must indicate that its plan for the review of health care services as approved in its contract with CMS is available for public inspection in the QIO's business office and give the address, telephone number and usual hours of business.

[50 FR 15330, Apr. 17, 1985. Redesignated at 52 FR 37457, Oct. 7, 1987, and further redesignated at 64 FR 66279, Nov. 24, 1999; 77 FR 68560, Nov. 15, 2012]

§ 476.74 General requirements for the assumption of review.

(a) A QIO must assume review responsibility in accordance with the schedule, functions and negotiated objectives specified in its contract with CMS.

(b) A QIO must notify the appropriate Medicare administrative contractor, fiscal intermediary, or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility.

(c) A QIO must maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with Medicare administrative contractors, fiscal intermediaries, and carriers;

(2) A copy of its currently approved review plan that includes the QIO's method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) A QIO must not subcontract with a facility to conduct any review activities except for the review of the quality of care. The QIO may subcontract with a non-facility organization to conduct review in a facility.

(e) If required by CMS, a QIO is responsible for compiling statistics based on the criteria contained in § 411.402 of this chapter and making limitation of liability determinations on excluded coverage of certain services that are made under section 1879 of the Act. If required by CMS, QIOs must also notify a provider of these determinations. These determinations and further appeals are governed by the reconsideration and appeals procedures in part 405, subpart G of this chapter for Medicare Part A related determinations and part 405, subpart H of this chapter for Medicare Part B related determinations.

(f) A QIO must make its responsibilities under its contract with CMS, primary to all other interests and activities that the QIO undertakes.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68560, Nov. 15, 2012]

§ 476.76 Cooperation with health care facilities.

Before implementation of review, a QIO must make a good faith effort to discuss the QIO's administrative and review procedures with each involved health care facility.

§ 476.78 Responsibilities of providers and practitioners.

(a) Every hospital seeking payment for services furnished to Medicare beneficiaries must maintain a written agreement with a QIO operating in the area in which the hospital is located. These agreements must provide for the QIO review specified in § 476.71.

(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review.

(1) Providers must allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Providers and practitioners must provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. When the QIO does postadmission, preprocedure review, the provider must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers and practitioners must—

(i) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, deliver to the QIO all required information within 14 calendar days of a request. A QIO is authorized to require the receipt of the medical information earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in part 1004 of this title and

circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(ii) Except if granted a waiver as described in paragraph (d) of this section, send secure transmission of an electronic version of each requested patient record to the QIO.

(A) Providers and practitioners must deliver electronic versions of patient records within 14 calendar days of the request.

(B) A QIO is authorized to require the receipt of the patient records earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in part 1004 of this title and circumstances warrant earlier receipt of the patient records.

(C) A practitioner's or provider's failure to comply with the request for patient records within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(3) Providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to QIO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 411.402(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the provider has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the QIO within 3 working days.

(5) Providers must assure, in accordance with the provisions of their agreements with the QIO, that each case subject to preadmission review has been reviewed and approved by the QIO before admission to the hospital or a timely request has been made for QIO review.

(6)(i) Providers must agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the QIO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a provider, in accordance with its agreement with a QIO, makes a timely request for preadmission review and the QIO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Hospitals must agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the QIO.

(c) *Submission of patient records in electronic format.* Except as specified in paragraph (d) of this section, a provider or practitioner must deliver patient records requested by a QIO for the purpose of fulfilling one or more QIO functions, in an electronic format, using the mechanism specified by the QIO. In the absence of any mechanism specified by the requesting QIO, the requested patient records must be submitted using any CMS-approved mechanism.

(d) *Waiver from the requirement to submit patient records in an electronic format.* (1) A provider or practitioner that lacks the capability to submit requested patient records to the requesting QIO in an electronic format may request a waiver from the requirements in paragraph (c) of this section.

(i) For providers that are required to execute a written agreement with the QIO, a request for a waiver must be made during execution of the written agreement with the QIO.

(ii) Providers that are required to execute a written agreement with the QIO must request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format, if their lack of capability arises after the written agreement is executed.

(iii) Upon approval of the waiver, the waiver becomes part of the written agreement with the QIO.

(iv) A provider with an approved waiver may submit patient records by

facsimile or by photocopying and mailing to the QIO.

(v) A provider with an approved waiver may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(vi) A QIO may not reimburse for any patient record submitted to the QIO by facsimile or by photocopying and mailing if the provider does not have an approved waiver.

(2) Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in an electronic format.

(i) Such providers and practitioners may request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format.

(ii) Upon approval of the waiver, a provider or practitioner may submit patient records by facsimile or by photocopying and mailing to the QIO.

(iii) Providers and practitioners with approved waivers may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(iv) A QIO may not reimburse for any patient records submitted to the QIO by facsimile or by photocopying and mailing, if the provider or practitioner does not have an approved waiver.

(e) *Reimbursement for submitting patient records to the QIO.* (1) For purposes of this paragraph (e), a *patient record* means all patient care data and other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.

(2) A QIO may reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per patient record.

(3) For a provider or practitioner that has an approved waiver under paragraph (d) of this section, a QIO may reimburse the provider or practitioner for requested records submitted by—

(i) Facsimile at the rate of $0.15 per page; or

(ii) Photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage.

(4) A QIO may only reimburse a provider or practitioner once for each patient record submitted, per request, even if a patient record is submitted using multiple formats, in fragments, or more than once in response to a single request by the QIO.

(f) *Appeals.* Reimbursement for the costs of submitting requested patient records to the QIO in electronic format, by facsimile or by photocopying and mailing is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and 484.265 of this chapter. Appeals concerning these costs are subject to the review process specified in part 405, subpart R, of this chapter.

(c) *Submission of patient records in electronic format.* Except as specified in paragraph (d) of this section, a provider or practitioner must deliver patient records requested by a QIO for the purpose of fulfilling one or more QIO functions, in an electronic format, using the mechanism specified by the QIO. In the absence of any mechanism specified by the requesting QIO, the requested patient records must be submitted using any CMS-approved mechanism.

(d) *Waiver from the requirement to submit patient records in an electronic format.* (1) A provider or practitioner that lacks the capability to submit requested patient records to the requesting QIO in an electronic format may request a waiver from the requirements in paragraph (c) of this section.

(i) For providers that are required to execute a written agreement with the QIO, a request for a waiver must be made during execution of the written agreement with the QIO.

(ii) Providers that are required to execute a written agreement with the QIO must request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format, if their lack of capability arises after the written agreement is executed.

(iii) Upon approval of the waiver, the waiver becomes part of the written agreement with the QIO.

(iv) A provider with an approved waiver may submit patient records by facsimile or by photocopying and mailing to the QIO.

(v) A provider with an approved waiver may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(vi) A QIO may not reimburse for any patient record submitted to the QIO by facsimile or by photocopying and mailing if the provider does not have an approved waiver.

(2) Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in an electronic format.

(i) Such providers and practitioners may request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format.

(ii) Upon approval of the waiver, a provider or practitioner may submit patient records by facsimile or by photocopying and mailing to the QIO.

(iii) Providers and practitioners with approved waivers may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(iv) A QIO may not reimburse for any patient records submitted to the QIO by facsimile or by photocopying and mailing, if the provider or practitioner does not have an approved waiver.

(e) *Reimbursement for submitting patient records to the QIO.* (1) For purposes of this paragraph (e), a *patient record* means all patient care data and other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.

(2) A QIO may reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per patient record.

(3) For a provider or practitioner that has an approved waiver under paragraph (d) of this section, a QIO may reimburse the provider or practitioner for requested records submitted by—

(i) Facsimile at the rate of $0.15 per page; or

(ii) Photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage.

(4) A QIO may only reimburse a provider or practitioner once for each patient record submitted, per request, even if a patient record is submitted using multiple formats, in fragments, or more than once in response to a single request by the QIO.

(f) *Appeals.* Reimbursement for the costs of submitting requested patient records to the QIO in electronic format, by facsimile or by photocopying and mailing is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and 484.265 of this chapter. Appeals concerning these costs are subject to the review process specified in part 405, subpart R, of this chapter.

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§ 476.80 Coordination with Medicare administrative contractors, fiscal intermediaries, and carriers

(a) *Procedures for agreements.* Medicare administrative contractor, fiscal intermediary, or carrier must have a written agreement with the QIO. The QIO must take the initiative 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 Medicare administrative contractor, fiscal intermediary, or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, CMS will assist them in resolving matters in dispute.

(2) The QIO must incorporate its administrative procedures into an agreement with the Medicare administrative