 26, 1974, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1851 Conduct of Board hearing.

The Board hearing shall be open to the parties, to representatives of the Centers for Medicare & Medicaid Services, and to such other persons as the Board deems necessary and proper. The Board shall inquire fully into all of the matters at issue and shall receive into evidence the testimony of witnesses and any documents which are relevant and material to such matters. If the Board believes that there is relevant and material evidence available which has not been presented at the hearing, it may at any time prior to the issuing of the notice of the decision, reconvene the hearing for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the Board.

[39 FR 34515, Sept. 26, 1974, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1853 Board proceedings prior to any hearing; discovery.

(a) *Preliminary narrowing of the issues.* Upon receiving notification that a request for a Board hearing is submitted, the contractor must—

(1) Promptly review both the materials submitted with the provider hearing request, and the information underlying each contractor or Secretary determination for each cost reporting period under appeal.

(2) Expeditiously attempt to join with the provider in resolving specific factual or legal issues and submitting to the Board written stipulations setting forth the specific issues that remain for Board resolution based on the review; and

(3) Ensure that the evidence it considered in making its determination, or, where applicable, the evidence the Secretary considered in making his or her determination, is included in the record.

(b) *Position papers.* (1) After any preliminary narrowing of the issues, the parties must file position papers in order to narrow the issues further. In each case, and as appropriate, the Board establishes the deadlines as to when the provider(s) and the contractor must submit position papers to the Board.

(2) The Board has the discretion to extend the deadline for submitting a position paper. Each position paper must set forth the relevant facts and arguments regarding the Board's jurisdiction over each remaining matter at issue in the appeal (as described in § 405.1840 of this subpart), and the merits of the provider's Medicare payment claims for each remaining issue.

(3) In the absence of a Board order or general instructions to the contrary, any supporting exhibits regarding Board jurisdiction must accompany the position paper. Exhibits regarding the merits of the provider's Medicare payment claims may be submitted in a timeframe to be decided by the Board through a schedule applicable to a specific case or through general instructions.

(c) *Initial status conference.* (1) Upon review of the parties' position papers, one or more members of the Board may conduct an initial status conference. An initial status conference may be conducted in person or telephone, at the discretion of the Board.

(2) The Board may use the status conference to discuss any of the following:

(i) Simplification of the issues.

(ii) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement.

(iii) Stipulations and admissions of fact or as to the content and authenticity of documents.

(iv) Whether the parties can agree to submission of the case on a stipulated record.

(v) Whether a party may waive appearance at an oral hearing and submit only documentary evidence (the admissibility of which is subject to objection from other parties) and written argument.

(vi) Limitation of the number of witnesses.

(vii) Scheduling dates for the exchange of witness lists and of proposed exhibits.

(viii) Discovery as permitted under this section.

(ix) The time and place for the hearing.

(x) Potential settlement of some or all of the issues.

(xi) Other matters that the Board deems necessary and appropriate. The Board may issue any orders at the conference found necessary and appropriate to narrow the issues further and expedite further proceedings in the appeal.

(3) After the status conference, the Board may—

(i) Issue in writing a report and order specifying what transpired and formalizing any orders issued at the conference; and

(ii) Require the parties to submit (jointly or otherwise) a proposed report and order, in order to facilitate issuance of a final report and order.

(d) *Further status conferences.* Upon a party's request, or on its own motion, the Board may conduct further status conferences where it finds the proceedings necessary and appropriate.

(e) *Discovery*—(1) *General rules.* (i) Discovery is limited in Board proceedings.

(ii) The Board may permit discovery of a matter that is relevant to the specific subject matter of the Board hearing, provided the matter is not privileged or otherwise protected from disclosure and the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

(iii) Any discovery initiated by a party must comply with all requirements and limitations of this section, and with any further requirements or limitations ordered by the Board.

(iv) The applicable provisions of the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence serve as guidance for any discovery that is permitted under this section or by Board order.

(2) *Limitations on discovery.* Any discovery before the Board is limited as follows:

(i) A party may request of another party, or of a nonparty other than CMS, the Secretary or any Federal agency, the reasonable production of documents for inspection and copying.

(ii) A party may also request another party to respond to a reasonable number of written interrogatories.

(iii)(A) A party may not take the deposition, upon oral or written examination, of another party or a nonparty, unless the proposed deponent agrees to the deposition or the Board finds that the proposed deposition is necessary and appropriate under the criteria set forth in Federal Rules of Civil Procedure 26 and 32(a)(3) in order to secure the deponent's testimony for a Board hearing.

(B) The regulations at 45 CFR Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) apply as to whether an employee or officer of CMS or HHS will appear for a deposition.

(iv) A party may not request admissions or take any other form of discovery not authorized under this section.

(3) *Time limits.* (i) A party's discovery request is timely if the date the request is served on another party or nonparty, as applicable, is no later than 120 days before the initially scheduled starting date of the Board hearing, unless the Board extends the time for the request.

(ii)(A) *Depositions.* (*1*) In the absence of an order or instruction by the Board setting a schedule for the holding of a deposition, a party desiring to take a deposition must give reasonable notice in writing to the deponent of a scheduled deposition.

(*2*) A deposition may not be held any later than 45 days before the initially scheduled starting of the Board hearing, unless the Board orders otherwise.

(B) *Responses.* (*1*) In the absence of a Board order or general instructions of the Board setting a schedule for responses, responses to interrogatories and requests for production of documents are due according to the schedule agreed upon by the party serving discovery and the party to which the discovery is directed, or within the time allotted by the Federal Rules of Civil Procedure.

(*2*) Responses by a party to interrogatories, and responses by a party or nonparty to requests for production of documents, must be served no later

than 45 days before the initially scheduled starting date of the Board hearing, unless the Board orders otherwise.

(iii) Before ruling on a request to extend the time for requesting discovery or for conducting or responding to discovery, the Board must give the other parties to the appeal, and any nonparty subject to a discovery request, a reasonable period to respond to the extension request.

(iv) The Board has the discretion to extend the time in which to request discovery or conduct or respond to discovery.

(v) If the Board grants the extension request, it sets a new discovery deadline and has the discretion to reschedule the hearing date.

(4) *Rights of nonparties.* If a discovery request is made of a nonparty to the Board appeal, the nonparty has the rights any party has in responding to a discovery request. The rights of the nonparty include, but are not limited to, the right to select and use any attorney or other representative, and to submit discovery responses, objections, or motions to the Board.

(5) *Motions to compel or for protective order.* (i) Each party is required to make a good faith effort to resolve or narrow any discovery dispute, regardless of whether the dispute is with another party or a nonparty.

(ii) A party may submit to the Board a motion to compel discovery that is permitted under this section or any Board order, and a party or nonparty may submit a motion for a protective order regarding any discovery request to the Board.

(iii) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute.

(iv) A self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute must be included with any response to a motion to compel or for protective order.

(v) The Board must decide any motion in accordance with this section and any prior discovery ruling.

(vi)(A) The Board must issue and send to each party and any affected nonparty a discovery ruling that grants or denies, in whole or in part, the motion to compel or the motion for a protective order, if applicable.

(B) The discovery ruling must—

(*1*) Specifically identify any part of the disputed discovery request upheld and any part rejected, and

(*2*) Impose any limits on discovery the Board finds necessary and appropriate.

(vii) Nothing in this section authorizes the Board to compel any action from the Secretary or CMS.

(6) *Reviewability of discovery and disclosure rulings*—(i) *General rule.* A Board discovery ruling, or a Board disclosure ruling, such as one issued at a hearing, is not subject to immediate review by the Administrator (as described in §405.1875(a)(3) of this subpart). The ruling may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final or deemed to be final, by the Administrator, under §405.1875(a)(2)of this subpart, or of judicial review of a final agency decision as described in §405.1877(a) and (c)(3) of this subpart, as applicable.

(ii) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the Board, that portion of the discovery or disclosure ruling may be reviewed immediately by the Administrator in accordance with §405.1875(a)(3)(i) of this subpart. Upon notice to the Board that a party or nonparty, as applicable, intends to seek Administrator review of the ruling,—

(A)(*1*) The Board must stay all proceedings affected by the ruling.

(*2*) The Board determines the length of the stay under the circumstances of a given case, but in no event may the length of the stay be less than 15 days after the day on which the Board received notice of the party or nonparty's intent to seek Administrator review.

(B) If the Administrator—

(*1*) Grants a request for review, or takes own motion review, of a ruling, the ruling is stayed until the time the Administrator issues a written decision

that affirms, reverses, modifies, or remands the Board's ruling.

(*2*) Does not grant a request or take own motion review within the time allotted for the stay, the stay is lifted and the ruling is not subject to immediate review.

[73 FR 30257, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1855 Evidence at Board hearing.

Evidence may be received at the Board hearing even though inadmissible under the rules of evidence applicable to court procedure. The Board shall give the parties opportunity for submission and consideration of facts and arguments and during the course of the hearing should, in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The Board shall render a final ruling on the admissibility of evidence.

§ 405.1857 Subpoenas.

(a) *Time limits.* (1) The Board may issue a subpoena—

(i) To a party to a Board appeal or to a nonparty other than CMS or the Secretary or any Federal agency, requiring the attendance and testimony of witnesses or the production of documents for inspection and copying, provided the Board makes a preliminary finding of its jurisdiction over the matters at issue in accordance with § 405.1840(a) of this subpart.

(ii) At the request of a party for purposes of discovery (as described in § 405.1853 of this subpart) or an oral hearing (as described in § 405.1845 of this subpart); and

(iii) On its own motion solely for purposes of a hearing.

(2) The date of receipt by the Board of a party's subpoena request may not be any later than for subpoenas requested for purposes of—

(i) Discovery, 120 days before the initially scheduled starting date of the Board hearing; and

(ii) An oral hearing, 45 days before the scheduled starting date of the Board hearing.

(3) Subject to paragraph (4) of this section, the Board may not issue a subpoena any later than for purposes of—

(i) Discovery, 90 days before the initially scheduled starting date of the Board hearing; and

(ii) An oral hearing, whether issued at a party's request or on the Board's own motion, 30 days before the scheduled starting date of the Board hearing.

(4) The Board may extend the deadlines specified in paragraphs (a)(2) and (a)(3) of this section provided the Board gives each party to the appeal and any nonparty subject to the subpoena request or subpoena a reasonable period of time to comment on any proposed extension. If the Board extends a deadline, it retains the discretion to reschedule the hearing date.

(b) *Criteria*—(1) *Discovery subpoenas.* The Board may issue a subpoena for purposes of discovery if all of the following are applicable:

(i) The subpoena was requested in accordance with the requirements of paragraph (c)(1) of this section.

(ii) The party's discovery request complies with the applicable provisions of § 405.1853(e) of this part.

(iii) A subpoena is necessary and appropriate to compel a response to the discovery request.

(2) *Hearing subpoenas.* The Board may issue a subpoena for purposes of an oral hearing if—

(i) The party's subpoena request meets the requirements of paragraph (c)(1) of this section;

(ii) A subpoena is necessary and appropriate to compel the attendance and testimony of witnesses or the production of documents for inspection or copying, provided the testimony or documents are relevant and material to a matter at issue in the appeal but not unduly repetitious (as described in § 405.1855 of this subpart); and

(iii) The subpoena does not compel the disclosure of matter that is privileged or otherwise protected from disclosure for reasons such as case preparation, confidentiality, or undue burden.

(iv) The subpoena does not impose undue burden or expense on the party or nonparty subject to the subpoena, and is not otherwise unreasonable or inappropriate.

(3) *Guiding principles.* In determining whether to issue, quash, or modify a

subpoena under this section, the Board uses the applicable provisions of the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence for guidance.

(c) *Procedures*— (1) *Subpoena requests.* The requesting party must send any subpoena request submitted to the Board promptly to the party or nonparty subject to the subpoena, and to any other party to the Board appeal. If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena request must be sent by certified mail. The request must—

(i) Identify with particularity any witnesses (and their addresses, if known) or any documents (and their location, if known) sought by the subpoena, and the means, time, or location for securing any witness testimony or documents;

(ii) Describe specifically, in the case of a hearing subpoena, the facts any witnesses, documents, or tangible materials are expected to establish, and why those facts cannot be established without a subpoena; and

(iii) Explain why a subpoena is appropriate under the criteria prescribed in paragraph (b) of this section.

(2) *Contents of subpoenas.* A subpoena issued by the Board, whether on its own motion or at the request of a party, must be in writing and either sent promptly by the Board to the party or nonparty subject to the subpoena by certified mail or overnight delivery (and to any other party and affected nonparty to the appeal by regular mail), or hand-delivered. Each subpoena must—

(i) Be issued in the name of the Board, and include the case number and name of the appeal;

(ii) Provide notice that—

(A) The subpoena is issued in accordance with section 1878(e) of the Act and §405.1857 of this subpart; and

(B) CMS must pay the fees and the mileage of any witnesses, as provided in section 205(d) of the Act.

(iii) If applicable, require named witnesses to attend a particular proceeding at a certain time and location and to testify on specific subjects; and

(iv) If applicable, require the production of specific documents for inspection or copying at a certain time and location.

(3) *Rights of nonparties.* If a nonparty to the Board appeal is subject to the subpoena or subpoena request, the nonparty has the rights any party has in responding to a subpoena or subpoena request. The rights of the nonparty include, but are not limited to, the right to select and use any attorney or other representative, and to submit responses, objections, motions, or any other pertinent materials to the Board regarding the subpoena or subpoena request.

(4) *Board action on subpoena requests and motions.* After issuing a subpoena or receiving a subpoena request, the Board must do the following:

(i) Give the party or nonparty subject to the subpoena or subpoena request a reasonable period of time for the submission of any responses, objections, or motions.

(ii) Consider the subpoena or subpoena request, and any responses, objections, or motions related thereto, under the criteria specified in paragraph (b) of this section.

(iii)(A) Issue in writing and send promptly to each party and any affected nonparty an order granting or denying any motion to quash or modify a subpoena, or granting or denying any subpoena request in whole or in part; and

(B) Issue, if applicable, an original or modified subpoena in accordance with paragraph (c)(2) of this section.

(d) *Reviewability*—(1) *General rules.* (i) If the Board issues, quashes, or modifies, or refuses to issue, quash, or modify, a subpoena under paragraphs (c)(2) or (c)(4) of this section, the Board's action is not subject to immediate review by the Administrator (as described in §405.1875(a)(3) of this subpart).

(ii) Any Board action on a subpoena may be reviewed solely during the course of Administrator review of one of the Board decisions specified in §405.1875(a)(2) of this subpart, or of judicial review of a final agency decision as described in §405.1877(a) and (c)(3) of this subpart, as applicable.

(2) *Exception.* (i) To the extent a subpoena compels disclosure of a matter

for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the Board, the Administrator may review immediately that portion of the subpoena in accordance with § 405.1875(a)(3)(ii) of this subpart.

(ii) Upon notice to the Board that a party or nonparty, as applicable, intends to seek Administrator review of the subpoena, the Board must stay all proceedings affected by the subpoena.

(iii) The Board determines the length of the stay under the circumstances of a given case, but in no event may the stay be less than 15 days after the day on which the Board received notice of the party or nonparty's intent to seek Administrator review.

(iv) If the Administrator grants a request for review, or takes own motion review, of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until such time as the Administrator issues a written decision that affirms, reverses, modifies, or remands the Board's action on the subpoena.

(v) If the Administrator does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the Board's action is not immediately reviewable.

(e) *Enforcement.* (i) If the Board determines, whether on its own motion or at the request of a party, that a party or nonparty subject to a subpoena issued under this section has refused to comply with the subpoena, the Board may request the Administrator to seek enforcement of the subpoena in accordance with section 205(e) of the Act.

(ii) Any enforcement request by the Board must consist of a written notice to the Administrator describing in detail the Board's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(iii) The Board must promptly mail a copy of the notice and related documents to the party or nonparty subject to the subpoena, and to any other party and affected nonparty to the appeal.

[73 FR 30258, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1859 Witnesses.

Witnesses at the hearing shall testify under oath or affirmation, unless excused by the Board for cause. The Board may examine the witnesses and shall allow the parties or their representatives to do so. Parties to the proceeding may also cross-examine witnesses.

§ 405.1861 Oral argument and written allegations.

The parties, upon their request, shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements of allegations as to facts or law. Copies of any brief or other written statement shall be filed in sufficient number that they may be made available to all parties and to the Centers for Medicare & Medicaid Services.

§ 405.1863 Administrative policy at issue.

Where a party to the Board hearing puts into issue an administrative policy which is interpretative of the law or regulations, the Board will promptly notify to the Centers for Medicare & Medicaid Services.

§ 405.1865 Record of administrative proceedings.

(a)(1) The Board and, if applicable, the Administrator must maintain a complete record of all proceedings in each appeal.

(2) For proceedings before the Board, the administrative record consists of all evidence, documents and any other tangible materials submitted by the parties to the appeal and by any nonparty (as described in §§ 405.1853(e)(4) and 405.1857(c)(3) of this subpart), along with all Board correspondence, rulings, subpoenas, orders, and decisions.

(3) The term ''record'' is intended to encompass both the unappended record and any appendix to the record (as described in § 405.1865(b) of this subpart).

(4) The record includes a complete transcription of the proceedings at any oral hearing before the Board.

(5) A copy of any transcription must be made available to any party upon written request.

(b) Any evidence ruled inadmissible by the Board (as described in § 405.1855 of this subpart) and any other submitted matter that the Board declines to consider (whether as untimely or otherwise) must be, to the extent practicable, clearly identified and segregated in an appendix to the record for purposes of any further review (as described in §§ 405.1875 and 405.1877 of this subpart).

(c) To the extent applicable, the administrative record also includes all documents (including written submissions) and any other tangible materials submitted to the Administrator by the parties to the appeal or by any nonparty (as described in §§ 405.1853(e)(4) and 405.1857(c)(3) of this subpart), in addition to all correspondence from the Administrator or the Office of the Attorney Advisor, and all rulings, orders, and decisions by the Administrator. The provisions of paragraph (b) of this section also pertain to any proceedings before the Administrator, to the extent the Administrator finds evidence inadmissible or declines to consider a specific matter (whether as untimely or otherwise).

[73 FR 30260, May 23, 2008; 73 FR 49356, Aug. 21, 2008]

§ 405.1867 Scope of Board's legal authority.

In exercising its authority to conduct proceedings under this subpart, the Board must comply with all the provisions of Title XVIII of the Act and regulations issued thereunder, as well as CMS Rulings issued under the authority of the Administrator as described in § 401.108 of this subchapter. The Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

[48 FR 22925, May 23, 1983, as amended at 73 FR 30260, May 23, 2008; 73 FR 49356, Aug. 21, 2008]

§ 405.1868 Board actions in response to failure to follow Board rules.

(a) The Board has full power and authority to make rules and establish procedures, not inconsistent with the law, regulations, and CMS Rulings, that are necessary or appropriate to carry out the provisions of section 1878 of the Act and of the regulations in this subpart. The Board's powers include the authority to take appropriate actions in response to the failure of a party to a Board appeal to comply with Board rules and orders or for inappropriate conduct during proceedings in the appeal.

(b) If a provider fails to meet a filing deadline or other requirement established by the Board in a rule or order, the Board may—

(1) Dismiss the appeal with prejudice;

(2) Issue an order requiring the provider to show cause why the Board should not dismiss the appeal; or

(3) Take any other remedial action it considers appropriate.

(c) If a contractor fails to meet a filing deadline or other requirement established by the Board, the Board may—

(1) Take other actions that it considers appropriate, such as—

(i) Issuing a decision based on the written record submitted to that point; or

(ii) Issuing a written notice to CMS describing the contractor's actions and requesting that CMS take appropriate action, such as review of the contractor's compliance with the contractual requirements of §§ 421.120, 421.122, and 421.124 of this chapter; and

(2) Not use its authority to take an action such as, a sanction, reversing or modifying the contractor's or Secretary's determination for the cost reporting period under appeal, or ruling against the contractor on a disputed issue of law or fact in the appeal.

(d)(1) If the Board dismisses the appeal with prejudice under this section, it must issue a dismissal decision dismissing the appeal. The decision by the Board must be in writing and include an explanation of the reason for the dismissal. A copy of the Board's dismissal decision must be sent promptly to each party to the appeal (as described in § 405.1843 of this subpart).

(2) A dismissal decision by the Board is final and binding on the parties unless the decision is reversed, affirmed, modified, or remanded by the Administrator under § 405.1875(a)(2)(ii), and § 405.1875(e) or § 405.1875(f) of this part, no later than 60 days after the date of receipt by the provider of the Board's decision.

(i) The Board decision is inoperative during the 60-day period for review by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands the decision within the period.

(ii) The Board may reopen and revise a final Board decision in accordance with §§ 405.1885 through 405.1889 of this subpart.

(e)(1) Any action taken by the Board under this section other than dismissal of the appeal is not subject to immediate Administrator review (as described in § 405.1875(a)(3) of this subpart) or judicial review (as described in § 405.1877(a)(3) of this subpart).

(2) A Board action other than dismissal of the appeal may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final, or deemed to be final by the Administrator, under § 405.1875(a)(2) of this subpart, or of judicial review of a final agency decision as described in § 405.1877(a) of this subpart, as applicable.

(f) *Ex parte* communications with Board staff concerning procedural matters are not prohibited.

(g) Upon receipt of a credible allegation that a party's representative has divulged to that party, or to the Board, information that was obtained during the course of the representative's relationship (such as legal counsel or employee) with an opposing party and that was intended by that party to be kept confidential, the Board—

(1) Investigates the allegation; and

(2) May take remedial action when it determines that it is appropriate to do so, against the party or the representative (such as prohibiting the representative from appearing before it, excluding such information from the record, or if the overall fairness of the hearing has been compromised, dismissing the case).

[73 FR 30260, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1869 Scope of Board's authority in a hearing decision.

(a) If the Board has jurisdiction to conduct a hearing on a specific matter at issue under section 1878(a) or (b) of the Act and § 405.1840 of this subpart, and the legal authority to fully resolve the matter in a hearing decision (as described in §§ 405.1842(f), 405.1867, and 405.1871 of this subpart), section 1878 of the Act, and paragraph (a) of this section give the Board the power to affirm, modify, or reverse the contractor's findings on each specific matter at issue in the contractor determination for the cost reporting period under appeal, and to make additional revisions on specific matters regardless of whether the contractor considered the matters in issuing the contractor determination. The Board's power to make additional revisions in a hearing decision does not authorize the Board to consider or decide a specific matter at issue for which it lacks jurisdiction (as described in § 405.1840(b) of this subpart) or which was not timely raised in the provider's hearing request. The Board's power under section 1878(d) of the Act and paragraph (a) of this section to make additional revisions is limited to those revisions necessary to resolve fully a specific matter at issue if—

(1) The Board has jurisdiction to grant a hearing on the specific matter at issue under section 1878(a) or (b) of the Act and § 405.1840 of this subpart; and

(2) The specific matter at issue was timely raised in an initial request for a Board hearing filed in accordance with § 405.1835 or § 405.1837 of this subpart, as applicable, or in a timely request to add issues to a single provider appeal submitted in accordance with § 405.1835(c) of this subpart.

(b)(1) If the Board has jurisdiction to conduct a hearing on a specific matter at issue solely under §§ 405.1840 and 405.1835 or § 405.1837 of this subpart, as applicable, and the legal authority to fully resolve the matter in a hearing decision (as described in §§ 405.1842(f),

405.1867, and 405.1871 of this subpart), the Board is authorized to do the following:

(i) Affirm, modify, or reverse the contractor's or Secretary's findings on each specific matter at issue in the contractor or Secretary determination under appeal.

(ii) Make additional revisions on each specific matter at issue regardless of whether the contractor considered these revisions in issuing the contractor determination under appeal, provided the Board does not consider or decide a specific matter for which it lacks jurisdiction (as described in § 405.1840(b) of this subpart) or that was not timely raised in the provider's hearing request.

(2) The Board's authority under this section to make the additional revisions is limited to those revisions necessary to resolve a specific matter at issue.

[73 FR 30261, May 23, 2008]

§ 405.1871 Board hearing decision.

(a)(1) If the Board finds jurisdiction over a specific matter at issue and conducts a hearing on the matter (as described in §§ 405.1840(a) and 405.1845(e) of this subpart), the Board must issue a hearing decision deciding the merits of the specific matter at issue.

(2) A Board hearing decision must be in writing and based on the admissible evidence from the Board hearing and other admissible evidence and written argument or comments as may be included in the record and accepted by the Board (as described in §§ 405.1845(g) and 405.1865 of this subpart).

(3) The decision must include findings of fact and conclusions of law regarding the Board's jurisdiction over each specific matter at issue (see § 405.1840(c)(1)), and whether the provider carried its burden of production of evidence and burden of proof by establishing, by a preponderance of the evidence, that the provider is entitled to relief on the merits of the matter at issue.

(4) The decision must include appropriate citations to the record evidence and to the applicable law, regulations, CMS Rulings, and other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS. Where the Board's decision reverses or modifies a contractor determination on an issue for which the policy expressed in an interpretive rule (other than a regulation or a CMS Ruling), general statement of policy or rule of agency organization, procedure or practice established by CMS would be dispositive of that issue (if followed by the Board), the Board decision must explain how it gave great weight to such interpretive rule or other such instruction but did not uphold the contractor's determination on the issue.

(5) A copy of the decision must be sent promptly to each party to the appeal.

(b)(1) A Board hearing decision issued in accordance with paragraph (a) of this section is final and binding on the parties to the Board appeal unless the hearing decision is reversed, affirmed, modified, or remanded by the Administrator under §§ 405.1875(a)(2)(i), 405.1875(e), and 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision.

(2) A Board hearing decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision within the period.

(3) A Board hearing decision that is final under paragraph (b)(1) of this section is subject to the provisions of § 405.1803(d) of this subpart, unless the decision is the subject of judicial review (as described in § 405.1877 of this subpart).

(4) A final Board decision under paragraph (a) and (b) of this section may be reopened and revised by the Board in accordance with §§ 405.1885 through 405.1889 of this subpart.

(5) When the contractor's denial of the relief that the provider seeks before the Board is based on procedural grounds (for example, the alleged failure of the provider to satisfy a time limit) or is based on the alleged failure to supply adequate documentation to support the provider's claim, and the Board rules that the basis of the contractor's denial is invalid, the Board

remands to the contractor for the contractor to make a determination on the merits of the provider's claim.

[73 FR 30261, May 23, 2008, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1873 Board review of compliance with the reimbursement requirement of an appropriate cost report claim.

(a) *General.* In order to receive or potentially receive reimbursement for a specific item, the provider must include in its cost report an appropriate claim for the specific item (as prescribed in § 413.24(j) of this chapter). If the provider files an appeal to the Board seeking reimbursement for the specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item, the Board must address such question in accordance with the procedures set forth in this section.

(b) *Summary of procedures*—(1) *Preliminary steps.* The Board must give the parties an adequate opportunity to submit factual evidence and legal argument regarding the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. Upon receipt of timely submitted factual evidence or legal argument (if any), the Board must review such evidence and argument and prepare written specific findings of fact and conclusions of law on the question of whether the provider's cost report complied with, for the specific item under appeal, the cost report claim requirements prescribed in § 413.24(j) of this chapter. In reaching such specific factual findings and legal conclusions, the Board must follow the procedures set forth in § 413.24(j)(3) of this chapter for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The Board must promptly give a copy of such written specific factual findings and legal conclusions to each party to the appeal, and such factual findings and legal conclusions must be included in the record of administrative proceedings for the appeal (as prescribed in § 405.1865).

(2) *Limits on Board actions.* The Board's specific findings of fact and conclusions of law (pursuant to paragraph (b)(1) of this section) must not be invoked or relied on by the Board as a basis to deny, or decline to exercise, jurisdiction over a specific item or take any other of the actions specified in paragraph (c) of this section. Upon giving the parties to the appeal the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate cost report claim for the specific item under appeal, the Board must proceed to issue one of the four types of overall decisions specified in paragraphs (d) and (e) of this section with respect to the specific item. If the Board issues either of two types of overall Board decisions (as specified in paragraph (d) of this section) regarding the specific item under appeal, the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must be included in such overall Board decision regarding the specific item, along with the other matters that are required by the regulations for the pertinent type of overall Board decision. However, if the Board issues either of two other types of overall Board decisions (as specified in paragraph (e) of this section) regarding the specific item under appeal, the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must not be included in the overall Board decision regarding the specific item. The Board may permit reimbursement for the specific item under appeal, as part of one of the two types of overall Board decisions that are specified in paragraph (d) of this section, but such reimbursement may be permitted only to the extent authorized by paragraph (f) of this section.

(c) *Prohibition of certain types of decisions, orders, and other actions.* (1) If the Board determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did not include an appropriate claim for the specific item under appeal, the Board may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole

or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section);

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section); or

(iii) Take any of the actions set forth in §405.1868(b), (c), or (d), impose any sanction, or take any other action against the interests of any party to the appeal, except as provided in paragraph (f) of this section, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section).

(2) Regardless of whether the Board determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did or did not include an appropriate claim for the specific item under appeal, the Board may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item. *Exception:* If the provider's appeal of the specific item is based on a reopening of such item (pursuant to §405.1885) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor or Secretary determination, the Board must deny jurisdiction over the specific item under appeal (as prescribed in §§405.1887(d) and 405.1889(b));

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item; or

(iii) Take any of the actions set forth in §405.1868(b), (c), or (d), impose any sanction, or take any other action against the interests of any party to the appeal, except as provided in paragraph (f) of this section, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item.

(d) *Two types of Board decisions that must include any factual findings and legal conclusions under paragraph (b)(1) of this section*—(1) *Board hearing decision.* If the Board issues a hearing decision regarding the specific item under appeal (pursuant to §405.1871), any specific findings of fact and conclusions of law by the Board (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such hearing decision along with the other matters prescribed by §405.1871(a). The Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section), about whether there was an appropriate cost report claim for the specific item under appeal, are subject to the provisions of §405.1871(b) just as those provisions apply to the other parts of the Board's hearing decision. If the Board determines that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in §413.24(j) of this chapter), the Board's hearing decision must also address whether the other substantive reimbursement requirements for the specific item are also satisfied; or

(ii) Did not include an appropriate claim for the specific item under appeal, the Board has discretion whether or not to address in the Board's hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

(2) *Board expedited judicial review (EJR) decision, where EJR is granted.* If the Board issues an EJR decision where EJR is granted regarding a legal question that is relevant to the specific item under appeal (in accordance with §405.1842(f)(1)), the Board's specific

findings of fact and conclusions of law (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such EJR decision along with the other matters prescribed by § 405.1842(f)(1). The Board's factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) about whether there was an appropriate cost report claim for the specific item under appeal are subject to the provisions of § 405.1842(g)(1), (g)(2), (h)(1), and (h)(3) in the same manner as those provisions apply to the other parts of the Board's EJR decision.

(e) *Two other types of Board decisions that must not include the Board's factual findings and legal conclusions under paragraph (b)(1) of this section*—(1) *Board jurisdictional dismissal decision*. If the Board issues a jurisdictional dismissal decision regarding the specific item under appeal (pursuant to § 405.1840(c)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must not be included in such jurisdictional dismissal decision.

(2) *Board expedited judicial review (EJR) decision, where EJR is denied*. If the Board issues an EJR decision where EJR is denied regarding a legal question that is relevant to the specific item under appeal (in accordance with § 405.1842(f)(2)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the same item, must not be included in such EJR decision. If the Board conducts further proceedings and issues another decision (as specified in § 405.1842(h)(2)(i)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section)—

(i) Must be included in any further hearing decision or EJR decision where EJR is granted regarding the specific item under appeal (as specified in paragraph (d) of this section); but

(ii) Must not be included in any further jurisdictional dismissal decision or EJR decision where EJR is denied regarding the specific item under appeal (as prescribed in paragraph (e) of this section).

(f) *Effects of the Board's factual findings and legal conclusions under paragraph (b)(1) of this section in two types of final decisions*—(1) *When part of a final hearing decision*. If the Board determines, or the Administrator of CMS determines (pursuant to § 405.1875(a)(2)(v)), as applicable, in a final and binding hearing decision (in accordance with § 405.1871(b) and paragraphs (b)(1) and (d)(1) of this section), that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only if the Board further determines in such final hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied; or

(ii) Did not include an appropriate cost report claim for the specific item under appeal, the specific item is not reimbursable, regardless of whether the Board further determines in such final hearing decision that the other substantive reimbursement requirements for the specific item are or are not satisfied.

(2) *When part of a final EJR decision that grants EJR*. If the Board determines or the Administrator of CMS determines (pursuant to § 405.1875(a)(2)(v)), as applicable, in a final and binding EJR decision that grants EJR regarding a legal question that is relevant to the specific item under appeal (in accordance with § 405.1842(g)(1) and paragraphs (b)(1) and (d)(2) of this section), that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only to the extent permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (refer also to §§ 405.1842 and 405.1877); or

(ii) Did not include an appropriate claim for the specific item under appeal, the specific item is not reimbursable, unless—

(A) The specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) of the Board or the Administrator, as applicable, on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal, are reversed or modified by the final decision of a Federal court (in accordance with section 1878(f)(1) of the Act and §405.1877); and

(B) Only to the extent otherwise permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (refer also to §§405.1842 and 405.1877) and by Medicare policy.

[80 FR 70600, Nov. 13, 2015]

§405.1875 Administrator review.

(a) *Basic rule: Time limit for rendering Administrator decisions, Board decisions, and action subject to immediate review.* The Administrator, at his or her discretion, may immediately review any decision of the Board specified in paragraph (a)(2) of this section. Nonfinal decisions or actions by the Board are not immediately reviewable, except as provided in paragraph (a)(3) of this section. The Administrator may exercise this discretionary review authority on his or her own motion, or in response to a request from: a party to the Board appeal; CMS; or, in the case of a matter specified in paragraph (a)(3)(i) or (a)(3)(ii) of this section, another affected nonparty to a Board appeal. All requests for Administrator review and any other submissions to the Administrator under paragraph (c) of this section must be sent to the Office of the Attorney Advisor. The Office of the Attorney Advisor must examine each Board decision specified in paragraph (a)(2) of this section, and each matter described in §405.1845(h)(3), §405.1853(e)(6)(ii), or §405.1857(d)(2) of this subpart, of which it becomes aware, together with any review requests or any other submission made in accordance with the provisions of this section, in order to assist the Administrator's exercise of this discretionary review authority. The Board is required to send to the Office of the Attorney Advisor a copy of each decision specified in paragraphs (a)(2)(i), (ii), and (iii) of this section upon issuance of the decision.

(1) The date of rendering any decision after the review by the Administrator must be no later than 60 days after the date of receipt by the provider of a reviewable Board decision or action. For purposes of this section, the date of rendering is the date the Administrator signs the decision, and not the date the decision is mailed or otherwise transmitted to the parties.

(2) The Administrator may immediately review:

(i) A Board hearing decision (as described in §405.1871 of this subpart).

(ii) A Board dismissal decision (as described in §§405.1836(e)(1) and (e)(2), 405.1840(c)(2) and (c)(3), 405.1868(d)(1) and (d)(2) of this subpart).

(iii) A Board EJR decision, but only the question of whether there is Board jurisdiction over a specific matter at issue in the decision; the Administrator may not review the Board's determination in a decision of its authority to decide a legal question relevant to the matter at issue (as described in §405.1842(h) of this subpart).

(iv) Any other Board decision or action deemed to be final by the Administrator.

(v) If the Administrator reviews a Board hearing decision regarding a specific item, or for a Board EJR decision the question of whether there is Board jurisdiction over a specific item, the Administrator's review of such a hearing decision or EJR decision, as applicable, will include, and any decision issued by the Administrator (under paragraph (e) of this section) will address, the Board's specific findings of fact and conclusions of law in such hearing decision or EJR decision (as prescribed in §405.1873(b)(1) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in §413.24(j) of this chapter).

(3) Any decision or action by the Board not specified in paragraph (a)(2)(i) through (a)(2)(iii) of this section, or not deemed to be final by the Administrator under paragraph

(a)(2)(iv) of this section, is nonfinal and not subject to Administrator review until the Board issues one of the decisions specified in paragraph (a)(2) of this section, except the Administrator may review immediately the following matters:

(i) A Board ruling authorizing discovery or disclosure of a matter for which an objection was made based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden (as described in § 405.1853(e)(6)(ii) of this subpart).

(ii) A Board subpoena compelling disclosure of a matter for which an objection was made based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden (as described in § 405.1857(d)(2) of this subpart).

(b) *Illustrative list of criteria for deciding whether to review.* In deciding whether to review a Board decision or other matter specified in paragraphs (a)(2) and (a)(3) of this section, either on his or her own motion or in response to a request for review, the Administrator considers criteria such as whether it appears that—

(1) The Board made an erroneous interpretation of law, regulation, CMS Ruling, or other interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice established by CMS.

(2) A Board hearing decision meets the requirements of § 405.1871(a) of this subpart.

(3) The Board erred in refusing to admit certain evidence or in not considering other submitted matter (as described in §§ 405.1855 and 405.1865(b) of this subpart), or in admitting certain evidence.

(4) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to the issuance of a CMS Ruling or other directive needed to clarify a statutory or regulatory provision.

(5) The Board has incorrectly found, assumed, or denied jurisdiction over a specific matter at issue or extended its authority in a manner not provided for by statute, regulation, CMS Ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(6) The decision or other action of the Board requires clarification, amplification, or an alternative legal basis.

(7) A remand to the Board may be necessary or appropriate under the criteria prescribed in paragraph (f) of this section.

(c) *Procedures*—(1) *Review requests.* (i)(A) A party to a Board appeal or CMS may request Administrator review of a Board decision specified in paragraph (a)(2) of this section or a matter described in paragraph (a)(3) of this section.

(B) A nonparty other than CMS may request Administrator review solely of a matter described in paragraph (a)(3)(i) or (a)(3)(ii) of this section.

(ii) The date of receipt by the Office of Attorney Advisor of any review request must be no later than 15 days after the date the party making the request received the Board's decision or other reviewable action.

(iii) A request for review (or a response to a request) must be submitted in writing, identify the specific issues for which review is requested, and explain why review is or is not appropriate, under the criteria specified in paragraph (b) of this section or for some other reason.

(iv) A copy of any review request (or response to a request) must be sent promptly to each party to the appeal, the Office of the Attorney Advisor, and, as applicable, CMS, and any other affected nonparty.

(2) *Exception to time for requesting review.* If a party, or nonparty, as applicable, seeks immediate review of a matter described in § 405.1875(a)(3)(i) or (a)(3)(ii) of this subpart, the request for review must be made as soon as practicable, but in no event later than 5 business days after the day the party or nonparty seeking review received notice of the ruling or subpoena. The request must state the reason(s) why the ruling was in error and the potential harm that may be caused if immediate review is not granted.

(3) *Notice of review.* (i) When the Administrator decides to review a Board decision or other matter specified in paragraphs (a)(2) or (a)(3) of this section, respectively, whether on his or

her own motion or upon request, the Administrator must send a written notice to the parties, CMS, and any other affected nonparty stating that the Board's decision is under review, and indicating the specific issues that are being considered.

(ii) The Administrator may decline to review a Board decision or other matter, or any issue in a decision or matter, even if a request for review is submitted in accordance with paragraph (c)(1) or (c)(2) of this section.

(4) *Written submissions on review.* If the Administrator accepts review of the Board's decision or other reviewable action, a party, CMS, or, another affected nonparty that requested review solely of a matter described in paragraph (a)(3)(i) or (a) (3)(ii) of this section, may tender written submissions regarding the review.

(i) The date of receipt by the Office of the Attorney Advisor of any material must be no later than 15 days after the date the party, CMS or other affected nonparty submitting comments received the Administrator's notice under paragraph (c)(3) of this section, taking review of the Board decision or other reviewable matter.

(ii) Any submission must be limited to the issues accepted for Administrator review (as identified in the notice) and be confined to the record of Board proceedings (as described in §405.1865 of this subpart). The submission may include—

(A) Argument and analysis supporting or taking exception to the Board's decision or other reviewable action;

(B) Supporting reasons, including legal citations and excerpts of record evidence, for any argument and analysis submitted under paragraph (c)(4)(ii)(A) of this section;

(C) Proposed findings of fact and conclusions of law;

(D) Rebuttal to any written submission filed previously with the Administrator in accordance with paragraph (c)(4) of this section; or

(E) A request, with supporting reasons, that the decision or other reviewable action be remanded to the Board.

(d) *Ex parte communications prohibited.* The Administrator does not consider any communication that does not meet the following requirements or is not submitted within the required time limits. All communications from any party, CMS, or other affected nonparty, concerning a Board decision (or other reviewable action) that is being reviewed or may be reviewed by the Administrator must—

(1) Be in writing.

(2) Contain a certification that copies were served on all other parties, CMS, and any other affected nonparty, as applicable.

(3) Include, but are not limited to—

(i) Requests for review and responses to requests for review submitted under paragraph (c)(1) or (c)(2) of this section; and

(ii) Written submissions regarding review submitted under paragraph (c)(4) of this section.

(e) *Administrator's decision.* (1) Upon completion of any review, the Administrator may render a written decision that—

(i) For purposes of review of a Board decision specified in paragraph (a)(2) of this section, affirms, reverses, or modifies the Board's decision, or vacates that decision and remands the case to the Board for further proceedings in accordance with paragraph (f)(1)(i) of this section; or

(ii) For purposes of review of a matter described in paragraph (a)(3) of this section, affirms, reverses, modifies, or remands the Board's discovery or disclosure ruling, or subpoena, as applicable, and remands the case to the Board for further proceedings in accordance with paragraph (f)(1)(ii) of this section.

(2) The date of rendering of any decision by the Administrator must be no later than 60 days after the date of receipt by the provider of the Board's decision or other reviewable action. The Administrator must promptly send a copy of his or her decision to the Board, to each party to the appeal, to CMS, and, if applicable, to any other affected nonparty.

(3) Any decision by the Administrator may rely on—

(i) Applicable provisions of the law, regulations, CMS Rulings, and other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(ii) Prior decisions of the Board, the Administrator, and the courts, and any other law that the Administrator finds applicable, whether or not cited in materials submitted to the Administrator.

(iii) The administrative record for the case (as described in § 405.1865 of this subpart).

(iv) Generally known facts that are not subject to reasonable dispute.

(4) A timely decision by the Administrator that affirms, reverses, or modifies one of the Board decisions specified in paragraph (a)(2) of this section is final and binding on each party to the Board appeal (as described in § 405.1877(a)(4) of this subpart).

(i) If the final Administrator decision follows review of a Board hearing decision, the Administrator's decision is subject to the provisions of § 405.1803(d) of this subpart, unless that final decision is the subject of judicial review (as described in § 405.1877 of this subpart).

(ii) The Administrator, in accordance with §§ 405.1885 through 405.1889 of this subpart, may reopen and revise a final Administrator decision.

(iii) A decision by the Administrator remanding a matter to the Board for further proceedings in accordance with paragraph (f) of this section is not a final decision for purposes of judicial review (as described in § 405.1877(a)(4) of this subpart) or the provisions of § 405.1803(d).

(f) *Remand.* (1) A remand to the Board by the Administrator has the effect for purposes of review—

(i) With respect to a Board decision specified in paragraph (a)(2) of this section, vacating the Board's decision and requiring further proceedings in accordance with the Administrator's decision and this subpart; or

(ii) With respect to a matter described in paragraph (a)(3) of this section, affirming, reversing, modifying, or remanding the Board's remand order, discovery ruling, or subpoena, as applicable, and returning the case to the Board for further proceedings in accordance with the Administrator's decision and this subpart.

(2) The Administrator may direct the Board to take further action for the development of additional facts or new issues, or to consider the applicability of laws or regulations other than those considered by the Board. The following are not acceptable bases for remand:

(i) Presentation of evidence existing at the time of the Board hearing that was known or reasonably may be known.

(ii) Introduction of a favorable court ruling, regardless of whether the ruling was made or was available at the time of the Board hearing or at the time the Board issued its decision.

(iii) Change in a party's representation, regardless when made.

(iv) Presentation of an alternative legal basis concerning an issue in dispute.

(v) Attempted retraction of a waiver of a right, regardless when made.

(3) After remand, the Board must take the actions required in the Administrator's remand order and issue a new decision in accordance with paragraph (f)(1)(i) of this section, or issue under paragraph (f)(1)(ii) of this section an initial decision or a further remand order, discovery ruling, or subpoena ruling, as applicable.

(4) Administrator review of any decision or other action by the Board after remand is, to the extent applicable, subject to the provisions of paragraphs (a)(2) or (a)(3) of this section.

(5) In addition to ordering a remand to the Board, the Administrator may order a remand to any component of HHS or CMS or to a contractor under appropriate circumstances, including, but not limited to, for the purpose of effectuating a court order (as described in § 405.1877(g)(2) of this subpart). When the contractor's denial of the relief, that the provider sought before the Board and that is under review by the Administrator, was based on procedural grounds (such as the alleged failure of the provider to satisfy a time limit) or was based on the alleged failure to supply adequate documentation to support the provider's claim, and the Administrator rules that the basis of the contractor's denial is invalid, the Administrator remands to the contractor for the contractor to make a determination on the merits of the provider's claim.

[73 FR 30262, May 23, 2008; 73 FR 49356, 49357, Aug. 21, 2008, as amended at 80 FR 70602, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1877 Judicial review.

(a) *Basis and scope.* (1) Notwithstanding the provisions of 5 U.S.C. 704 or any other provision of law, sections 205(h) and 1872 of the Act provide that a decision or other action by a reviewing entity is subject to judicial review solely to the extent authorized by section 1878(f)(1) of the Act. This section, along with the EJR provisions of § 405.1842 of this subpart, implements section 1878(f)(1) of the Act.

(2) Section 1878(f)(1) of the Act provides that a provider has a right to obtain judicial review of a final decision of the Board, or of a timely reversal, affirmation, or modification by the Administrator of a final Board decision, by filing a civil action in accordance with the Federal Rules of Civil Procedure in a Federal district court with venue no later than 60 days after the date of receipt by the provider of a final Board decision or a reversal, affirmation, or modification by the Administrator. The Secretary (and not the Administrator or CMS itself, or the contractor) is the only proper defendant in a civil action brought under section 1878(f)(1) of the Act.

(3) A Board decision is final and subject to judicial review under section 1878(f)(1) of the Act only if the decision—

(i) Is one of the Board decisions specified in § 405.1875(a)(2)(i) through (a)(2)(iii) of this subpart or, in a particular case, is deemed to be final by the Administrator under § 405.1875(a)(2)(iv) of this subpart; and

(ii) Is not reversed, affirmed, modified, or remanded by the Administrator under §§ 405.1875(e) and 405.1875(f) of this subpart within 60 days of the date of receipt by the provider of the Board's decision. A provider is not required to seek Administrator review under § 405.1875(c) first in order to seek judicial review of a Board decision that is final and subject to judicial review under section 1878(f)(1) of the Act.

(4) If the Administrator timely reverses, affirms, or modifies one of the Board decisions specified in § 405.1875(a)(2)(i) through (a)(2)(iii) of this subpart or deemed to be final by the Administrator in a particular case under § 405.1875(a)(2)(iv) of this subpart, the Administrator's reversal, affirmation, or modification is the only decision subject to judicial review under section 1878(f)(1) of the Act. A remand of a Board decision by the Administrator to the Board vacates the decision. Neither the Board's decision nor the Administrator's remand is a final decision subject to judicial review under section 1878(f)(1) of the Act (as described in § 405.1875(e)(4), § 405.1875(f)(1), and § 405.1875(f)(4) of this subpart).

(b) *Determining when a civil action may be filed*—(1) *General rule.* Under section 1878(f)(1) of the Act, the 60-day periods for Administrator review of a decision by the Board, and for judicial review of any final Board decision, respectively, both begin to run on the same day. Paragraphs (b)(2), (b)(3) and (b)(4) of this section identify how various actions or inaction by the Administrator within the 60-day review period determine the scope and timing of any right a provider may have to judicial review under section 1878(f)(1) of the Act.

(2) *Administrator declines review.* If the Administrator declines any review of a Board decision specified in § 405.1875(a)(2) of this subpart, whether through inaction or in a written notice issued under § 405.1875(c)(3) of this subpart, the provider must file any civil action seeking judicial review of the Board's final decision under section 1878(f)(1) of the Act no later than 60 days after the date of receipt by the provider of the Board's decision.

(3) *Administrator accepts review and renders timely decision.* When the Administrator decides to review, in a notice under § 405.1875(c)(3) of this subpart, any issue in a Board decision specified as final, or deemed as final by the Administrator, under § 405.1875(a)(2) of this subpart, and he or she subsequently renders a decision within the 60-day review period (as described in § 405.1875(a)(1) of this subpart), the provider has no right to obtain judicial review of the Board's decision under section 1878(f)(1) of the Act.

(i) If the Administrator timely reverses, affirms, or modifies the Board's decision, the provider's only right under section 1878(f)(1) of the Act is to request judicial review of the Administrator's decision by filing a civil action no later than 60 days after the date of

receipt by the provider of the Administrator's decision (as described in § 405.1877(a)(3) of this subpart).

(ii) If the Administrator timely vacates the Board's decision and remands for further proceedings (as described in § 405.1875(f)(1)(i) of this subpart), a provider has no right to judicial review under section 1878(f)(1) of the Act of the Board's decision or of the Administrator's remand (as described in § 405.1877(a)(3) of this subpart).

(4) *Administrator accepts review and timely decision is not rendered.* If the Administrator decides to review, in a notice under § 405.1875(c)(3) of this subpart, any issue in a Board decision specified as final, or deemed to be final by the Administrator, under § 405.1875(a)(2), but he or she does not render a decision within the 60-day review period, this subsequent inaction constitutes an affirmation of the Board's decision by the Administrator, for purposes of the time in which to seek judicial review. In this case, the provider must file any civil action requesting judicial review of the Administrator's final decision under section 1878(f)(1) of the Act no later than 60 days after the expiration of the 60-day period for a decision by the Administrator under § 405.1875(a)(1) and § 405.1875(e)(2) of this subpart.

(c) *Statutory limitations on and preclusion of judicial review.* The Act limits or precludes judicial review of certain matters at issue. Limitations on and preclusions of judicial review include the following:

(1) A finding in a contractor determination that expenses incurred for items and services furnished by a provider to an individual are not payable under title XVIII of the Act because those items or services are excluded from coverage under section 1862 of the Act, and the regulations at 42 CFR part 411, is not reviewable by the Board (as described in § 405.1840(b)(1) of this subpart) and is not subject to judicial review under section 1878(f)(1) of the Act; the finding is subject to judicial review solely in accordance with the applicable provisions of sections 1155, 1869, and 1879(d) of the Act, and of subpart I of part 405 and subpart B of part 478, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system are completely removed from administrative and judicial review, as provided in section 1886(d)(7) of the Act, and §§ 405.1804 and 405.1840(b)(2) of this subpart.

(3) Any Board remand order, or discovery or disclosure ruling or subpoena specified in § 405.1875(a)(3)(i) through (a)(3)(ii) of this subpart, or a decision by the Administrator following immediate review of a Board remand order, discovery ruling, or subpoena, is not subject to immediate judicial review under section 1878(f)(1) of the Act. Judicial review of all nonfinal Board actions, including any such Board remand order, discovery or disclosure ruling, or subpoena (except as provided in § 405.1857(e) of this subpart), is limited to review of a final agency decision as described in § 405.1877(a) of this subpart.

(d) *Group appeals.* If a final decision is issued by the Board or rendered by the Administrator, as applicable, in any group appeal brought under § 405.1837, those providers in the group appeal that seek judicial review of the final decision under section 1878(f)(1) of the Act must file a civil action as a group (as described in § 405.1877(e)(2) of this subpart) for the specific matter at issue and common factual or legal question that was addressed in the final agency decision in the group appeal.

(e) *Venue for civil actions*—(1) *Single provider appeals.* A civil action under section 1878(f)(1) of the Act requesting judicial review of a final decision of the Board or the Administrator, as applicable, in a single provider appeal under § 405.1835 of this subpart must be brought in the District Court of the United States for the judicial district in which the provider is located or in the United States District Court for the District of Columbia.

(2) *Group appeals.* A civil action under section 1878(f)(1) of the Act seeking judicial review of a final decision of the Board or the Administrator, as applicable, in a group appeal under § 405.1837 of this subpart must be brought in the District Court of the United States for the judicial district in which the greatest number of providers participating

in both the group appeal and the civil action are located or in the United States District Court for the District of Columbia.

(f) *Service of process.* Process must be served as described under 45 CFR part 4.

(g) *Remand by a court*—(1) *General rule.* Under section 1874 of the Act, and §421.5(b) of this chapter, the Secretary is the real party in interest in a civil action seeking relief under title XVIII of the Act. The Secretary has delegated to the Administrator the authority under section 1878(f)(1) of the Act to review decisions of the Board and, as applicable, render a final agency decision. If a court, in a civil action brought by a provider against the Secretary as the real party in interest regarding a matter pertaining to Medicare payment to the provider, orders a remand for further action by the Secretary, any component of HHS or CMS, or the contractor, the remand order must be deemed, except as provided in paragraph (g)(3) of this section, to be directed to the Administrator in the first instance, regardless of whether the court's remand order refers to the Secretary, the Administrator, the Board, any other component of HHS or CMS, or the contractor.

(2) *Procedures.* (i) Upon receiving notification of a court remand order, the Administrator must prepare an appropriate remand order and, if applicable, file the order in any Board appeal at issue in the civil action.

(ii) The Administrator's remand order must—

(A) Describe the specific requirements of the court's remand order;

(B) Require compliance with those requirements by the pertinent component of HHS or CMS or by the contractor, as applicable; and

(C) Remand the matter to the appropriate entity for further action.

(iii) After the entity named in the Administrator's remand order completes its response to that order, the entity's response after remand is subject to further proceedings before the Board or the Administrator, as applicable, in accordance with this subpart. For example—

(A) If the contractor issues a revised contractor determination after remand, the provider may request a Board hearing on the revised determination (as described in §§405.1803(d) and 405.1889 of this subpart); or,

(B) If the contractor hearing officer(s) or the Board issues a new decision after remand, a decision may be reviewed by a CMS reviewing official or the Administrator, respectively (as described in §§405.1834 and 405.1875(f)(4) of this subpart).

(3) *Exception.* The provisions of paragraphs (g)(1) and (g)(2) of this section do not apply to the extent they may be inconsistent with the court's remand order or any other order of the court regarding the civil action.

(h) *Implementation of final court judgment.* (1) When a final, non-appealable court judgment is issued in a civil action brought by a provider against the Secretary as the real party in interest regarding a matter affecting Medicare payment, a court judgment is subject to the provisions of §405.1803(d) of this subpart.

(2) The provisions of paragraph (h)(1) of this section do not apply to the extent they may be inconsistent with the court's final judgment or any other order of a court regarding the civil action.

[73 FR 30264, May 23, 2008]

§405.1881 Appointment of representative.

A provider or other party may be represented by legal counsel or any other person it appoints to act as its representative at the proceedings, conducted in accordance with §§405.1819 and 405.1851.

§405.1883 Authority of representative.

A representative appointed by a provider or other party may accept or give on behalf of the provider or other party any request or notice relative to any proceeding before a hearing officer or the Board. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to a request for a contractor hearing or a Board hearing made in accordance with §405.1811, §405.1835, or §405.1837 to the same extent as the

party he represents. Notice to a provider or other party of any action, determination, or decision, or a request for the production of evidence by a hearing officer or the Board sent to the representative of the provider or other party shall have the same force and effect as if it had been sent to the provider or other party.

§ 405.1885 Reopening a contractor determination or reviewing entity decision.

(a) *General.* (1) A Secretary determination, a contractor determination, or a decision by a reviewing entity (as described in § 405.1801(a)) may be reopened, with respect to specific findings on matters at issue in a determination or decision, by CMS (with respect to Secretary determinations), by the contractor (with respect to contractor determinations), or by the reviewing entity that made the decision (as described in paragraph (c) of this section).

(i) A specific finding on a matter at issue may be legal or factual in nature or a mixed matter of both law and fact.

(ii) A specific finding on a matter at issue may include a factual matter that arose in or was determined for the same cost reporting period as the period at issue in an appeal filed, or a reopening requested by a provider or initiated by a contractor, under this subpart.

(iii) A specific finding on a matter at issue may include a predicate fact, which is a finding of fact based on a factual matter that first arose in or was first determined for a cost reporting period that predates the period at issue (in an appeal filed, or a reopening requested by a provider or initiated by a contractor, under this subpart), and once determined, was used to determine an aspect of the provider's reimbursement for one or more later cost reporting periods.

(iv) Except as provided for by this section, § 405.1887, and § 405.1889, a specific finding on a matter at issue may not be reopened and, if reopened, revised.

(2) A determination or decision may be reopened either through own motion of CMS (for Secretary determinations), the contractor or reviewing entity, by notifying the parties to the determination or decision (as specified in § 405.1887), or by granting the request of the provider affected by the determination or decision.

(3) A contractor's discretion to reopen or not reopen a matter is subject to a contrary directive from CMS to reopen or not reopen that matter.

(4) If CMS directs a contractor to reopen a matter, reopening is considered an own motion reopening by the contractor. A reopening may result in a revision of any matter at issue in the determination or decision.

(5) If a matter is reopened and a revised determination or decision is made, a revised determination or decision is appealable to the extent provided in § 405.1889 of this subpart.

(6) A determination or decision to reopen or not to reopen a determination or decision is not a final determination or decision within the meaning of this subpart and is not subject to further administrative review or judicial review.

(b) *Time limits*—(1) *Own motion reopening of a determination not procured by fraud or similar fault.* An own motion reopening is timely only if the notice of intent to reopen (as described in § 405.1887) is sent no later than 3 years after the date of the determination or decision that is the subject of the reopening. The date the notice is sent is presumed to be the date indicated on the notice unless it is shown by a preponderance of the evidence that the notice was sent on a later date.

(2) *Request for reopening of a determination not based on fraud or similar fault.* (i) A reopening made upon request is timely only if the request to reopen is received by CMS, the contractor, or reviewing entity, as appropriate, no later than 3 years after the date of the determination or decision that is the subject of the requested reopening. The date of receipt by CMS, the contractor, or the reviewing entity of the request to reopen is determined by applying the date of receipt presumption criteria for reviewing entities defined in § 405.1801(a), unless it is shown by clear and convincing evidence that CMS, the contractor, or the reviewing entity received the request on an earlier date.

(ii) A request to reopen does not toll the time in which to appeal an otherwise appealable determination or decision.

(iii) A request to reopen that is received within the 3-year period described in this paragraph is timely, notwithstanding that the notice of reopening required under §405.1887 of this subpart is issued after such 3-year period.

(iv) The 3-year period described in paragraphs (b)(2)(i) through (b)(2)(iii) of this section applies to, and is calculated separately for, each specific finding on a matter at issue (as described in paragraphs (a)(1)(i) through (a)(1)(iv) of this section, but not to such findings when made as part of a determination of reasonable cost under section 1861(v)(1)(A) of the Act.

(3) *Reopening of a determination procured by fraud or similar fault.* A Secretary or contractor determination or decision by the reviewing entity may be reopened and revised at any time if it is established that the determination or decision was procured by fraud or similar fault of any party to the determination or decision.

(c) *Jurisdiction for reopening.* Jurisdiction for reopening a contractor determination or contractor hearing decision rests exclusively with the contractor or contractor hearing officer(s) that rendered the determination or decision (or, when applicable, with the successor contractor), subject to a directive from CMS to reopen or not reopen the determination or decision. Jurisdiction for reopening a Secretary determination, CMS reviewing official decision, a Board decision, or an Administrator decision rests exclusively with CMS, the CMS reviewing official, Board or Administrator, respectively.

(1) *CMS-directed reopenings.* CMS may direct a contractor or contractor hearing officer(s) to reopen and revise any matter, subject to the time limits specified in paragraph (b) of this section, and subject to the limitation expressed in paragraph (c)(2) of this section, by providing explicit direction to the contractor or contractor hearing officer(s) to reopen and revise.

(i) *Examples.* A contractor determination or contractor hearing decision must be reopened and revised if CMS provides explicit notice to the contractor that the contractor determination or the contractor hearing decision is inconsistent with the applicable law, regulations, CMS ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS in effect, and as CMS understood those legal provisions, at the time the determination or decision was rendered by the contractor. CMS may also direct the contractor to reopen a particular contractor determination or decision in order to implement a final agency decision (as described in §§405.1833, 405.1871(b) and 405.1875 of this subpart), a final, non-appealable court judgment §405.1877, or an agreement to settle an administrative appeal or a lawsuit, regarding the same determination or decision.

(ii) [Reserved]

(2) *Prohibited reopenings.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS, whether made in response to judicial precedent or otherwise, is not a basis for reopening a CMS or contractor determination, a contractor hearing decision, a CMS reviewing official decision, a Board decision, or an Administrator decision, under this section.

(3) *Reopening by CMS or contractor of determination currently on appeal to the Board or Administrator.* CMS or a contractor may reopen, on its own motion or on request of the provider(s), a Secretary or contractor determination that is currently pending on appeal before the Board or Administrator.

(i) The scope of the reopening may include any matter covered by the determination, including those specific matters that are appealed to the Board or the Administrator.

(ii) The contractor must send a copy of the notice required under §405.1887(a) to the Board or to the Administrator, through the Office of the Attorney Advisor, specifically informing that the matter(s) to be addressed by the reopening is currently under appeal to the Board or to the Administrator or is

covered by the same determination that is under appeal.

(4) *Reopening of determination within the time for appealing that determination to the Board.* CMS or a contractor may reopen, on its own motion or on request of the provider(s), a Secretary or contractor determination for which no appeal was taken to the Board, but for which the time to appeal to the Board has not yet expired, by sending the notice specified in § 405.1887(a) of this subpart.

[73 FR 30265, May 23, 2008, as amended at 78 FR 75195, Dec. 10, 2013; 85 FR 59019, Sept. 18, 2020]

§ 405.1887 Notice of reopening; effect of reopening.

(a) In exercising its reopening authority under § 405.1885, CMS (for Secretary determinations), the contractor or the reviewing entity, as applicable, must provide written notice to all parties to the determination or decision that is the subject of the reopening. Notices of—

(1) Reopening by a CMS reviewing official or the Board must be sent promptly to the Administrator.

(2) Contractor reopenings of determinations that are currently pending before the Board or the Administrator must meet the requirements specified in § 405.1885(c)(3) and (c)(4) of this subpart.

(b) Upon receipt of the notice required under § 405.1887(a) of this subpart, the parties to the prior Secretary or contractor determination or decision by a reviewing entity, as applicable, must be allowed a reasonable period of time in which to present any additional evidence or argument in support of their positions.

(c) Upon concluding its reopening, CMS, the contractor or the reviewing entity, as applicable, must provide written notice promptly to all parties to the determination or decision that is the subject of the reopening, informing the parties as to what matter(s), if any, is revised, with a complete explanation of the basis for any revision.

(d) A reopening by itself does not extend appeal rights. Any matter that is reconsidered during the course of a reopening, but is not revised, is not within the proper scope of an appeal of a revised determination or decision (as described in § 405.1889 of this subpart).

[73 FR 30266, May 23, 2008]

§ 405.1889 Effect of a revision; issue-specific nature of appeals of revised determinations and decisions.

(a) If a revision is made in a Secretary or contractor determination or a decision by a reviewing entity after the determination or decision is reopened as provided in § 405.1885 of this subpart, the revision must be considered a separate and distinct determination or decision to which the provisions of §§ 405.1811, 405.1834, 405.1835, 405.1837, 405.1875, 405.1877 and 405.1885 of this subpart are applicable.

(b)(1) Only those matters that are specifically revised in a revised determination or decision are within the scope of any appeal of the revised determination or decision.

(2) Any matter that is not specifically revised (including any matter that was reopened but not revised) may not be considered in any appeal of the revised determination or decision.

[73 FR 30266, May 23, 2008]

Subparts S–T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§§ 405.2100–405.2101 [Reserved]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990; 72 FR 15273, Mar. 30, 2007; 73 FR 20473, Apr. 15, 2008; 79 FR 66261, Nov. 6, 2014]

§405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility*. The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks*. CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in §405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§405.2111 [Reserved]

§405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

(i) Self-care;

(ii) Transplants; and

(iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

§ 405.2113 Medical review board.

(a) *General.* The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members.* (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§ 405.2114 [Reserved]

§§ 405.2131–405.2184 [Reserved]

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§ 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act:

(a) Section 1833—Amounts of payment for supplementary medical insurance services.

(b) Section 1861(aa)—Rural health clinic services and Federally qualified health center services covered by the Medicare program.

(c) Section 1834(o)—Federally qualified health center prospective payment system beginning October 1, 2014.

(d) Section 1834(y)—Payment for certain services furnished by rural health clinics.

[79 FR 25473, May 2, 2014, as amended at 88 FR 82176, Nov. 22, 2023]

§ 405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

Allowable costs means costs that are incurred by a RHC or FQHC that is authorized to bill based on reasonable costs and are reasonable in amount and proper and necessary for the efficient delivery of RHC and FQHC services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Certified nurse midwife (CNM) means an individual who meets the applicable education, training, and other requirements of § 410.77(a) of this chapter.

Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter.

Clinical social worker (CSW) means an individual who meets the applicable education, training, and other requirements of § 410.73(a) of this chapter.

CMS stands for Centers for Medicare & Medicaid Services.

Coinsurance means that portion of the RHC's charge for covered services or that portion of the FQHC's charge or PPS rate for covered services for which the beneficiary is liable (in addition to the deductible, where applicable).

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means the amount incurred by the beneficiary during a calendar year as specified in § 410.160 and § 410.161 of this chapter.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of

section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under § 405.2434 and—

(1) Is receiving a grant under section 330 of the Public Health Service (PHS) Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 330 of the PHS Act;

(2) Is determined by the HRSA to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of Medicare Part B, as a comprehensive federally funded health center as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

HRSA means the Health Resources and Services Administration.

Intensive outpatient services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and that furnishes the services as described in § 410.44 of this chapter.

Marriage and family therapist (MFT) means an individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter.

Medicare Administrative Contractor (MAC) means an organization that has a contract with the Secretary to administer the benefits covered by this subpart as described in § 421.404 of this chapter.

Mental health counselor (MHC) means an individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

Nurse practitioner (NP) means individuals who meet the applicable education, training, and other requirements of § 410.75(b) of this chapter.

Physician assistant (PA) means an individual who meet the applicable education, training, and other requirements of § 410.74(c) of this chapter.

Prospective payment system (PPS) means a method of payment in which Medicare payment is made based on a predetermined, fixed amount.

Reporting period generally means a period of 12 consecutive months specified by the MAC as the period for which a RHC or FQHC must report required costs and utilization information. The first and last reporting periods may be less than 12 months.

Rural health clinic (RHC) means a facility that has—

(1) Been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval; and

(2) Filed an agreement with CMS that meets the requirements in § 405.2402 to provide RHC services under Medicare.

Secretary means the Secretary of Health and Human Services or his or her delegate.

Visiting nurse services means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395*l*, 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996; 69 FR 74815, Dec. 24, 2003; 71 FR 55345, Sept. 22, 2006; 79 FR 25473, May 2, 2014; 83 FR 60072, Nov. 23, 2018; 88 FR 79523, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2402 Rural health clinic basic requirements.

(a) *Certification by the State survey agency.* The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish RHC services.* If the Secretary, after reviewing the survey agency or accrediting organization recommendation, as applicable, and other evidence relating to the qualifications of the clinic, determines that the clinic meets the requirements of this subpart and of part 491 of this chapter, the clinic is provided with—

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the clinic.* If the clinic wishes to participate in the program, it must—

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the clinic, the Secretary returns to the clinic one copy of the agreement with a notice of acceptance specifying the effective date.

(e) *Appeal rights.* If CMS declines to enter into an agreement or if CMS terminates an agreement, the clinic is entitled to a hearing in accordance with § 498.3(b)(5) and (6) of this chapter.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987; 79 FR 25474, May 2, 2014]

§ 405.2403 Rural health clinic content and terms of the agreement with the Secretary.

(a) Under the agreement, the RHC agrees to the following:

(1) *Maintaining compliance with conditions.* The RHC agrees to maintain compliance with the conditions set forth in part 491 of this chapter and to report promptly to CMS any failure to do so.

(2) *Charges to beneficiaries.* The RHC agrees not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part (or for which the beneficiary would have been entitled if the RHC had filed a request for payment in accordance with § 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under § 405.2410.

(3) *Refunds to beneficiaries.* (i) The RHC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, *money incorrectly collected* means sums collected in excess of the amount for which the beneficiary was liable under § 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

(A) The beneficiary is later determined to have been entitled to Medicare benefits; and

(B) The beneficiary's entitlement period falls within the time the RHC's agreement with the Secretary is in effect.

(4) *Beneficiary treatment.* (i) The RHC agrees to accept beneficiaries for care and treatment; and

(ii) The RHC agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) *Additional provisions.* The agreement may contain any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986; 79 FR 25474, May 2, 2014]

§ 405.2404 Termination of rural health clinic agreements.

(a) *Termination by RHC*—(1) *Notice to Secretary.* If the RHC wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) *Action by the Secretary.* (i) The Secretary may approve the date proposed by the RHC, or set a different date no later than 6 months after the date of the RHC's notice.

(ii) The Secretary may approve a date which is less than 6 months after the date of notice if the Secretary determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the RHC; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Cessation of business.* If a RHC ceases to furnish services to the community, the Secretary deems it to be a voluntary termination of the agreement by the RHC, effective on the last day of business.

(b) *Termination by the Secretary*—(1) *Cause for termination.* The Secretary may terminate an agreement if he or she determines that the RHC:

(i) No longer meets the conditions for certification under part 491 of this chapter;

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

(iii) Has undergone a change of ownership.

(2) *Notice of termination.* The Secretary gives notice of termination to the RHC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the RHC.* A RHC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment will not be available for RHC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination must be given to the public by either of the following:

(1) The RHC, after the Secretary has approved or set a termination date.

(2) The Secretary, when he or she has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by the Secretary.* When an agreement with a RHC is terminated by the Secretary, the RHC may not file another agreement to participate in the Medicare program unless the Secretary:

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987; 79 FR 25474, May 2, 2014; 82 FR 38509, Aug. 14, 2017]

§ 405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for RHC services begins only after the beneficiary has incurred the deductible.

(2) Medicare payment for services covered under the FQHC benefit is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* Except for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter, a beneficiary's responsibility is either of the following:

(1) For RHCs that are authorized to bill on the basis of the reasonable cost system—

(i) A coinsurance amount that does not exceed 20 percent of the RHC's reasonable customary charge for the covered service; and

(ii)(A) The beneficiary's deductible and coinsurance amount for any one item or service furnished by the RHC may not exceed a reasonable amount customarily charged by the RHC for that particular item or service; or

(B) For any one item or service furnished by a FQHC, a coinsurance amount that does not exceed 20 percent of a reasonable customary charge by the FQHC for that particular item or service.

(2) For FQHCs authorized to bill under the PPS, a coinsurance amount which is 20 percent of the lesser of—

(i) The FQHC's actual charge; or

(ii) The FQHC PPS rate for the covered service.

(c) *Application of deductible and coinsurance for RHCs and FQHCs paid on the basis of the special payment rule described under § 405.2462(j).* (1) For RHCs, the coinsurance amount is determined as described in paragraph (b)(1) of this section; or

(2) For FQHCs, the coinsurance amount is 20 percent of the lesser of—

(i) The FQHC's actual charge; or

(ii) The payment determined under § 405.2462(j)(2).

[71 FR 55345, Sept. 22, 2006, as amended at 79 FR 25474, May 2, 2014; 80 FR 71371, Nov. 16, 2015; 88 FR 82176, Nov. 22, 2023; 89 FR 98553, Dec. 9, 2024]

§ 405.2411 Scope of benefits.

(a) The following RHC and FQHC services are reimbursable under this subpart:

(1) The physicians' services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional service.

(3) The nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(5) Visiting nurse services when provided in accordance with 1861(aa)(1) of the Act and § 405.2416.

(6) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services as specified in § 405.2450.

(7) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

(b) RHC and FQHC services are—

(1) Covered when furnished in a RHC, FQHC, or other outpatient setting, including a patient's place of residence;

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed or under contract with the RHC or FQHC at the time the services are furnished;

(3) Inclusive of hospice attending physician services, and are covered when furnished during a patient's hospice election only when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant designated by the patient as his or her attending physician and employed or under contract with the RHC or FQHC at the time the services are furnished; and

(4) Not covered in a—

(i) Hospital as defined in section 1861(e) of the Act; or

(ii) Critical access hospital as defined in section 1861(mm)(1) of the Act.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014; 86 FR 65660, Nov. 19, 2021; 88 FR 79523, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2412 Physicians' services.

Physicians' services are professional services that are furnished by either of the following:

(a) By a physician at the RHC or FQHC.

(b) Outside of the RHC or FQHC by a physician whose agreement with the RHC or FQHC provides that he or she will be paid by the RHC or FQHC for such services and certification and cost reporting requirements are met.

[79 FR 25475, May 2, 2014]

§ 405.2413 Services and supplies incident to a physician's services.

(a) Services and supplies incident to a physician's professional service are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the RHC's or FQHC's bill;

(3) Furnished as an incidental, although integral, part of a physician's professional services;

(4) Services and supplies must be furnished in accordance with applicable State law; and

(5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care Model, and behavioral health services can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

[43 FR 8261, Mar. 1, 1978, as amended at 78 FR 74810, Dec. 10, 2013; 79 FR 25475, May 2, 2014; 79 FR 68001, Nov. 13, 2014; 81 FR 80552, Nov. 15, 2016; 82 FR 53358, Nov. 15, 2017; 88 FR 79523, Nov. 16, 2023]

§ 405.2414 Nurse practitioner, physician assistant, and certified nurse midwife services.

(a) Professional services are payable under this subpart if the services meet all of the following:

(1) Furnished by a nurse practitioner, physician assistant, or certified nurse midwife who is employed by, or receives compensation from, the RHC or FQHC.

(2) Furnished under the medical supervision of a physician.

(3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician.

(4) Are of a type which the nurse practitioner, physician assistant or certified nurse midwife who furnished the service is legally permitted to perform by the State in which the service is rendered.

(5) The services would be covered if furnished by a physician.

(b) The physician supervision requirement is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of nurse practitioners, physician assistants or certified nurse midwives are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014]

§ 405.2415 Incident to services and direct supervision.

(a) Services and supplies incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor are payable under this subpart if the service or supply is all of the following:

(1) Of a type commonly furnished in physicians' offices.

(2) Of a type commonly rendered either without charge or included in the RHC's or FQHC's bill.

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, certified nurse-midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(4) Furnished in accordance with applicable State law.

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care model, and behavioral health services can be furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) The direct supervision requirement is met in the case of any of the following persons only if the person is permitted to supervise these services under the written policies governing the RHC or FQHC:

(1) Nurse practitioner.

(2) Physician assistant.

(3) Certified nurse-midwife.

(4) Clinical psychologist.

(5) Clinical social worker.

(6) Marriage and family therapist.

(7) Mental health counselor.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

[79 FR 25475, May 2, 2014, as amended at 79 FR 68001, Nov. 13, 2014; 81 FR 80552, Nov. 15, 2016; 82 FR 53358, Nov. 15, 2017; 88 FR 79523, Nov. 16, 2023]

§ 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if the services meet all of the following:

(1) The RHC or FQHC is located in an area in which the Secretary has determined that there is a shortage of home health agencies.

(2) The services are rendered to a homebound individual.

(3) The services are furnished by a registered professional nurse or licensed practical nurse that is employed by, or receives compensation for the services from the RHC or FQHC.

(4) The services are furnished under a written plan of treatment that is both of the following:

(i)(A) Established and reviewed at least every 60 days by a supervising physician of the RHC or FQHC; or

(B)(*1*) Established by a nurse practitioner, physician assistant or certified nurse midwife; and

(*2*) Reviewed at least every 60 days by a supervising physician.

(ii) Signed by the supervising physician, nurse practitioner, physician assistant or certified nurse midwife of the RHC or FQHC.

(5) During a PHE, as defined in § 400.200 of this chapter, an area typically served by the RHC, and an area that is included in the FQHC's service area plan, is determined to have a shortage of home health agencies, and no request for this determination is required.

(b) The nursing care covered by this section includes the following:

(1) Services that must be performed by a registered professional nurse or licensed practical nurse if the safety of the patient is to be assured and the medically desired results achieved.

(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, *homebound* means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, ''place of residence'' does not include a hospital or long term care facility.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014; 85 FR 19285, Apr. 6, 2020]

§ 405.2417 Visiting nurse services: Determination of shortage of agencies.

A shortage of home health agencies exists if the Secretary determines that the RHC or FQHC:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the RHC or FQHC.

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency.

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25476, May 2, 2014]

FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24978, June 12, 1992, unless otherwise noted.

§ 405.2430 Basic requirements.

(a) *Filing procedures.* (1) In response to a request from an entity that wishes to participate in the Medicare program, CMS enters into an agreement with an entity when all of the following occur:

(i) HRSA approves the entity as meeting the requirements of section 330 of the PHS Act.

(ii) The entity assures CMS that it meets the requirements specified in this subpart and part 491 of this chapter, as described in § 405.2434(a).

(iii) The FQHC terminates other provider agreements, unless the FQHC assures CMS that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

(2) CMS sends the entity a written notice of the disposition of the request.

(3) When the requirement of paragraph (a)(1) of this section is satisfied, CMS sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to CMS.

(4) If CMS accepts the agreement filed by the FQHC, CMS returns to the center one copy of the agreement with the notice of acceptance specifying the

effective date (see § 489.11), as determined under § 405.2434.

(b) *Prior HRSA FQHC determination.* An entity applying to become a FQHC must do the following:

(1) Be determined by HRSA as meeting the applicable requirements of the PHS Act, as specified in § 405.2401(b).

(2) Receive approval by HRSA as a FQHC under section 330 of the PHS Act (42 U.S.C. 254b).

(c) *Appeals.* An entity is entitled to a hearing in accordance with part 498 of this chapter when CMS fails to enter into an agreement with the entity.

[57 FR 24978, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25476, May 2, 2014]

§ 405.2434 Content and terms of the agreement.

Under the agreement, the FQHC must agree to the following:

(a) *Maintain compliance with the requirements.* (1) The FQHC must agree to maintain compliance with the FQHC requirements set forth in this subpart and part 491, except that the provisions of § 491.3 do not apply.

(2) FQHCs must promptly report to CMS any changes that result in noncompliance with any of these requirements.

(b) *Effective date of agreement.* The effective date of the agreement is determined in accordance with the provisions of § 489.13 of this chapter.

(c) *Charges to beneficiaries.* (1) For non-FQHC services that are billed to Part B, the beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the FQHC for the covered services.

(2) The beneficiary is responsible for blood deductible expenses, as specified in § 410.161.

(3) The FQHC agrees not to charge the beneficiary (or any other person acting on behalf of a beneficiary) for any FQHC services for which the beneficiary is entitled to have payment made on his or her behalf by the Medicare program (or for which the beneficiary would have been entitled if the FQHC had filed a request for payment in accordance with § 410.165 of this chapter), except for coinsurance amounts.

(4) The FQHC may charge the beneficiary for items and services that are not FQHC services. If the item or service is covered under Medicare Part B, the FQHC may not charge the beneficiary more than 20 percent of the Part B payment amount.

(d) *Refunds to beneficiaries.* (1) The FQHC must agree to refund as promptly as possible any money incorrectly collected from Medicare beneficiaries or from someone on their behalf.

(2) As used in this section, ''money incorrectly collected'' means any amount for covered services that is greater than the amount for which the beneficiary was liable because of the coinsurance requirements specified in part 410, subpart E.

(3) Amounts also are considered incorrectly collected if the FQHC believed the beneficiary was not entitled to Medicare benefits but—

(i) The beneficiary was later determined to have been so entitled;

(ii) The beneficiary's entitlement period fell within the time the FQHC's agreement with CMS was in effect; and

(iii) The amounts exceed the beneficiary's coinsurance liability.

(e) *Treatment of beneficiaries.* (1) The FQHC must agree to accept Medicare beneficiaries for care and treatment.

(2) The FQHC may not impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose upon all other persons seeking care and treatment from the FQHC. Failure to comply with this requirement is a cause for termination of the FQHC's agreement with CMS in accordance with § 405.2436(d).

(3) If the FQHC does not furnish treatment for certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

§ 405.2436 Termination of agreement.

(a) *Termination by FQHC.* The FQHC may terminate its agreement by—

(1) Filing with CMS a written notice stating its intention to terminate the agreement; and

(2) Notifying CMS of the date on which the FQHC requests that the termination take effect.

(b) *Effective date.* (1) Upon receiving a FQHC's notice of intention to terminate the agreement, CMS will set a date upon which the termination takes effect. This effective date may be—

(i) The date proposed by the FQHC in its notice of intention to terminate, if that date is acceptable to CMS; or

(ii) Except as specified in paragraph (2) of this section, a date set by CMS, which is no later than 6 months after the date CMS receives the FQHC's notice of intention to terminate.

(2) The effective date of termination may be less than 6 months following CMS's receipt of the FQHC's notice of intention to terminate if CMS determines that termination on such a date would not—

(i) Unduly disrupt the furnishing of FQHC services to the community; or

(ii) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) The termination is effective at the end of the last day of business as a FQHC.

(c) *Termination by CMS.* (1) CMS may terminate an agreement with a FQHC if it finds that the FQHC—

(i) No longer meets the requirements specified in this subpart; or

(ii) Is not in substantial compliance with—

(A) The provisions of the agreement; or

(B) The requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act.

(2) *Notice by CMS.* CMS will notify the FQHC in writing of its intention to terminate an agreement at least 15 days before the effective date stated in the written notice.

(3) *Appeal.* A FQHC may appeal CMS's decision to terminate the agreement in accordance with part 498 of this chapter.

(d) *Effect of termination.* When a FQHC's agreement is terminated whether by the FQHC or CMS, payment will not be available for FQHC services furnished on or after the effective date of termination.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

§ 405.2440 Conditions for reinstatement after termination by CMS.

When CMS has terminated an agreement with a FQHC, CMS does not enter into another agreement with the FQHC to participate in the Medicare program unless CMS—

(a) Finds that the reason for the termination no longer exists; and

(b) Is assured that the reason for the termination of the prior agreement will not recur.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

§ 405.2442 Notice to the public.

(a) When the FQHC voluntarily terminates the agreement and an effective date is set for the termination, the FQHC must notify the public in the area serviced by the FQHC prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set. The notice must include—

(1) Effective date of termination of the provision of services; and

(2) Effect of termination of the agreement.

(b) When CMS terminates the agreement, CMS will notify the public in the area serviced by the FQHC.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014; 82 FR 38509, Aug. 14, 2017]

§ 405.2444 Change of ownership.

(a) *What constitutes change of ownership*—(1) *Incorporation.* The incorporation of an unincorporated FQHC constitutes change of ownership.

(2) *Merger.* The merger of the FQHC corporation into another corporation, or the consolidation of two or more corporations, one of which is the FQHC corporation, resulting in the creation of a new corporation, constitutes a change of ownership. (The merger of another corporation into the FQHC corporation does not constitute change of ownership.)

(3) *Leasing*. The lease of all or part of an entity constitutes a change of ownership of the leased portion.

(b) *Notice to CMS*. A FQHC which is contemplating or negotiating change of ownership must notify CMS.

(c) *Assignment of agreement*. When there is a change of ownership as specified in paragraph (a) of this section, the agreement with the existing FQHC is automatically assigned to the new owner if it continues to meet the conditions to be a FQHC.

(d) *Conditions that apply to assigned agreements*. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Compliance with applicable health and safety standards.

(2) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C of this subchapter.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

§ 405.2446 Scope of services.

(a) For purposes of this section, the terms rural health clinic and RHC when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers and FQHCs.

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as incident to a physician's professional service, as specified in § 405.2413.

(3) Nurse practitioner, physician assistant or certified nurse midwife services as specified in § 405.2414.

(4) Services and supplies furnished as incident to a nurse practitioner, physician assistant, or certified nurse midwife service, as specified in § 405.2415.

(5) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services specified in § 405.2450.

(6) Services and supplies furnished as incident to the services of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Preventive primary services specified in § 405.2448 of this subpart.

(9) Medical nutrition therapy services as specified in part 410, subpart G of this chapter, and diabetes outpatient self-management training services as specified in part 410, subpart H of this chapter.

(10) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

(c) FQHC services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility, other institution used as a patient's home, or are hospice attending physician services furnished during a hospice election.

(d) FQHC services are not covered in a hospital, as defined in section 1861(e)(1) of the Act.

[57 FR 24979, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 71 FR 69782, Dec. 1, 2006; 79 FR 25476, May 2, 2014; 86 FR 65660, Nov. 19, 2021; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2448 Preventive primary services.

(a) Preventive primary services are those health services that—

(1) A FQHC is required to provide as preventive primary health services under section 330 of the PHS Act; and

(2) Are furnished by a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed by or under contract with the FQHC.

(i) By a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor; or

(ii) By a member of the FQHC's health care staff who is an employee of the FQHC or by a physician under arrangements with the FQHC.

(3) Except as specifically provided in section 1861(s) of the Act, include only drugs and biologicals that cannot be self-administered.

(b) Preventive primary services which may be paid for when provided by FQHCs are the following:

(1) Medical social services.

(2) Nutritional assessment and referral.

(3) Preventive health education.

(4) Children's eye and ear examinations.

(5) Prenatal and post-partum care.

(6) Perinatal services.

(7) Well child care, including periodic screening.

(8) Immunizations, including tetanus-diptheria booster and influenza vaccine.

(9) Voluntary family planning services.

(10) Taking patient history.

(11) Blood pressure measurement.

(12) Weight.

(13) Physical examination targeted to risk.

(14) Visual acuity screening.

(15) Hearing screening.

(16) Cholesterol screening.

(17) Stool testing for occult blood.

(18) Dipstick urinalysis.

(19) Risk assessment and initial counseling regarding risks.

(20) Tuberculosis testing for high risk patients.

(21) For women only.

(i) Clinical breast exam.

(ii) Referral for mammography; and

(iii) Thyroid function test.

(c) Preventive primary services do not include group or mass information programs, health education classes, or group education activities, including media productions and publications.

(d) Screening mammography is not considered a FQHC service, but may be provided at a FQHC if the FQHC if the center meets the requirements applicable to that service specified in § 410.34 of this subchapter. Payment is made under applicable Medicare requirements.

(e) Preventive primary services do not include eyeglasses, hearing aids, or preventive dental services.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25477, May 2, 2014; 80 FR 71371, Nov. 16, 2015; 88 FR 79524, Nov. 16, 2023]

§ 405.2449 Preventive services.

For services furnished on or after January 1, 2011, preventive services covered under the Medicare FQHC benefit are those preventive services defined in section 1861(ddd)(3) of the Act, and § 410.2 of this chapter. Specifically, these include the following:

(a) The specific services currently listed in section 1861(ww)(2) of the Act, with the explicit exclusion of electrocardiograms.

(b) The Initial Preventive Physical Examination (IPPE) (as specified by section 1861(ww)(1) of the Act as added by section 611 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173) and § 410.16 of this chapter).

(c) The Personalized Prevention Plan Services (PPPS), also known as the ''Annual Wellness Visit'' (as specified by section 1861(hhh) of the Act as added by section 4103 of the Affordable Care Act (Pub. L. 111–148) and § 410.15 of this chapter).

[75 FR 73613, Nov. 29, 2010, as amended at 79 FR 25477, May 2, 2014]

§ 405.2450 Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) For clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor professional services to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

(2) Of a type that the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker, clinical psychologist, marriage

and family therapist, or mental health counselor who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

(4) Covered if furnished by a physician.

(b) If State law prescribes a physician supervision requirement, it is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of clinical psychologists, clinical social workers, marriage and family therapist, or mental health counselors are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 88 FR 79524, Nov. 16, 2023]

§ 405.2452 Services and supplies incident to clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) Services and supplies incident to a clinical psychologist's, clinical social worker's, marriage and family therapist's, and mental health counselor's services are reimbursable under this subpart if the service or supply is —

(1) Of a type commonly furnished in a physician's office;

(2) Of a type commonly furnished either without charge or included in the FQHC's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor;

(4) Services and supplies must be furnished in accordance with applicable State law; and

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor is permitted to supervise such services under the written policies governing the FQHC.

[43 FR 8261, Mar. 1, 1978, as amended at 78 FR 74810, Dec. 10, 2013; 79 FR 25477, May 2, 2014; 79 FR 68001, Nov. 13, 2014; 88 FR 79524, Nov. 16, 2023]

Payment for Rural Health Clinic and Federally Qualified Health Center Services

SOURCE: 57 FR 24976, 24977, June 12, 1992, unless otherwise noted.

§ 405.2460 Applicability of general payment exclusions.

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for services provided by RHCs and FQHCs, except that preventive primary services, as defined in § 405.2448, are statutorily authorized for FQHCs and not excluded by the provisions of section 1862(a) of the Act.

[79 FR 25477, May 2, 2014]

§ 405.2462 Payment for RHC and FQHC services.

(a) *Payment to independent RHCs that are authorized to bill under the reasonable cost system.* (1) RHCs that are authorized to bill under the reasonable cost system are paid on the basis of an all-inclusive rate, subject to a payment limit per visit determined in paragraph (b) of this section, for each beneficiary visit for covered services. This rate is determined by the Medicare Administration Contractor (MAC), in accordance with this subpart and general instructions issued by CMS.

(2) The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(b) *RHC payment limit per visit.* (1) In establishing limits on payment for rural health clinic services provided by rural health clinics the limit for services provided prior to April 1, 2021:

(i) In 1988, after March 31, at $46 per visit; and

(ii) In a subsequent year (before April 1, 2021), at the limit established for the previous year increased by the percentage increase in the Medicare Economic Index (MEI) (as defined in section

1842(i)(3) of the Act) applicable to primary care services (as defined in section 1842(i)(4) of the Act) furnished as of the first day of that year.

(2) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by rural health clinics or any rural health clinic that is enrolled on or after January 1, 2021 under section 1866(j) of the Act), the limit for services provided:

(i) In 2021, after March 31, at $100 per visit;

(ii) In 2022, at $113 per visit;

(iii) In 2023, at $126 per visit;

(iv) In 2024, at $139 per visit;

(v) In 2025, at $152 per visit;

(vi) In 2026, at $165 per visit;

(vii) In 2027, at $178 per visit; and

(viii) In 2028, at $190 per visit.

(ix) In a subsequent year, at the limit established for the previous year increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such year.

(3) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by provider-based rural health clinics as described in section (c)(4) of this part, the limit for services provided:

(i) In 2021, after March 31, at an amount equal to the greater of:

(A) For rural health clinics that had an all-inclusive rate established for services furnished in 2020—

(*1*) The all-inclusive rate applicable to the rural health clinic for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021, or

(*2*) The payment limit per visit applicable in paragraph (b)(2) of this section.

(B) For rural health clinics that did not have an all-inclusive rate established for services furnished in 2020—

(*1*) The all-inclusive rate applicable to the rural health clinic for services furnished in 2021, or

(*2*) The payment limit per visit applicable in paragraph (b)(2) of this section.

(ii) In a subsequent year, at an amount equal to the greater of:

(A) The amount established under paragraph (b)(3)(i)(A) or (B) of this section, as applicable for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year, or

(B) The payment limit per visit applicable under paragraph (b)(2) of this section for such subsequent year.

(c) *Payment to provider-based RHCs that are authorized to bill under the reasonable cost system.* (1) An RHC that is authorized to bill under the reasonable cost system is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if the RHC is—

(i) An integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (that is, a provider of services); and

(ii) Operated with other departments of the provider under common licensure, governance and professional supervision.

(2) An RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraphs (b)(1) and (2) of this section, for each beneficiary visit for covered services when in a hospital with greater than 50 beds as determined in §412.105(b) of this subchapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(3) Prior to April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate and is not subject to a payment limit per visit described in paragraphs (b)(1) and (2) of this section for each beneficiary visit for covered services when in a hospital with less than 50 beds as determined in §412.105(b) of this subchapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(4) On or after April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-

inclusive rate, subject to a payment limit per visit, described in paragraph (b)(3) of this section, for each beneficiary visit for covered services when it meets the specified qualifications in paragraph(d) of this section. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(d) *Specified qualifications.* A provider-based rural health clinic must meet the following qualifications to have a payment limit per visit established in accordance with paragraph (b)(3) of this section.

(1) As of December 31, 2020, was in a hospital with less than 50 beds (as determined in §412.105(b) of this subchapter) and after December 31, 2020, in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the COVID–19 Public Health Emergency (PHE)); and one of the following circumstances:

(i) As of December 31, 2020, was enrolled under section 1866(j) of the Act (including temporary enrollment during the COVID–19 PHE); or

(ii) Submitted an application for enrollment under section 1866(j) of the Act (or a request for temporary enrollment during the COVID–19 PHE) that was received not later than December 31, 2020.

(2) [Reserved]

(e) *Payment to FQHCs that are authorized to bill under the PPS.* A FQHC that is authorized to bill under the PPS is paid a single, per diem rate based on the prospectively set rate for each beneficiary visit for covered services. Except as noted in paragraph (f) of this section, this rate is adjusted for the following:

(1) Geographic differences in cost based on the Geographic Practice Cost Indices (GPCIs) in accordance with section 1848(e) of the Act and 42 CFR 414.2 and 414.26 are used to adjust payment under the physician fee schedule during the same period, limited to only the work and practice expense GPCIs.

(2) Furnishing of care to a beneficiary that is a new patient with respect to the FQHC, including all sites that are part of the FQHC. A new patient is one that has not been treated by the FQHC's organization within the previous 3 years.

(3) Furnishing of care to a beneficiary receiving a comprehensive initial Medicare visit (that is an initial preventive physical examination or an initial annual wellness visit) or a subsequent annual wellness visit.

(f) *Payment to historically excepted tribal FQHCs.* (1) A ''historically excepted tribal FQHC'' is a FQHC that:

(i) Is operated by a tribe or tribal organization under the Indian Self-Determination Education and Assistance Act (ISDEAA);

(ii) Was billing as if it were provider-based to an IHS hospital on or before April 7, 2000; and

(iii) Is not operating as a provider-based department of an IHS hospital.

(2) A historically excepted tribal FQHC is paid at the Medicare outpatient per visit rate as set annually by the IHS.

(3) The payment rate is not adjusted:

(i) By the FQHC Geographic Adjustment Factor;

(ii) For new patients, annual wellness visits, or initial preventive physical examinations; or

(iii) Annually by the Medicare Economic Index or a FQHC PPS market basket.

(4) The payment rate is adjusted annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Pub. L. 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

(g)(1) Except for preventive services for which Medicare pays 100 percent under §410.152(l) of this chapter, Medicare pays—

(i) Eighty (80) percent of the lesser of the FQHC's actual charge or the PPS encounter rate for FQHCs authorized to bill under the PPS; or

(ii) Eighty (80) percent of the lesser of a historically excepted tribal FQHC's actual charge, or the outpatient rate for Medicare as set annually by the IHS for historically excepted tribal FQHCs that are authorized to bill at this rate.

(2) No deductible is applicable to FQHC services.

(h) For RHCs visits, payment is made in accordance with one of the following:

(1) If the deductible has been fully met by the beneficiary prior to the RHC visit, Medicare pays 80 percent of the all-inclusive rate.

(2) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the RHC's reasonable customary charge for the services that is applied to the deductible is less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-inclusive rate and 80 percent of the remainder, if any, is paid to the RHC.

(3) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the RHC's reasonable customary charge for the services that is applied to the deductible is equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(i) To receive payment, the RHC or FQHC must do all of the following:

(1) Furnish services in accordance with the requirements of subpart X of part 405 of this chapter and subpart A of part 491 of this chapter.

(2) File a request for payment on the form and manner prescribed by CMS.

(3) *HCPCS coding.* FQHCs and RHCs are required to submit HCPCS and other codes as required in reporting services furnished.

(j) *Payment amount for intensive outpatient services.* (1) An RHC is paid the payment rate determined under §419.21(a) of this chapter for services described under §410.44 of this chapter. There are no adjustments to this rate.

(i) If the deductible has been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the payment amount determined under this paragraph (j)(1).

(ii) If the deductible has not been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the difference between the remaining deductible and the payment amount determined under this paragraph (j)(1); or

(iii) If the deductible has not been fully met by the beneficiary prior to the RHC service, no payment is made to the RHC if the deductible is equal to or exceeds the payment amount determined under this paragraph (j)(1).

(2) FQHCs are paid the payment rate determined under §419.21(a) of this chapter for services described under §410.44 of this chapter. There are no adjustments to this rate, except that historically excepted tribal FQHCs are paid pursuant to paragraph (j)(2)(ii) of this section.

(i) Medicare pays eighty (80) percent of the lesser of the FQHC's actual charge or the payment rate determined under paragraph (j)(1)(ii) of this section; or

(ii) Medicare pays eighty (80) percent of the lesser of a historically excepted tribal FQHC's actual charge or the amount described under paragraphs (f)(2) and (3) of this section.

(iii) No deductible is applicable to FQHC services.

[79 FR 25477, May 2, 2014, as amended at 80 FR 71371, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 86 FR 65660, Nov. 19, 2021; 88 FR 82176, Nov. 22, 2023; 89 FR 98553, Dec. 9, 2024]

§ 405.2463 What constitutes a visit.

(a) *Visit—General.* (1) For RHCs, a visit is either of the following:

(i) Face-to-face encounter (or, for mental health disorders only, an encounter that meets the requirements under paragraph (b)(3) of this section) between an RHC patient and one of the following:

(A) Physician.

(B) Physician assistant.

(C) Nurse practitioner.

(D) Certified nurse midwife.

(E) Visiting registered professional or licensed practical nurse.

(G) Clinical psychologist.

(H) Clinical social worker.

(I) Marriage and family therapist.

(J) Mental health counselor.

(ii) Qualified transitional care management service.

(2) For FQHCs, a visit is either of the following:

(i) A visit as described in paragraph (a)(1)(i) or (ii) of this section.

(ii) A face-to-face encounter between a patient and either of the following:

(A) A qualified provider of medical nutrition therapy services as defined in part 410, subpart G, of this chapter.

(B) A qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H, of this chapter.

(b) *Visit—Medical.* (1) A medical visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

(i) Physician.

(ii) Physician assistant.

(iii) Nurse practitioner.

(iv) Certified nurse midwife.

(v) Visiting registered professional or licensed practical nurse.

(2) A medical visit for a FQHC patient may be either of the following:

(i) Medical nutrition therapy visit.

(ii) Diabetes outpatient self-management training visit.

(3) *Visit-Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning January 1, 2026, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

(i) Clinical psychologist.

(ii) Clinical social worker.

(iii) Marriage and family therapist.

(iv) Mental health counselor.

(v) Other RHC or FQHC practitioner, in accordance with paragraph (b)(1) of this section, for mental health services.

(c) *Visit—Multiple.* (1) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when the patient—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day;

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day; or

(iii) Has an initial preventive physical exam visit and a separate medical, mental health, or intensive outpatient services visit on the same day.

(2) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, Medicare pays RHCs and FQHCs for more than 1 visit per day when the conditions in paragraph (c)(1) of this section are met.

(3) For FQHCs that are authorized to bill under the reasonable cost system, Medicare pays for more than 1 visit per day when a DSMT or MNT visit is furnished on the same day as a visit described in paragraph (c)(1) of this section are met.

(4) For FQHCs billing under PPS, and historically excepted tribal FQHCs that are authorized to bill as a FQHC at the outpatient per visit rate for Medicare as set annually by the Indian Health Service—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day; or

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day.

[79 FR 68001, Nov. 13, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 86 FR 65661, Nov. 19, 2021; 87 FR 70222, Nov. 18, 2022; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023; 89 FR 98554, Dec. 9, 2024]

§ 405.2464 Payment rate.

(a) *Payment rate for RHCs that are authorized to bill under the reasonable cost system.* (1) Except as specified in paragraphs (d) and (e) of this section, an RHC that is authorized to bill under the reasonable cost system is paid an

all-inclusive rate that is determined by the MAC at the beginning of the cost reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for RHC services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(4) The MAC, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits and adjusts the rate if:

(i) There is a significant change in the utilization of services;

(ii) Actual allowable costs vary materially from allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(5) The RHC may request the MAC to review the rate to determine whether adjustment is required.

(b) *Payment rate for FQHCs that are authorized to bill under the prospective payment system.* (1) Except as specified in paragraphs (d) and (e) of this section, a per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

(2) The per diem rate is adjusted as follows:

(i) For geographic differences in the cost of inputs according to § 405.2462(c)(1).

(ii) When the FQHC furnishes services to a new patient, as defined in § 405.2462(c)(2).

(iii) When a beneficiary receives either of the following:

(A) A comprehensive initial Medicare visit (that is, an initial preventive physical examination or an initial annual wellness visit).

(B) A subsequent annual wellness visit.

(c) *Payment for care coordination services.* RHCs and FQHCs are paid for the non-face-to-face care management work involved in coordinating care.

(1) For Chronic Care Management (CCM) services furnished between January 1, 2016, and December 31, 2017, payment to RHCs and FQHCs is based on the physician fee schedule national non-facility payment rate.

(2) For psychiatric collaborative care model (CoCM) services furnished on or after January 1, 2018, payment is based on the average of the national non-facility PFS payment rate set for each psychiatric CoCM service and updated annually based on the PFS amounts.

(3) For CCM and general Behavioral Health Integration (BHI) services furnished between January 1, 2018, and December 31, 2020, payment is based on the average of the national non-facility PFS payment rate set for each CCM and general BHI service and updated annually based on the PFS amounts.

(4) For CCM, general BHI, and Principal Care Management (PCM) services furnished between January 1, 2021, and December 31, 2022, payment is based on the average of the national non-facility PFS payment rate set for each CCM, general BHI, and PCM service and updated annually based on the PFS amounts.

(5) For CCM, general BHI, PCM, Chronic Pain Management (CPM) services furnished between January 1, 2023, and December 31, 2023, payment is based on the average of the national non-facility PFS payment rate set for each CCM, general BHI, PCM and CPM service and updated annually based on the PFS amounts.

(6) For CCM, general BHI, PCM, CPM, Remote Physiologic Monitoring (RPM), Remote Therapeutic Monitoring (RTM), Community Health Integration (CHI), Principal Illness Navigation (PIN), and PIN—Peer Support services furnished between January 1, 2024, and December 31, 2024, the payment amount is based on a weighted average of each CCM, general BHI, PCM, CPM, RPM, RTM, CHI, PIN, and PIN—Peer Support service using the most recently available PFS utilization data.

(7) For CCM, general BHI, PCM, CPM, RPM, RTM, CHI, PIN, PIN—Peer Support, and Advance Primary Care Management services furnished on or after January 1, 2025, payment is based on the PFS national non-facility payment rate.

(d) *Payment for FQHCs that are authorized to bill as historically excepted tribal FQHCs.* Historically excepted tribal FQHCs are paid at the outpatient per visit rate for Medicare as

set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

(e) *Payment for communication technology-based and remote evaluation services.* For communication technology-based and remote evaluation services furnished on or after January 1, 2019, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for communication technology-based and remote evaluation services.

(f) *Payment for intensive outpatient services.* Payment to RHCs and FQHCs is at the rate determined under §405.2462(j).

(g) *Payment for non-behavioral health telecommunication technology services.* For an encounter furnished using interactive, real-time, audio and video telecommunications technology or for certain audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology services that are not described in §405.2463(b)(3), payment to RHCs and FQHCs are subject to the national average payment rates for comparable services under the physician fee schedule (PFS) and costs associated with these services shall not be used in determining payments under the RHC all-inclusive rate or the FQHC prospective payment system.

(h) *Payment for drugs covered as additional preventive services (DCAPS).* For drugs covered as additional preventive services, as defined at §410.64 of this subchapter, and for the administration and supplying fees for those drugs, payment to RHCs or FQHCs is 100 percent of the Medicare payment amount per §405.2410(b) and §410.152(l)(11) of this chapter, subject to the payment limitations described at §410.152(o) of this chapter.

[79 FR 25478, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023; 89 FR 98554, Dec. 9, 2024]

§405.2466 Annual reconciliation.

(a) *General.* Payments made to RHCs or FQHCs that are authorized to bill under the reasonable cost system during a reporting period are subject to annual reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation for RHCs or FQHCs that are authorized to bill under the reasonable cost system.* (1) The total reimbursement amount due the RHC or FQHC for covered services furnished to Medicare beneficiaries is based on the report specified in §405.2470(c)(2) and is calculated by the MAC as follows:

(i) The average cost per visit is calculated by dividing the total allowable cost incurred for the reporting period by total visits for RHC or FQHC services furnished during the period. The average cost per visit is subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of RHC or FQHC services furnished to Medicare beneficiaries is calculated by multiplying the average cost per visit by the number of visits for covered RHC or FQHC services by beneficiaries.

(iii) The total payment due the RHC is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to RHC services from the cost of these services. FQHC services are not subject to a deductible and the payment computation for FQHCs does not include a reduction related to the deductible.

(iv) For RHCs and FQHCs, payment for pneumococcal, influenza, hepatitis B and COVID–19 vaccine and their administration is 100 percent of Medicare reasonable cost.

(2) The total reimbursement amount due is compared with total payments made to the RHC or FQHC for the reporting period, and the difference constitutes the amount of the reconciliation.

(c) *Notice of program reimbursement.* The MAC notifies the RHC or FQHC that is authorized to bill under the reasonable-cost system:

(1) Setting forth its determination of the total reimbursement amount due the RHC or FQHC for the reporting period and the amount, if any, of the reconciliation; and

(2) Informing the RHC or FQHC of its right to have the determination reviewed at a hearing under the procedures set forth in subpart R of this part.

(d) *Payment of reconciliation amount*—(1) *Underpayments.* If the total reimbursement due the RHC or FQHC that is authorized to bill under the reasonable cost system exceeds the payments made for the reporting period, the MAC makes a lump-sum payment to the RHC or FQHC to bring total payments into agreement with total reimbursement due the RHC or FQHC.

(2) *Overpayments.* If the total payments made to a RHC or FQHC for the reporting period exceed the total reimbursement due the RHC or FQHC for the period, the MAC arranges with the RHC or FQHC for repayment through a lump-sum refund, or, if that poses a hardship for the RHC or FQHC, through offset against subsequent payments or a combination of offset and refund. The repayment must be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the MAC if the MAC is satisfied that unusual circumstances exist which warrant a longer period.

[57 FR 24976, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25478, May 2, 2014; 86 FR 65662, Nov. 19, 2021; 89 FR 98554, Dec. 9, 2024]

§ 405.2467 Requirements of the FQHC PPS.

(a) *Cost reporting.* For cost reporting periods beginning on or after October 1, 2014, FQHCs are paid the lesser of their actual charges or the FQHC PPS rate that does all of the following:

(1) Includes a process for appropriately describing the services furnished by FQHCs.

(2) Establishes payment rates for specific payment codes based on such appropriate descriptions of services.

(3) Takes into account the type, intensity and duration of services furnished by FQHCs.

(4) May include adjustments (such as geographic adjustments) determined by the Secretary.

(b) *Initial payments.* (1) Beginning October 1, 2014, for the first 15 months of the PPS, the estimated aggregate amount of PPS rates is equal to 100 percent of the estimated amount of reasonable costs that would have occurred for that period if the PPS had not been implemented.

(2) Payment rate is calculated based on the reasonable cost system, prior to productivity adjustments and any payment limitations.

(c) *Payments in subsequent years.* (1) Beginning January 1, 2016, PPS payment rates will be increased by the percentage increase in the Medicare economic index.

(2) Beginning January 1, 2017, PPS rates will be increased by the percentage increase in a market basket of FQHC goods and services as established through regulations, or, if not available, the Medicare economic index.

[79 FR 25479, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015]

§ 405.2468 Allowable costs.

(a) *Applicability of general Medicare principles.* In determining whether and to what extent a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the MAC applies the principles for reimbursement of provider costs, as set forth in part 413 of this subchapter.

(b) *Typical RHC and FQHC costs.* The following types and items of cost are included in allowable costs to the extent that they are covered and reasonable:

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, certified nurse-midwife, visiting registered professional or licensed practical nurse, clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor who owns, is employed by, or furnishes services under contract to a FQHC or RHC.

(2) Compensation for the duties that a supervising physician is required to perform under the agreement specified in § 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner,

nurse-midwife, qualified clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(4) Overhead costs, including RHC or FQHC administration, costs applicable to use and maintenance of the entity, and depreciation costs.

(5) Costs of services purchased by the RHC or FQHC.

(c) *Tests of reasonableness of cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by CMS or the MAC with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. For RHCs and FQHCs that are authorized to bill under the reasonable cost system, these tests include, but are not limited to, screening guidelines and payment limits.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines are not included unless the RHC or FQHC that is authorized to bill under the reasonable cost system provides reasonable justification satisfactory to the MAC.

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other RHC or FQHC personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the RHC or FQHC, subject to the limitation that the costs of physician services purchased by the RHC or FQHC may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

(e) *Payment limitations.* Limits on payments may be set by CMS, on the basis of costs estimated to be reasonable for the provision of such services.

(f) *Graduate medical education.* (1) Effective for portions of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs ''all or substantially all'' of the costs for the training program in the nonhospital setting as defined in §413.75(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents. However, in connection with cost reporting periods for which ''all or substantially all of the costs for the training program in the nonhospital setting'' is not defined in §413.75(b) of this chapter, if an RHC or an FQHC incurs the salaries and fringe benefits (including travel and lodging where applicable) of residents training at the RHC or FQHC, the RHC or FQHC may receive direct graduate medical education payments for those residents.

(2) Direct graduate medical education costs are not included as allowable cost under §405.2466(b)(1)(i); and therefore, are not subject to the limit on the all-inclusive rate for allowable costs.

(3) Allowable graduate medical education costs must be reported on the RHC's or the FQHC's cost report under a separate cost center.

(4) Allowable graduate medical education costs are non-reimbursable if payment for these costs are received from a hospital or a Medicare Advantage organization.

(5) Allowable direct graduate medical education costs under paragraphs (f)(6) and (f)(7)(i) of this section, are subject to reasonable cost principles under part 413 and the reasonable compensation equivalency limits in §§415.60 and 415.70 of this chapter.

(6) The allowable direct graduate medical education costs are those costs incurred by the nonhospital site for the educational activities associated with patient care services of an approved program, subject to the redistribution and community support principles in §413.85(c).

(i) The following costs are allowable direct graduate medical education

costs to the extent that they are reasonable—

(A) The costs of the residents' salaries and fringe benefits (including travel and lodging expenses where applicable).

(B) The portion of teaching physicians' salaries and fringe benefits that are related to the time spent teaching and supervising residents.

(C) Facility overhead costs that are allocated to direct graduate medical education.

(ii) The following costs are not allowable graduate medical education costs—

(A) Costs associated with training, but not related to patient care services.

(B) Normal operating and capital-related costs.

(C) The marginal increase in patient care costs that the RHC or FQHC experiences as a result of having an approved program.

(D) The costs associated with activities described in § 413.85(h) of this chapter.

(7) Payment is equal to the product of—

(i) The RHC's or the FQHC's allowable direct graduate medical education costs; and

(ii) Medicare's share, which is equal to the ratio of Medicare visits to the total number of visits (as defined in § 405.2463).

(8) Direct graduate medical education payments to RHCs and FQHCs made under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

(g) *Intensive outpatient services.* (1) For RHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for RHC services under the methodology for all-inclusive rates under section 1833(a)(3) of the Act as described in § 405.2464(a).

(2) For FQHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for FQHC services under the prospective payment system under section 1834(o)(2)(B) of the Act as described in § 405.2464(b).

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24977, June 12, 1992; 60 FR 63176, Dec. 8, 1995; 61 FR 14658, Apr. 3, 1996; 63 FR 41002, July 31, 1998; 66 FR 39932, Aug. 1, 2001; 70 FR 47484, Aug. 12, 2005; 79 FR 25479, May 2, 2014; 79 FR 50351, Aug. 22, 2014; 88 FR 79525, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2469 FQHC supplemental payments.

(a) *Eligibility for supplemental payments.* FQHCs under contract (directly or indirectly) with MA organizations are eligible for supplemental payments for FQHC services furnished to enrollees in MA plans offered by the MA organization to cover the difference, if any, between their payments from the MA plan and what they would receive under one of the following:

(1) The PPS rate if the FQHC is authorized to bill under the PPS;

(2) The Medicare outpatient per visit rate as set annually by the Indian Health Service for historically excepted tribal FQHCs; or

(3) The payment rate as determined in § 405.2462(j).

(b) *Calculation of supplemental payment.* The supplemental payment for FQHC covered services provided to Medicare patients enrolled in MA plans is based on the difference between—

(1) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHCs all-inclusive cost-based per visit rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(2) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC PPS rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(3) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC outpatient rate as set forth in this section under paragraph (a)(2) of this section, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(4) Payments received by the FQHC from the MA plan as determined on a

per visit basis and the payment rate as determined in §405.2462(j), less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

(c) *Financial incentives.* Any financial incentives provided to FQHCs under their MA contracts, such as risk pool payments, bonuses, or withholds, are prohibited from being included in the calculation of supplemental payments due to the FQHC.

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in §405.2463. Additionally, beginning January 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

[79 FR 25479, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 86 FR 65662, Nov. 19, 2021; 87 FR 70222, Nov. 18, 2022; 88 FR 79525, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023; 89 FR 98555, Dec. 9, 2024]

§405.2470 Reports and maintenance of records.

(a) *Maintenance and availability of records.* The RHC or FQHC must:

(1) Maintain adequate financial and statistical records, in the form and containing the data required by CMS, to allow the MAC to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets is allowable rather than the expenditure for the capital asset.

(b) *Adequacy of records.* (1) The MAC may suspend reimbursement if it determines that the RHC or FQHC does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension continues until the RHC or FQHC demonstrates to the MAC's satisfaction that it does, and will continue to, maintain adequate records.

(c) *Reporting requirements*—(1) *Initial report.* At the beginning of its initial reporting period, the RHC or FQHC must submit an estimate of budgeted costs and visits for RHC or FQHC services for the reporting period, in the form and detail required by CMS, and such other information as CMS may require to establish the payment rate.

(2) *Annual reports.* Within 90 days after the end of its reporting period, the RHC or FQHC must submit, in such form and detail as may be required by CMS, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for RHC or FQHC services furnished during the period; and

(ii) The estimated costs and visits for RHC services or FQHC services for the succeeding reporting period and such other information as CMS may require to establish the payment rate.

(3) *Late reports.* If the RHC or FQHCdoes not submit an adequate annual report on time, the MAC may reduce or suspend payments to preclude excess payment to the RHC or FQHC.

(4) *Inadequate reports.* If the RHC or FQHC does not furnish a report or furnishes a report that is inadequate for the MAC to make a determination of program payment, CMS may deem all payments for the reporting period to be overpayments.

(5) *Postponement of due date.* For good cause shown by the RHC or FQHC, the MAC may, with CMS's approval, grant a 30-day postponement of the due date for the annual report.

(6) *Reports following termination of agreement or change of ownership.* The report from a RHC or FQHC which voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change in ownership (see §§ 405.2436–405.2438) is due no later than 45 days following the effective date of the termination of agreement or change of ownership.

(d) *Collection of additional claims data.* Beginning January 1, 2011, a Medicare FQHC must report on its Medicare claims such information as the Secretary determines is needed to develop and implement a prospective payment system for FQHCs including, but not limited to all pertinent HCPCS (Healthcare Common Procedure Coding System) code(s) corresponding to the service(s) provided for each Medicare FQHC visit (as defined in § 405.2463).

[43 FR 8261, Mar. 1, 1978, as amended at 75 FR 73613, Nov. 29, 2010; 79 FR 25479, May 2, 2014]

§ 405.2472 Beneficiary appeals.

A beneficiary may request a hearing by an intermediary (subject to the limitations and conditions set forth in subpart H of this part) if:

(a) The beneficiary is dissatisfied with a MAC's determination denying a request for payment made on his or her behalf by a RHC or FQHC;

(b) The beneficiary is dissatisfied with the amount of payment; or

(c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24978, June 12, 1992; 79 FR 25480, May 2, 2014]

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

Subpart A—General Provisions

Sec.

406.1 Statutory basis.
406.2 Scope.
406.3 Definitions.
406.5 Basis of eligibility and entitlement.
406.6 Application or enrollment for hospital insurance.
406.7 Forms to apply for entitlement under Medicare Part A.

Subpart B—Hospital Insurance Without Monthly Premiums

406.10 Individual age 65 or over who is entitled to social security or railroad retirement benefits, or who is eligible for social security benefits.
406.11 Individual age 65 or over who is not eligible as a social security or railroad retirement benefits beneficiary, or on the basis of government employment.
406.12 Individual under age 65 who is entitled to social security or railroad retirement disability benefits.
406.13 Individual who has end-stage renal disease.
406.15 Special provisions applicable to Medicare qualified government employment.

Subpart C—Premium Hospital Insurance

406.20 Basic requirements.
406.21 Individual enrollment.
406.22 Effect of month of enrollment on entitlement.
406.24 Special enrollment period related to coverage under group health plans.
406.25 Special enrollment period for volunteers outside the United States.
406.26 Enrollment under State buy-in.
406.27 Special enrollment periods for exceptional conditions.
406.28 End of entitlement.
406.32 Monthly premiums.
406.33 Determination of months to be counted for premium increase: Enrollment.
406.34 Determination of months to be counted for premium increase: Reenrollment.
406.38 Prejudice to enrollment rights because of Federal Government error.

Subpart D—Special Circumstances That Affect Entitlement to Hospital Insurance

406.50 Nonpayment of benefits on behalf of certain aliens.
406.52 Conviction of certain offenses.

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