process specified in part 405, subpart R
of this chapter.
[50 FR 15330, Apr. 17, 1985, as amended at 57
FR 47787, Oct. 20, 1992; 59 FR 45402, Sept. 1,
1994. Redesignated at 64 FR 66279, Nov. 24,
1999; 68 FR 67960, Dec. 5, 2003]
§ 476.80 Coordination with Medicare
fiscal intermediaries and carriers.
(a) Procedures for agreements. The
Medicare fiscal intermediary or carrier
must have a written agreement with
the QIO. The QIO must take the initia-
tive with the fiscal intermediary or
carrier in developing the agreement.
The following steps must be taken in
developing the agreement.
(1) The QIO and the fiscal inter-
mediary or carrier must negotiate in
good faith in an effort to reach written
agreement. If they cannot reach agree-
ment, CMS will assist them in resolv-
ing matters in dispute.
(2) The QIO must incorporate its ad-
ministrative procedures into an agree-
ment with the fiscal intermediary or
carrier and obtain approval from CMS,
before it makes conclusive determina-
tions for the Medicare program, unless
CMS finds that the fiscal intermediary
or carrier has—
(i) Refused to negotiate in good faith
or in a timely manner, or
(ii) Insisted on including in the
agreement, provisions that are outside
the scope of its authority under the
Act.
(b) Content of agreement. The agree-
ment must include procedures for—
(1) Informing the appropriate Medi-
care fiscal intermediaries and carriers
of—
(i) Changes as a result of DRG valida-
tions and revisions as a result of the
review of these changes; and
(ii) Initial denial determinations and
revisions of these determinations as a
result of reconsideration, or reopening
all approvals and denials with respect
to cases subject to preadmission re-
view, and outlier claims in hospitals
under a prospective payment system
for health care services and items;
(2) Exchanging data or information;
(3) Modifying the procedures when
additional review responsibility is au-
thorized by CMS; and
(4) Any other matters that are nec-
essary for the coordination of func-
tions.
(c) Action by CMS. (1) Within the time
specified in its contract, the QIO must
submit to CMS for approval its agree-
ment with the Medicare fiscal inter-
mediaries and carriers, or if an agree-
ment has not been established, the
QIO's proposed administrative proce-
dures, including any comments by the
Medicare fiscal intermediaries and car-
riers.
(2) If CMS approves the agreement or
the administrative procedures (after a
finding by CMS as specified in para-
graph (a)(2) of this section), the QIO
may begin to make determinations
under its contract with CMS.
(3) If CMS disapproves the agreement
or procedures, it will—
(i) Notify the QIO and the appro-
priate fiscal agents in writing, stating
the reasons for disapproval; and
(ii) Require the QIO and fiscal inter-
mediary or carrier to revise its agree-
ments or procedures.
(d) Modification of agreements. Agree-
ments or procedures may be modified,
with CMS's approval—
(1) Through a revised agreement with
the fiscal intermediary or carrier, or
(2) In the case of procedures, by the
QIO, after providing opportunity for
comment by the fiscal intermediary or
carrier.
(e) Role of the fiscal intermediary. (1)
The fiscal intermediary will not pay
any claims for those cases which are
subject to preadmission review by the
QIO, until it receives notice that the
QIO has approved the admission after
preadmission or retrospective review.
(2) A QIO's determination that an
admission is medically necessary is not a
guarantee of payment by the fiscal
intermediary. Medicare coverage re-
quirements must also be applied.
30, 1985. Redesignated at 64 FR 66279, Nov. 24,
1999]
§ 476.82 Continuation of functions not
assumed by QIOs.
Any of the duties and functions under
Part B of Title XI of the Act for which
a QIO has not assumed responsibility
under its contract with CMS must be
§ 476.83 Initial denial determinations.

A determination by a QIO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under part 473 of this chapter.

§ 476.84 Changes as a result of DRG validation.

A provider or practitioner may obtain a review by a QIO under part 473 of this chapter for changes in diagnostic and procedural coding that resulted in a change in DRG assignment as a result of QIO validation activities.

§ 476.85 Conclusive effect of QIO initial denial determinations and changes as a result of DRG validations.

A QIO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in part 473—
(a) The initial denial determination is reconsidered and revised; or
(b) The change as a result of DRG validation is reviewed and revised.

§ 476.86 Correlation of Title XI functions with Title XVIII functions.

(a) Payment determinations. (1) QIO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:
   (i) Whether inpatient care furnished in a psychiatric hospital meets the requirements of §424.14 of this chapter.
   (ii) Whether payment for inpatient hospital or SNF care beyond 20 consecutive days is precluded under §489.50 of this chapter because of failure to perform review of long-stay cases.
   (iii) Whether the care furnished was custodial care or care not reasonable and necessary and, as such, excluded under §405.310(g) or §405.310(k) of this chapter.
   (iv) Whether the care was appropriately furnished in the inpatient or outpatient setting.
   (2) Reviews with respect to determinations listed in paragraph (a)(1) of this section must not be conducted, for purposes of payment, by Medicare fiscal intermediaries or carriers except as outlined in paragraph (c) of this section.
   (3) QIOs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the QIO determines that it could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.
   (4) QIO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.
(b) Utilization review activities. QIO review activities to determine whether inpatient hospital or SNF care services are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in §§405.1035, 405.1042, and 405.1137 of this chapter.
(c) Coverage. Nothing in paragraphs (a) (1) and (3) of this section will be construed as precluding CMS or a Medicare fiscal intermediary or carrier, in the proper exercise of its duties and functions, from reviewing claims to determine:
   (1) In the case of items or services not reviewed by a QIO, whether they meet coverage requirements of Title XVIII relating to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care. However, if a coverage determination pertains to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care, the fiscal intermediary or carrier...