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per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process except that during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). Beginning with the second week, as defined in § 412.622, of admission to the IRF, a non-physician practitioner who is determined by the IRF to have specialized training and experience in inpatient rehabilitation may conduct 1 of the 3 required face-to-face visits with the patient per week, provided that such duties are within the non-physician practitioner's scope of practice under applicable state law.

(f) Furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.

(g) Have a director of rehabilitation who—

(1) Provides services to the IRF hospital and its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least 2 years of training or experience in the medical-management of inpatients requiring rehabilitation services.

(h) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in con-

sultation with other professional personnel who provide services to the patient.

(i) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.

(j) *Retroactive adjustments.* If a new IRF (or new beds that are added to an existing IRF) are excluded from the prospective payment systems specified in § 412.1(a)(1) and paid under the prospective payment system specified in § 412.1(a)(3) for a cost reporting period under paragraph (c) of this section, but the inpatient population actually treated during that period does not meet the requirements of paragraph (b) of this section, we adjust payments to the IRF retroactively in accordance with the provisions in § 412.130.

[76 FR 47891, Aug. 5, 2011, as amended at 78 FR 47934, Aug. 6, 2013; 85 FR 19287, Apr. 6, 2020; 85 FR 27621, May 8, 2020; 85 FR 48462, Aug. 10, 2020]

§ 412.30 [Reserved]

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.40 General requirements.

(a) A hospital must meet the conditions of this subpart to receive payment under the prospective payment systems for inpatient hospital services furnished to Medicare beneficiaries.

(b) If a hospital fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, CMS may, as appropriate—

(1) Withhold Medicare payment (in full or in part) to the hospital until the hospital provides adequate assurances of compliance; or

(2) Terminate the hospital's provider agreement.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992]

§ 412.42 Limitations on charges to beneficiaries.

(a) *Prohibited charges.* A hospital may not charge a beneficiary for any services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment systems.

(b) *Permitted charges—Stay covered.* A hospital receiving payment under the prospective payment systems for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the following:

(1) The applicable deductible and co-insurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter.

(2) Noncovered items and services, furnished at any time during a covered stay, unless they are excluded from coverage only on the basis of the following:

(i) The exclusion of custodial care under § 411.15(g) of this chapter (see paragraph (c) of this section for when charges may be made for custodial care).

(ii) The exclusion of medically unnecessary items and services under § 411.15(k) of this chapter (see paragraphs (c) and (d) of this section for when charges may be made for medically unnecessary items and services).

(iii) The exclusion under § 411.15(m) of this chapter of nonphysician services furnished to hospital inpatients by other than the hospital or a provider or supplier under arrangements made by the hospital.

(iv) The exclusion of items and services furnished when the patient is not entitled to Medicare Part A benefits under subpart A of part 406 of this chapter (see paragraph (e) of this section for when charges may be made for items and services furnished when the patient is not entitled to benefits).

(v) The exclusion of items and services furnished after Medicare Part A benefits are exhausted under § 409.61 of this chapter (see paragraph (e) of this section for when charges may be made for items and services furnished after benefits are exhausted).

(c) *Custodial care and medically unnecessary inpatient hospital care.* A hospital may charge a beneficiary for services excluded from coverage on the basis of § 411.15(g) of this chapter (custodial care) or § 411.15(k) of this chapter (medically unnecessary services) and furnished by the hospital after all of the following conditions have been met:

(1) The hospital (acting directly or through its utilization review committee) determines that the beneficiary no longer requires inpatient hospital care. (The phrase "inpatient hospital care" includes cases where a beneficiary needs a SNF level of care, but, under Medicare criteria, a SNF-level bed is not available. This also means that a hospital may find that a patient awaiting SNF placement no longer requires inpatient hospital care because either a SNF-level bed has become available or the patient no longer requires SNF-level care.)

(2) The attending physician agrees with the hospital's determination in writing (for example, by issuing a written discharge order). If the hospital believes that the beneficiary does not require inpatient hospital care but is unable to obtain the agreement of the physician, it may request an immediate review of the case by the QIO as described in § 405.1208 of this chapter. Concurrence by the QIO in the hospital's determination will serve in lieu of the physician's agreement.

(3) The hospital (acting directly or through its utilization review committee) notifies the beneficiary (or his or her representative) of his or her discharge rights in writing consistent with § 405.1205 and notifies the beneficiary, in accordance with § 405.1206 of this chapter (if applicable) that in the hospital's opinion, and with the attending physician's concurrence or that of the QIO, the beneficiary no longer requires inpatient hospital care.

(4) If the beneficiary remains in the hospital after the appropriate notification, and the hospital, the physician who concurred in the hospital determination on which the notice was based, or QIO subsequently finds that the beneficiary requires an acute level of inpatient hospital care, the hospital may not charge the beneficiary for continued care until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence, and notifies the beneficiary, as required in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(d) *Medically unnecessary diagnostic and therapeutic services.* A hospital may charge a beneficiary for diagnostic procedures and studies, and therapeutic procedures and courses of treatment (for example, experimental procedures) that are excluded from coverage under § 411.15(k) of this chapter (medically unnecessary items and services), even though the beneficiary requires continued inpatient hospital care, if those services are furnished after the beneficiary (or the person acting on his or her behalf) has acknowledged in writing that the hospital (acting directly or through its utilization review committee and with the concurrence of the intermediary) has informed him or her as follows:

(1) In the hospital's opinion, which has been agreed to by the intermediary, the services to be furnished are not considered reasonable and necessary under Medicare.

(2) Customary charges will be made if he or she receives the services.

(3) If the beneficiary receives the services, a formal determination on the validity of the hospital's finding is made by the intermediary and, to the extent that the decision requires the exercise of medical judgment, the QIO.

(4) The determination is appealable by the hospital, the attending physician, or the beneficiary under the appeals procedure that applies to determinations affecting Medicare Part A payment.

(5) The charges for the services will be invalid and, to the extent collected, will be refunded by the hospital if the services are found to be covered by Medicare.

(e) *Services furnished on days when the individual is not entitled to Medicare Part A benefits or has exhausted the available benefits.* The hospital may charge the beneficiary its customary charges for noncovered items and services furnished on outlier days (as described in Subpart F of this part) for which payment is denied because the beneficiary is not entitled to Medicare Part A or his or her Medicare Part A benefits are exhausted. (1) If payment is considered for outlier days, the entire stay is reviewed and days up to the number of days in excess of the outlier threshold may be denied on the basis of non-entitlement to Part A or exhaustion of benefits. (2) In applying this rule, the latest days will be denied first.

(f) *Differential for private room or other luxury services.* The hospital may charge the beneficiary the customary charge differential for a private room or other luxury service that is more expensive than is medically required and is furnished for the personal comfort of the beneficiary at his or her request (or the request of the person acting on his or her behalf).

(g) *Review.* (1) The QIO or intermediary may review any cases in which the hospital advises the beneficiary (or the person acting on his or her behalf) of the noncoverage of the services in accordance with paragraph (c)(3) or (d) of this section.

(2) The hospital must identify such cases to the QIO or intermediary in accordance with CMS instructions.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 54 FR 41747, Oct. 11, 1989; 57 FR 39821, Sept. 1, 1992; 71 FR 48137, Aug. 18, 2006; 71 FR 68722, Nov. 27, 2006; 85 FR 72909, Nov. 16, 2020]

§ 412.44 Medical review requirements: Admissions and quality review.

Beginning on November 15, 1984, a hospital must have an agreement with a QIO to have the QIO review, on an ongoing basis, the following:

(a) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges.

(b) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier

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provisions of §§ 412.82 and 412.84 of this chapter.

(c) The validity of the hospital's diagnostic and procedural information.

(d) The completeness, adequacy, and quality of the services furnished in the hospital.

(e) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

[50 FR 15326, Apr. 17, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 50 FR 41886, Oct. 16, 1985]

§ 412.46 Medical review requirements.

(a) *Physician acknowledgement.* (1) *Basis.* Because payment under the prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's medical record, physicians must complete an acknowledgement statement to this effect.

(2) *Content of physician acknowledgement statement.* When a claim is submitted, the hospital must have on file a signed and dated acknowledgement from the attending physician that the physician has received the following notice:

Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

(3) *Completion of acknowledgement.* The acknowledgement must be completed by the physician at the time that the physician is granted admitting privileges at the hospital, or before or at the time the physician admits his or her first patient. Existing acknowledgements signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

(b) *Physician's order and certification regarding medical necessity.* No presumptive weight shall be assigned to the physician's order under § 412.3 or the

physician's certification under Subpart B of Part 424 of the chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order or certification will be evaluated in the context of the evidence in the medical record.

[78 FR 50965, Aug. 19, 2013]

§ 412.48 Denial of payment as a result of admissions and quality review.

(a) If CMS determines, on the basis of information supplied by a QIO that a hospital has misrepresented admissions, discharges, or billing information, or has taken an action that results in the unnecessary admission of an individual entitled to benefits under Part A, unnecessary multiple admissions of an individual, or other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries, CMS may as appropriate—

(1) Deny payment (in whole or in part) under Part A with respect to inpatient hospital services provided with respect to such an unnecessary admission or subsequent readmission of an individual; or

(2) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(b) When payment with respect to admission of an individual patient is denied by a QIO under paragraph (a)(1) of this section, and liability is not waived in accordance with §§ 411.400 through 411.402 of this chapter, notice and appeals are provided under procedures established by CMS to implement the provisions of section 1155 of the Act, Right to Hearing and Judicial Review.

(c) A determination under paragraph (a) of this section, if it is related to a pattern of inappropriate admissions and billing practices that has the effect of circumventing the prospective payment systems, is referred to the Department's Office of Inspector General, for handling in accordance with § 1001.301 of this title.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, 35689, Sept. 3, 1985; 51 FR 34787, Sept. 30, 1986; 57 FR 39821, Sept. 1, 1992; 71 FR 48137, Aug. 18, 2006]

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§ 412.50 Furnishing of inpatient hospital services directly or under arrangements.

(a) The applicable payments made under the prospective payment systems, as described in subparts H and M of this part, are payment in full for all inpatient hospital services, as defined in § 409.10 of this chapter. Inpatient hospital services do not include the following types of services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69 of this chapter.

(b) CMS does not pay any provider or supplier other than the hospital for services furnished to a beneficiary who is an inpatient, except for the services described in paragraphs (a)(1) through (a)(6) of this section.

(c) The hospital must furnish all necessary covered services to the beneficiary either directly or under arrangements (as defined in § 409.3 of this chapter).

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 38527, Sept. 30, 1988; 57 FR 39821, Sept. 1, 1992; 60 FR 63188, Dec. 8, 1995; 65 FR 18537, Apr. 7, 2000]

§ 412.52 Reporting and recordkeeping requirements.

All hospitals participating in the prospective payment systems must meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 57 FR 39821, Sept. 1, 1992]

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Subpart D—Basic Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

§ 412.60 DRG classification and weighting factors.

(a) *Diagnosis-related groups.* CMS establishes a classification of inpatient hospital discharges by Diagnosis-Related Groups (DRGs).

(b) *DRG weighting factors.* CMS assigns, for each DRG, an appropriate weighting factor that reflects the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups, subject to a maximum ten percent reduction to the weighting factor for a DRG as compared to the weighting factor for the same DRG for the prior fiscal year.

(c) *Assignment of discharges to DRGs.* CMS establishes a methodology for classifying specific hospital discharges within DRGs which ensures that each hospital discharge is appropriately assigned to a single DRG based on essential data abstracted from the inpatient bill for that discharge.

(1) The classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, procedures performed, and discharge status.

(2) Each discharge is assigned to only one DRG (related, except as provided in paragraph (c)(3) of this section, to the patient's principal diagnosis) regardless of the number of conditions treated or services furnished during the patient's stay.

(3) When the discharge data submitted by a hospital show a surgical procedure unrelated to a patient's principal diagnosis, the bill is returned to the hospital for validation and reverification. CMS's DRG classification system provides a DRG, and an appropriate weighting factor, for the group of cases for which the unrelated diagnosis and procedure are confirmed.

(d) *Review of DRG assignment.* (1) A hospital has 60 days after the date of the notice of the initial assignment of