



DYKEMA GOSSETT PLLC

Health Law Developments

Federal Court Quashes Subpoena for Testimony of QIO Physician in EMTALA Case

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Dykema Gossett recently assisted the Michigan Peer Review Organization in successfully resisting a subpoena for the testimony of MPRO's physician reviewers. In one of the first cases of its kind, a federal district court judge declined to permit a party to call a quality improvement organization (QIO) physician reviewer to testify in a court proceeding brought by a deceased patient's representative under the Emergency Medical Treatment and Active Labor Act (EMTALA). (*Smith v. Botsford General Hospital*, United States District Court for the Eastern District of Michigan, No. 00-71459, April 15, 2003.)

The parties had previously obtained directly from CMS copies of both a 5-day and 60-day report prepared by the QIO, as the regulations permit. The issue before the court was whether the identity of physician reviewers could be disclosed, and the physicians could be required to testify about the deliberations of the QIO.

The court noted that physician identity had been excluded from the copies of reports provided to the parties, and concluded that the physician could not be subpoenaed, even though certain of the parties knew or could speculate as to physician identity, as a result of having participated in a QIO meeting.

The parties briefed issues related to:

- Whether the privileged status granted to QIO information and deliberations by CMS regulations applies under the EMTALA portion of the regulations, and
- Whether QIO reports are admissible in private EMTALA actions because they

are prepared to help CMS and the OIG determine whether a provider should be subject to administrative sanctions for failure to stabilize or treat a patient with an emergency medical condition before a transfer out of the hospital, not for the purpose of determining liability to affected patients or their representatives.

The court did not rule directly on these issues, and based its rulings rather on the principle that QIO deliberations are confidential; physician identity is confidential absent physician consent; and affected patients or patient representatives are not bound by QIO findings because they are not given an opportunity to participate in QIO proceedings or to have discovery relating to the proceedings or to any potential bias of any physician reviewer. The court ordered the subpoenas sealed to protect physician reviewer identity.

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CMS Publishes Guidance on Provider-Based Determination Process



Background re Provider-Based Criteria

In April 2002 CMS published new, more rigorous, standards for qualifying a facility as being part of a hospital, SNF or other Medicare "provider." The new standards

became effective in 2001. However, facilities that were treated as provider-based on October 1, 2000 were “grandfathered” and are not required to comply with the new standards until the provider’s first cost reporting period beginning on or after July 1, 2003.

CMS’ Attestation Process

Last month CMS published instructions for its fiscal intermediaries (FIs) regarding the standards and procedures to be used in determining whether individual facilities satisfy the provider-based criteria. Providers may (but are not required to) file with CMS a voluntary attestation regarding specific facility(s). CMS will determine if the facility is provider-based on the basis of the information submitted.

Highlights of the instructions include:

- A provider must send a copy of each attestation to both its FI and the CMS Regional Office. The FI will recommend approval/disapproval. The CMS Regional Office makes the decision.
- The attestation may be in any format that contains the necessary information. CMS’ instructions include a sample.
- CMS’ instructions describe the type of documentation which the provider must either submit or keep on file to support the position that a facility is provider-based.
- CMS acknowledges that a single building may contain both provider-based space (e.g. a hospital outpatient radiology department) and non-provider-based space (e.g. office space leased to private physicians). The attestation needs to identify specifically the offices/suites which are claimed to be provider-based.
- A single attestation may cover any number of different facilities that are claimed to be provider-based.

Benefits of Filing Attestations

The benefits of filing an attestations are:

- If CMS makes a favorable determination and the provider notifies CMS in writing of any subsequent material changes relating to the facility, any decision by CMS that the facility is no longer provider-based will be effective prospectively only.
- If a provider files an attestation and receives a negative decision, CMS will only recoup the difference between provider-based and freestanding rates on claims paid since the attestation was submitted. In contrast, a provider that does not file an attestation may face recoupment of the payment differential for all periods that are subject to reopening.

- Filing an attestation that includes a complete description of all relevant factors enables a provider to obtain clear guidance from CMS as to whether the provider-based criteria are satisfied, and hence protects the provider against claims of fraudulent billing.

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HHS Issues HIPAA Enforcement Regulation



On April 17 HHS hurriedly issued skeletal interim-final regulations for imposing civil money penalties (CMPs) for violation of the HIPAA Privacy Rule. Although HHS’ immediate need was a regulation dealing with violations of the Privacy Rule, this interim Enforcement Rule expressly applies to all of the following standards issued under HIPAA’s administrative simplification provisions:

- The Privacy Rule – compliance mandated as of April 14, 2003
- The Transactions and Code Sets Rule (a/k/a EDI) – compliance mandated by October 16, 2003
- The Unique Employer Identification Rule – compliance mandated by July 21, 2004
- The Security Rule – compliance mandated by April 20, 2005.

Interim Nature of the Rule

The Enforcement Rule is effective as of May 19, 2003. However, it is only an interim final rule; HHS expects to replace it with a more comprehensive rule in the fall. Hence, the interim Enforcement Rule sunsets on September 16, 2003. HHS has solicited public comments on the interim rule. Comments are due to HHS by June 16, 2003.

Key Issues

The interim Enforcement Rule does not address several key issues, such as:

- aggravating and mitigating factors
- the knowledge required before a provider, health plan or clearinghouse can be held liable for a violation
- computation of the CMP

Instead, the interim rule reiterates HHS’ policy of encouraging voluntary compliance through technical assistance,

and focuses on due process once HHS concludes that it must impose a CMP.

HHS borrows heavily from existing procedural rules governing the imposition of CMPs for fraud and abuse violations. Affected providers, health plans or clearinghouses will be given notice of the intended imposition of a CMP, an opportunity for a formal evidentiary hearing before an administrative law judge, and an opportunity to appeal an unfavorable decision through the federal court system. As with other CMPs, failure to request a hearing results in automatic imposition of the suggested CMP.

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Proposed JCAHO Emergency Room Standard May Implicate EMTALA



On May 9, 2003, the Joint Commission on Accreditation of Healthcare Organizations released a proposed leadership standard for public review and comment. The standard calls on hospital leaders to develop and implement plans to identify and mitigate situations that result in emergency department overcrowding. Leaders would have to assess the causes, scope and impact of overcrowding; institute specific steps to plan for, address and monitor overcrowding; and adopt indicators to measure hospital performance. One specific element leaders must address is “coordination with community resources” to expedite discharge. These resources include long term care facilities, home health agencies and other hospitals.

As JCAHO focuses on moving patients out of emergency facilities promptly, hospitals must continue to give careful attention to the Emergency Medical Treatment and Active Labor Act to avoid unanticipated EMTALA violations. EMTALA requires that each emergency department patient receive a medical screening examination to determine whether the individual has an emergency medical condition and, with certain exceptions, that each patient be treated or stabilized before any transfer outside the facility, including a discharge.

The proposed standard can be found on the JCAHO website. Comments are due June 2, 2003.

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Are Assisted Living Facilities Candidates for Additional Regulation?



In 2001, the U.S. Senate Special Committee on Aging commissioned the formation of a national workgroup to make recommendations regarding protection of seniors residing in assisted living facilities. Recognizing the great variation among assisted living service providers, the Special Committee on Aging aimed to develop consensus standards for service delivery, oversight, consumer protection, and related issues in this fast growing industry. To this end, roughly 50 national assisted living stakeholders formed the Assisted Living Workgroup, which in April 2003 issued a comprehensive report to Congress. Workgroup participants included national associations like the American Association of Homes and Services to the Aging, the National Assisted Living Association, and the American Association of Retired Persons, as well as representatives of regulators, ombudsmen, health professionals, disease-specific interest groups and grass roots consumer advocacy groups. On April 29, 2003, the Special Committee on Aging held its first hearing on the workgroup report.

Key issues of concern to the Workgroup were:

- quality indicators
- dementia care
- outcome measures
- accountability
- regulations and legislation
- facility size
- research
- best practices
- affordability.

Topic-oriented subcommittees produced a comprehensive report replete with detailed recommendations approved by at least 2/3 of the Workgroup. The report also contains information on other issues that did not receive the 2/3 vote necessary to become official recommendations, along with the dissenting votes and commentary.

- The Workgroup predicts that its comprehensive report will have implications for an audience much broader than the Senate Special Committee on Aging, including federal and state policymakers; federal and state agencies involved in service delivery, regulation, quality monitoring and enforcement; insurers and financiers.



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As part of our service to you, we regularly compile short reports on new and interesting developments in health law and the issues the developments raise. Please recognize that these reports do not constitute legal advice and that we do not attempt to cover all such developments. Your comments on this newsletter, or any Dykema publication, are always welcome. © 2003 Dykema Gossett PLLC.

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The Workgroup recommendations are likely to impact assisted living providers in Michigan.

- Some providers of assisted living care are unlicensed in Michigan – the report may prompt legislators or regulators to encourage or demand licensure.
- Even if licensed, assisted living providers in Michigan can function under differing licensure schemes depending on the definitional category into which they fall – home for the aged or adult foster care. The report may prompt consolidation of various licensure regimes to ensure more consistent standards.

- Service options in unlicensed assisted living facilities vary greatly, as do staffing levels, resident rights, and a host of other operational issues. The Workgroup’s recommendations suggest minimum criteria and best practices for the industry that may promote more uniformity.

In short, it is quite plausible that the Workgroup’s report will in some measure change the Michigan assisted living landscape within the next several years. It is a document that all stakeholders should carefully review and understand.

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