cause shown in relation to the manufacturer’s participation in the Discount Program.

(2) The termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (5) of this section.

(3)(i) CMS provides the manufacturer with an opportunity to cure any ground for termination for cause or to show the manufacturer is in compliance with the Discount Program Agreement within 30 calendar days of receipt of the written termination notice.

(ii) If the manufacturer cures the violation, or establishes that it was in compliance within the cure period, CMS repeals the termination notice by written notice.

(4) CMS provides upon request a manufacturer with a hearing with the hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination. The hearing takes place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate.

(5)(i) CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(b)(1) The manufacturer may terminate the Discount Program Agreement for any reason.

(2) Such termination is effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year, or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year.

(c) Any termination does not affect the manufacturer’s responsibility to reimburse Part D sponsors for applicable discounts incurred before the effective date of the termination.

(d) Upon the effective date of termination of the Discount Program Agreement, CMS ceases releasing data to the manufacturer except as necessary to ensure that the manufacturer reimburses applicable discounts for previous time periods in which the Discount Program Agreement was in effect, and notifies the manufacturer to destroy data files provided by CMS under the Discount Program Agreement.

(e) Manufacturer reinstatement is available only upon payment of any and all outstanding applicable discounts incurred during any previous period under the Discount Program Agreement. The timing of any such reinstatement is consistent with the requirements for entering into a Discount Program Agreement under §423.2315(c) of this subpart.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

Subpart A—General Provisions

Sec.
424.1 Basis and scope.
424.3 Definitions.
424.5 Basic conditions.
424.7 General limitations.

Subpart B—Certification and Plan Requirements

424.10 Purpose and scope.
424.11 General procedures.
424.13 Requirements for inpatient services of hospitals other than psychiatric hospitals.
424.14 Requirements for inpatient services of inpatient psychiatric facilities.
424.15 Requirements for inpatient CAH services.
424.16 Timing of certification for individual admitted to a hospital before entitlement to Medicare benefits.
424.20 Requirements for posthospital SNF care.
424.22 Requirements for home health services.
424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.
424.27 Requirements for comprehensive outpatient rehabilitation facility (CORF) services.

Subpart C—Claims for Payment

424.30 Scope.
424.32 Basic requirements for all claims.
Centers for Medicare & Medicaid Services, HHS

424.33 Additional requirements: Claims for services of providers and claims by suppliers and nonparticipating hospitals.
424.34 Additional requirements: Beneficiary’s claim for direct payment.
424.36 Signature requirements.
424.37 Evidence of authority to sign on behalf of the beneficiary.
424.40 Request for payment effective for more than one claim.
424.44 Time limits for filing claims.

Subpart D—To Whom Payment is Ordinarily Made

424.50 Scope.
424.51 Payment to the provider.
424.52 Payment to a nonparticipating hospital.
424.53 Payment to the beneficiary.
424.54 Payment to the beneficiary’s legal representative or representative payee.
424.55 Payment to the supplier.
424.56 Payment to a beneficiary and to a supplier.
424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.
424.58 Accreditation.

Subpart E—To Whom Payment is Made in Special Situations

424.60 Scope.
424.62 Payment after beneficiary’s death: Bill has been paid.
424.64 Payment after beneficiary’s death: Bill has not been paid.
424.66 Payment to entities that provide coverage complementary to Medicare Part B.

Subpart F—Limitations on Assignment and Reassignment of Claims

424.70 Basis and scope.
424.71 Definitions.
424.73 Prohibition of assignment of claims by providers.
424.74 Termination of provider agreement.
424.80 Prohibition of reassignment of claims by suppliers.
424.82 Revocation of right to receive assigned benefits.
424.83 Hearings on revocation of right to receive assigned benefits.
424.84 Final determination on revocation of right to receive assigned benefits.
424.86 Prohibition of assignment of claims by beneficiaries.
424.90 Court ordered assignments: Conditions and limitations.

Subpart G—Special Conditions: Emergency Services Furnished by a Nonparticipating Hospital

424.100 Scope.
424.101 Definitions.
424.102 Situations that do not constitute an emergency.
424.103 Conditions for payment for emergency services.
424.104 Election to claim payment for emergency services furnished during a calendar year.
424.106 Criteria for determining whether the hospital was the most accessible.
424.108 Payment to a hospital.
424.109 Payment to the beneficiary.

Subpart H—Special Conditions: Services Furnished in a Foreign Country

424.120 Scope.
424.121 Scope of payments.
424.122 Conditions for payment for emergency inpatient hospital services.
424.123 Conditions for payment for non-emergency inpatient services furnished by a hospital closer to the individual’s residence.
424.124 Conditions for payment for physician services and ambulance services.
424.126 Payment to the hospital.
424.127 Payment to the beneficiary.

Subparts I–L [Reserved]

Subpart M—Replacement and Reclamation of Medicare Payments

424.350 Replacement of checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.
424.352 Intermediary and carrier checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

Subparts N–O [Reserved]

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

424.500 Scope.
424.502 Definitions.
424.505 Basic enrollment requirement.
424.506 National Provider Identifier (NPI) on all enrollment applications and claims.
424.507 Ordering and referring covered items and services for Medicare beneficiaries.
424.510 Requirements for enrolling in the Medicare program.
424.514 Application fee.
§ 424.1 Basis and scope.

(a) Statutory basis. (1) This part is based on the indicated provisions of the following sections of the Act:

1814—Basic conditions for, and limitations on, Medicare payments for Part A services.

1815—Payment to providers for Part A services.

1820—Conditions for designating certain hospitals as critical access hospitals.

1833(e)—Requirement to furnish information to determine payment.

1834(a)—Payment for durable medical equipment.

1834(j)—Requirements for suppliers of medical equipment and supplies.

1835—Procedures for payment to providers for Part B services.


1842(b)(6)—Payment to entities other than the supplier.

1848—Payment for physician services.

1870(e) and (f)—Settlement of claims after death of the beneficiary.

(b) Scope. This part sets forth certain specific conditions and limitations applicable to Medicare payments and cites other conditions and limitations set forth elsewhere in this chapter. This subpart A provides a general overview. Other subparts deal specifically with—

(1) The requirement that the need for services be certified and that a physician establish a plan of treatment (subpart B);

(2) The procedures and time limits for filing claims (subpart C);

(3) The individuals or entities to whom payment may be made (subparts D and E);

(4) The limitations on assignment and reassignment of claims (subpart F);

(5) Special requirements that apply to services furnished by nonparticipating U.S. hospitals and foreign hospitals (subparts G and H); and

(6) The replacement and reclamation of Medicare payment checks (subpart M).

(c) Other applicable rules. Except for § 424.40(c)(3), this part does not deal with the conditions for payment of rural health clinic (RHC) services, Federally qualified health center (FQHC) services, or ambulatory surgical center (ASC) services. Those conditions are set forth in part 405, subpart X, and part 416 subpart A of this chapter for RHC and FQHC services; and in part 416 of this chapter, for ASC services. The rules for physician certification of terminal illness, required in connection with hospice care, are set forth in § 418.22 of this chapter.