The Law Offices of
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Health Care Provider
Legal Alert

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CMS Proposes Changes To The QIO Review Program

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Health care providers regularly deal with medical reviews as part of Medicare program participation. For the past thirty years, peer review organizations, now known as Quality Improvement Organizations (QIOs), have reviewed the services of Medicare providers in an effort to maintain and improve the quality of care. Because QIO reviews follow a formal audit protocol, the process can be both time consuming and impersonal. With these and other issues in mind, on July 9, 2012, the Department of Health & Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) proposed changes to the regulations governing QIO reviews and solicited input from the public as part of the larger hospital outpatient prospective payment system (HOPPS) proposed rule.[1] Overall, the proposed changes would increase the role of Medicare beneficiaries in the complaint review process and may shorten decision timeframes, but at the cost of certain provider rights. Most if not all Medicare providers will be impacted and should consider filing comments with CMS.

Public comments on the proposed changes to the QIO program must be submitted to CMS by **September 4, 2012**. Please let us know if you would like assistance preparing a comment letter.

Background. Established under the Peer Review Improvement Act of 1982,[2] the Utilization and Quality Control Peer Review Program was designed to "improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries"[3] through the creation of peer review organizations (PROs). Now known as QIOs, these are private organizations staffed by qualified health care professionals that operate under five year contracts with CMS.[4] QIO contracts are awarded based on a geographic area – local, state, regional or national.[5] Per the current "Scope of Work" under these contracts, QIO responsibilities include mandatory case review, review of written beneficiary complaints and general improvement of health care quality.[6]

Federal law, in turn, requires that all physicians, health care professionals, providers and suppliers furnishing services to Medicare beneficiaries enter into agreements with QIOs. For example, 42 C.F.R. § 412.508 imposes such a requirement for long-term acute care hospitals (LTACHs), as follows:

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> **(a)** ***Admission and quality review.—*** A long-term care hospital must have an agreement with a QIO to have the QIO review, on an ongoing basis, the following:
>
> **(1)** The medical necessity, reasonableness, and appropriateness of hospital admissions and discharges.
>
> **(2)** The medical necessity, reasonableness, and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§412.523(d)(1) and 412.525(a).
>
> **(3)** The validity of the hospital's diagnostic and procedural information.
>
> **(4)** The completeness, adequacy, and quality of the services furnished in the hospital.
>
> **(5)** Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.[7]

Such agreements, typically called a Memorandum of Agreement (MOA), legally bind service providers to cooperate with the QIOs. Cooperation requires providers to grant QIOs access to and examination of operations and records. Providers are also responsible for supplying all pertinent data to the QIO and allocating sufficient space for onsite reviews. In the case of offsite reviews, providers are required to photocopy and deliver to the QIO all required documents within thirty days.[8] Failure to fully cooperate with the QIO may result in sanctions by the HHS Inspector General and/or the assignment of financial liability for Medicare claims.[9] Sanctions may include Civil Monetary Penalties ranging from $10,000 to $100,000, suspension of Medicare enrollment, suspension of payment to the health care provider, or suspension of marketing activities to Medicare beneficiaries.[10]

Proposed Changes to the QIO Program. CMS is proposing a number of changes to the QIO program. CMS is adding a new alternative dispute resolution (ADR) option. In addition, CMS is adding provisions for the processing of beneficiary complaints to give beneficiaries more information about the QIO review process. QIOs also would have new authority to send and receive the secure transmission of electronic health information. Beneficiaries would be given the right to authorize QIOs to use and disclose their confidential health information.[11] CMS is adding new procedures for QIOs to use in completing general quality of care reviews as well.

CMS is proposing its most far-reaching changes to the beneficiary complaint review process. These changes address issues regarding the efficiency and responsiveness of these reviews and to allow beneficiaries to play a greater role in the process. For example, CMS found that it can take over 150 days to resolve a beneficiary complaint. In response, CMS is proposing an alternative dispute resolution process called "immediate advocacy."[12] Immediate advocacy is defined as "an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received."[13] CMS suggests that the new dispute resolution process will be better for beneficiaries by addressing

pressing complaints more quickly, while the issue is most relevant. It will be better for providers, according to CMS, by avoiding the more costly beneficiary complaint review process that involves formal complaint letters, the time and cost of submitting medical records, and an inability to immediately address beneficiary concerns.[14] According to the proposal, immediate advocacy would not be available where the QIO determines that elements of the complaint could constitute "significant, substantial or gross and flagrant violations of the standard of care to which a beneficiary is entitled."[15] For these more substantial violations, the written beneficiary complaint review process would still be utilized.

To improve QIO processing of beneficiary complaints and give beneficiaries more information about the QIO review process, CMS is proposing to (i) allow electronic beneficiary complaint review requests to be accepted as written requests, (ii) allow providers only ten calendar days to respond to QIO information requests,[16] and (iii) require QIOs to issue interim initial determinations within seven calendar days of receiving all medical information.[17] Further, CMS is proposing to *broaden* the ability of beneficiaries to provide additional related information after a written complaint has been submitted. However, CMS would *restrict* the right of providers to submit new or additional medical evidence after an initial determination has been made. CMS is also proposing to revise current rules to allow beneficiaries to receive more information regarding the QIO's determination. Accordingly, beneficiaries would have access to patient-specific information about him or herself that previously was available only from the provider. CMS suggests that greater access to information, including QIO determination criteria, will allow more parity between providers and Medicare beneficiaries when challenging QIO complaint review determinations.

In addition to allowing QIOs to release more information about reviews to affected beneficiaries, CMS is proposing to give QIOs the authority to receive and send electronic health information and, subject to beneficiary authorization, use confidential health information. In order to facilitate these various procedural changes, CMS is also proposing 14 new defined terms.[18]

Finally, CMS is proposing new procedures for QIOs to use in completing general quality of care reviews. First, CMS is proposing to establish the circumstances in which QIOs may perform a general quality of care review. According to the proposal, a QIO would be entitled to conduct a review based on "(i) Concerns identified during the course of other QIO review activities; (ii) Referrals from other sources, including but not limited to individuals, contractors, other Federal or State agencies; or (iii) Analysis of data."[19] Second, QIOs would use evidence-based standards of care in carrying out general quality of care reviews.[20] Third, CMS is proposing to implement shorter response timeframes,[21] restrict the opportunity of providers to discuss the QIO's initial determination before it becomes final,[22] and specify the manner in which a QIO final determination is issued.[23]

Impact on Providers. The changes that CMS is proposing to the QIO program are largely favorable to Medicare beneficiaries, but are somewhat of a mixed bag for health care providers. Although proposals to increase the participation of beneficiaries and streamline review procedures are meant to improve the QIO program, only the new "immediate advocacy" ADR process holds significant promise to reduce the burden of QIO reviews on providers. The expansion of beneficiary complaints to include complaints that are oral (to be addressed via "immediate advocacy") and electronic (sufficient to qualify as "written complaint") may actually *increase* the volume of QIO reviewed beneficiary complaints. This could lead to increased provider expense and resource allocation to QIO reviews. Similarly, beneficiaries' increased access to QIO determinations may encourage beneficiaries to pursue additional recompense outside the QIO program—namely, through medical malpractice litigation. In contrast, there should be greater confidence in QIO determinations if CMS finalizes its proposal that QIOs use evidence-based standards of care in carrying out general quality of care reviews. However, shorter document submission timeframes and restrictions on a provider's ability to discuss reviews with QIOs prior to initial determination and submit new or additional medical evidence after an initial determination are steps in the wrong direction.

In sum, CMS's attempt to create greater parity between providers and beneficiaries when it comes to QIO reviews may actually tilt the scales in favor of beneficiaries. Of course, providers have the ability to submit written comments to CMS during the comment period to seek a better balance between the two.

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[1] Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations, __ Fed. Reg. __ (July 30, 2012) (hereinafter, the "Proposed Rule"). All page references are to the display copy.

[2] Part of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (P.L. 97-248).

[3] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html.

[4] On January 1, 2012 the contract term was increased from three to five years as a result of the Trade Adjustment Assistance Extension Act of 2011(TAAEA) (P.L. 112-40).

[5] The traditional arrangement of one QIO per state or territory was modified by the TAAEA, effective January 1, 2012.

[6] Medicare Program; Evaluation Criteria and Standards for Quality Improvement Program Contracts (10th Statement of Work), 76 Fed. Reg. 46814 (Aug. 3, 2011); CMS Pub 100-10 § 1005.

[7] 42 C.F.R. § 412.508(a).

[8] See 42 C.F.R. § 476.78. Hospitals are compensated according to CMS established guidelines for resources used in complying with QIO requirements.

[9] 42 C.F.R. § 476.90.

[10] 42 C.F.R. § 422.750.

[11] Proposed Rule, at 531 *et seq*; *see also* http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4397&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date.

[12] Proposed Rule, 534-36.

[13] Proposed Rule, 660.

[14] Proposed Rule, 540-41.

[15] Proposed Rule, 539.

[16] This is a change from the 21 to 30 days that providers are currently allowed to respond.

[17] Providers would also have seven days from the date of a QIO's initial determination to discuss the QIO's decision before it is final.

[18] The proposed defined terms include: "appointed representative" ; "authorized representative" ; "beneficiary complaint"; "beneficiary complaint review"; "beneficiary representative"; "general quality of care review"; "gross and flagrant violation"; "immediate advocacy"; "preadmission certification"; "quality improvement initiative"; "quality of care concern"; "quality of care review"; "significant quality of care concern"; and "substantial violation in a substantial number of cases."

[19] Proposed Rule, 675.

[20] Proposed Rule, 675.

[21] Ten calendar days for providers/practitioners to respond to requests by QIOs and 7 calendar days for QIOs to issue an initial determination from the time it receives all medical information. Proposed Rule, 675-76.

[22] Proposed Rule, 559. This is in contrast to the right to discuss the initial determination in beneficiary complaint reviews. CMS suggests that a provider's right to appeal the final determination renders the discussion period unnecessary.

[23] Proposed Rule, 559-60.

About Us

The Law Offices of Jason M. Healy PLLC is a Washington, D.C. based law firm serving national and local clients. We focus primarily on legal issues affecting health care providers and welfare benefit plans. We help health care providers and their trade associations understand Medicare and Medicaid laws and regulations, and address compliance matters. We also represent health care providers in reimbursement audits, appeals, litigation, and transactions. We help sponsors of welfare benefit plans understand and comply with federal and state laws and prepare plan documents. Located in Washington, DC, just minutes from the Department of Health and Human Services, Congressional offices, and the White House, we are well positioned to provide legal support for advocacy efforts. Our Principal, Jason M. Healy, is a health care lawyer with over 14 years of experience with the array of legal issues facing health care providers.