

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 non-experimental/investigational (Category B) device.
- 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.
- 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.

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 Renewal and early termination of opt-out.
- 405.450 Appeals.
- 405.455 Application to Medicare+Choice 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.

Subpart F [Reserved]

Subpart G—Reconsiderations and Appeals Under Medicare Part A

- 405.701 Basis, purpose and definitions.
- 405.702 Notice of initial determination.
- 405.704 Actions which are initial determinations.
- 405.705 Actions which are not initial determinations.
- 405.706 Decisions of utilization review committees.
- 405.708 Effect of initial determination.
- 405.710 Right to reconsideration.
- 405.711 Time and place of filing request for reconsideration.
- 405.712 Extension of time to request reconsideration.
- 405.714 Withdrawal of request for reconsideration.
- 405.715 Reconsidered determination.
- 405.716 Notice of reconsidered determination.
- 405.717 Effect of a reconsidered determination.
- 405.718 Expedited appeals process.
- 405.720 Hearing; right to hearing.
- 405.722 Time and place of filing request for a hearing.
- 405.724 Departmental Appeals Board (DAB) review.
- 405.730 Court review.
- 405.732 Review of a national coverage determination (NCD).
- 405.740 Principles for determining the amount in controversy.
- 405.745 Amount in controversy ascertained after reconsideration.
- 405.747 Dismissal of request for hearing; amount in controversy less than \$100.
- 405.750 Time period for reopening initial, revised, or reconsidered determinations and decisions or revised decisions of an ALJ or the Departmental Appeals Board (DAB); binding effect of determination and decisions.
- 405.753 Appeal of a categorization of a device.

Subpart H—Appeals Under the Medicare Part B Program

- 405.801 Part B appeals—general description.
- 405.802 Definitions.
- 405.803 Initial determination.
- 405.804 Notice of initial determination.
- 405.805 Parties to the initial determination.
- 405.806 Effect of initial determination.
- 405.807 Request for review of initial determination.
- 405.808 Parties to the review.
- 405.809 Opportunity to submit evidence.
- 405.810 Review determination.
- 405.811 Notice of review determination.
- 405.812 Effect of review determination.
- 405.815 Amount in controversy for carrier hearing, ALJ hearing and judicial review.
- 405.817 Principles for determining amount in controversy.
- 405.821 Request for carrier hearing.
- 405.822 Parties to a carrier hearing.
- 405.823 Carrier hearing officer.
- 405.824 Disqualification of carrier hearing officer.
- 405.825 Location of carrier hearing.
- 405.826 Notice of carrier hearing.
- 405.830 Conduct of the carrier hearing.
- 405.831 Waiver of right to appear at carrier hearing and present evidence.
- 405.832 Dismissal of request for carrier hearing.
- 405.833 Record of carrier hearing.
- 405.834 Carrier hearing officer's decision.
- 405.835 Effect of carrier hearing officer's decision.
- 405.836 Authority of the carrier hearing officer.
- 405.841 Reopening initial or review determination of the carrier, and decision of a carrier hearing officer.
- 405.842 Notice of reopening and revision.
- 405.850 Change of ruling or legal precedent.
- 405.853 Expedited appeals process.
- 405.855 ALJ hearing.
- 405.856 Departmental Appeals Board (DAB) review.
- 405.857 Court review.
- 405.860 Review of a national coverage determination (NCD).
- 405.870 Appointment of representative.
- 405.871 Qualifications of representatives.
- 405.872 Authority of representatives.
- 405.874 Appeals of carrier decisions that supplier standards are not met.

Pt. 405

42 CFR Ch. IV (10–1–07 Edition)

405.877 Appeal of a categorization of a device.

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

- 405.900 Basis and scope.
- 405.902 Definitions.
- 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.
- 405.926 Actions that are not initial determinations.
- 405.927 Initial determinations subject to the reopenings process.
- 405.928 Effect of the initial determination.

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.
- 405.948 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 Time frame for making a reconsideration.
- 405.972 Withdrawal or dismissal of a request for a reconsideration.
- 405.974 Reconsideration.
- 405.976 Notice of a reconsideration.
- 405.978 Effect of a reconsideration.

REOPENINGS

- 405.980 Reopenings of initial determinations, redeterminations, and reconsiderations, hearings 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: General rule.
- 405.1002 Right to an ALJ hearing.
- 405.1004 Right to ALJ review of QIC notice of dismissal.
- 405.1006 Amount in controversy required to request an ALJ hearing and judicial review.
- 405.1008 Parties to an ALJ hearing.
- 405.1010 When CMS or its contractors may participate in an ALJ hearing.
- 405.1012 When CMS or its contractors may be a party to a hearing.
- 405.1014 Request for an ALJ hearing.
- 405.1016 Time frames for deciding an appeal before an ALJ.
- 405.1018 Submitting evidence before the ALJ hearing.
- 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.
- 405.1028 Prehearing case review of evidence submitted to the ALJ.
- 405.1030 ALJ hearing procedures.
- 405.1032 Issues before an ALJ.
- 405.1034 When an ALJ may remand a case to 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 hearing before an ALJ.
- 405.1046 Notice of an ALJ decision.
- 405.1048 The effect of an ALJ's decision.
- 405.1050 Removal of a hearing request from an ALJ to the MAC.
- 405.1052 Dismissal of a request for a hearing before an ALJ.
- 405.1054 Effect of dismissal of a request for a hearing before an ALJ.

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 and MAC.
- 405.1063 Applicability of CMS rulings.
- 405.1064 ALJ decisions involving statistical samples.
- MEDICARE APPEALS COUNCIL REVIEW**
- 405.1100 Medicare Appeals Council review: General.
- 405.1102 Request for MAC review when an ALJ issues decision or dismissal.
- 405.1104 Request for MAC review when an ALJ does not issue a decision timely.
- 405.1106 Where a request for review or escalation may be filed.
- 405.1108 MAC actions when request for review or escalation is filed.
- 405.1110 MAC 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 MAC review or request for hearing.
- 405.1118 Obtaining evidence from the MAC.
- 405.1120 Filing briefs with the MAC.
- 405.1122 What evidence may be submitted to the MAC.
- 405.1124 Oral argument.
- 405.1126 Case remanded by the MAC.
- 405.1128 Action of the MAC.
- 405.1130 Effect of the MAC's decision.
- 405.1132 Request for escalation to Federal district 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 MAC review of ALJ decision in a case remanded by a Federal district court.
- Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for Inpatient Hospital Discharges**
- 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.
- Subparts K–Q [Reserved]**
- Subpart R—Provider Reimbursement Determinations and Appeals**
- 405.1801 Introduction.
- 405.1803 Intermediary 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 intermediary determination.
- 405.1807 Effect of intermediary determination.
- 405.1809 Intermediary hearing procedures.
- 405.1811 Right to intermediary hearing; time, place, form, and content of request for intermediary hearing.
- 405.1813 Failure to timely request an intermediary hearing.
- 405.1815 Parties to the intermediary hearing.
- 405.1817 Hearing officer or panel of hearing officers authorized to conduct intermediary hearing; disqualification of officers.
- 405.1819 Conduct of intermediary hearing.
- 405.1821 Prehearing discovery and other proceedings prior to the intermediary hearing.
- 405.1823 Evidence at intermediary hearing.
- 405.1825 Witnesses at intermediary hearing.
- 405.1827 Record of intermediary hearing.
- 405.1829 Authority of hearing officer(s) at intermediary hearing.
- 405.1831 Intermediary hearing decision and notice.
- 405.1833 Effect of intermediary hearing decision.
- 405.1835 Right to Board hearing.
- 405.1837 Group appeal.
- 405.1839 Amount in controversy.
- 405.1841 Time, place, form, and content of request for Board hearing.
- 405.1842 Expediting Board proceedings.
- 405.1843 Parties to Board hearing.
- 405.1845 Composition of Board.
- 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 Prehearing discovery and other proceedings prior to the Board hearing.
- 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 Board hearing.
- 405.1867 Sources of Board's authority.
- 405.1869 Scope of Board's decision-making authority.
- 405.1871 Board hearing decision and notice.
- 405.1873 Board's jurisdiction.
- 405.1875 Administrator's review.
- 405.1877 Judicial review.
- 405.1881 Appointment of representative.
- 405.1883 Authority of representative.
- 405.1885 Reopening a determination or decision.

Pt. 405

- 405.1887 Notice of reopening.
- 405.1889 Effect of a revision.

Subparts S–T [Reserved]

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

- 405.2100 Scope of subpart.
- 405.2101 Objectives of the end-stage renal disease (ESRD) program.
- 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 Condition: Provider status: Renal transplantation center or renal dialysis center.
- 405.2132 [Reserved]
- 405.2133 Condition: Furnishing data and information for ESRD program administration.
- 405.2134 Condition: Participation in network activities.
- 405.2135 Condition: Compliance with Federal, State, and local laws and regulations.
- 405.2136 Condition: Governing body and management.
- 405.2137 Condition: Patient long-term program and patient care plan.
- 405.2138 Condition: Patients' rights and responsibilities.
- 405.2139 Condition: Medical records.
- 405.2140 Condition: Physical environment.
- 405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.
- 405.2160 Condition: Affiliation agreement or arrangement.
- 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.
- 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.
- 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.
- 405.2164 Conditions for coverage of special purpose renal dialysis facilities.
- 405.2180 Termination of Medicare coverage.
- 405.2181 Alternative sanctions.
- 405.2182 Notice of sanction and appeal rights: Termination of coverage.
- 405.2184 Notice of appeal rights: Alternative sanctions.

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 Basic requirements.

42 CFR Ch. IV (10–1–07 Edition)

- 405.2403 Content and terms of the agreement with the Secretary.
- 405.2404 Terminations of 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 and physician assistant services.
- 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.
- 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.
- 405.2450 Clinical psychologist and clinical social worker services.
- 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

- 405.2460 Applicability of general payment exclusions.
- 405.2462 Payment for rural health clinic and Federally qualified health center services.
- 405.2463 What constitutes a visit.
- 405.2464 All-inclusive rate.
- 405.2466 Annual reconciliation.
- 405.2468 Allowable costs.
- 405.2469 Federally Qualified Health Centers 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 non-experimental/investigational (Category B).

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

Class I refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III refers to devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Contractors refers to carriers, fiscal intermediaries, and other entities that contract with CMS to review and adjudicate claims for Medicare services.

Experimental/investigational (Category A) device refers to an innovative device believed to be in Class III 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).

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying 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 approval for that device type.

PMA stands for “premarket approval” and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

Sponsor refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

§ 405.203 FDA categorization of investigational devices.

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

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

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

§ 405.205 Coverage of a non-experimental/investigational (Category B) device.

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