The Law Offices of Jason M. Healy PLLC

Long-Term Acute Care Hospital Legal Alert

December 2011 Vol. 1, No. 7

In This Issue

A health law firm in the nation's capital

www.HealyLawDC.com

Contact Us:

Jason M. Healy
1667 K Street NW
Suite 1050
Washington, DC 20006
(202) 706-7926
(888) 503-1585 fax

jhealy@healylawdc.com

CMS Issues Final Rule on Medicare Data Sharing for Performance Evaluation

The Centers for Medicare & Medicaid Services (CMS) recently published a final rule that will make more information available to the public about the performance of long-term acute care hospitals (LTACHs) and other providers and suppliers. The new regulations will give qualified entities access to Medicare Part A, B, and D claims data for the purpose of measuring provider and supplier performance. These regulations are primarily concerned with how this data will be used by qualified entities, with little in the way of provider protections or recourse in the event that erroneous information is published. As a result, providers will have to be increasingly vigilant to protect their reputation.

Required under the Affordable Care Act. Section 10332 of the Affordable Care Act (collectively, Pub. L. 111-148 and Pub. L. 111-152) added Section 1874(e) of the Social Security Act ("the Act"), which requires Medicare to make standardized extracts of claims data under Medicare Parts A, B, and D available to certain entities that are qualified to use this data to make performance evaluations on "measures of quality, efficiency, effectiveness, and resource use." The final rule from CMS implements this section of the Act ("Final Rule").[1] The new regulations at Subpart G of 42 C.F.R. Part 401[2] define qualified entities, describe the data and measures to be shared, and define a process that allows providers to preview any reports and correct any errors.

Qualified Entities. Section 1874(e)(2) of the Act allows the Secretary to develop standards for determining the types of public and private entities that are qualified to receive and evaluate claims data. CMS refused to limit qualified entities to non-profit and government organizations, instead allowing "any organization that meets the eligibility requirements" to qualify.[3] To be eligible to receive data as a qualified entity, the applicant must "demonstrate expertise and sustained experience, defined as 3 or more years" in defined areas.[4] The entity must meet organizational and governance criteria, which include expertise and experience in accurately calculating measures from claims data, a business model that will cover the costs of performance and fees

for obtaining the data, and combining data from multiple payers. The entity must also show that it is capable of (i) designing and improving the format of performance reports, (ii) preparing an understandable description of the measures used, (iii) protecting privacy and data security, (iv) accurately preparing reports for the public at the provider level, and (v) implementing a process for providers to review and comment upon reports prior to publication.[5] Qualified entities are required to combine Medicare data with private sector data they already possess, and must explain why such data is statistically sufficient.[6] To allow entities with less experience or limited other claims data to gain the experience and data needed to be approved, an entity can enter into a contractual arrangement with other entities to meet all of these requirements to qualify.[7]

To apply for approval, an entity must submit to CMS a list of the measures it intends to calculate and report, the source of those measures, the rationale for using each measure, a description of the geographic area to be served, and a description of the methodologies to be used, among other things.[8] Entities will be approved for three years, with an expedited re-application process available at the end of the three-year period.[9]

Data and Measures. Two types of measures may be used by qualified entities – standard measures and alternative measures. A standard measure is one that will be used as designed and that can be calculated "in full or in part from claims data [or] from other sources," meaning that it is endorsed by the National Quality Forum, identified by the Agency for Healthcare Research and Quality, calculable from standardized extracts of claims or prescription drug event data, or endorsed by a CMS-approved consensus-based entity.[10] CMS will allow qualified entities to use clinical data (*e.g.*, registry data, chart-abstracted data, laboratory results, or electronic health record information) in combination with Medicare and other claims data to calculate these standard and alternative measures.[11] CMS will divulge beneficiary identifiable information to qualified entities that wish to report combined clinical and claims data.[12]

An alternative measure is one that the Secretary, through either notice-and-comment rulemaking or a stakeholder consultation approval process, has found to be preferable to a standard measure.[13] This will give providers and suppliers a chance to provide input on the alternative measures proposed. An alternative measure approved by rulemaking is available to all qualified entities, whereas one approved through stakeholder consultation is available only to the entity that proposed it.[14] CMS will publish a list of all approved standard and alternative measures, which will be updated periodically.[15]

Provider Appeals and Error Correction. A qualified entity must confidentially share review measures, measurement methodologies, and evaluation results with providers 60 days prior to making the reports based upon that information available to the public.[16] During this 60-day timeframe, the provider must be given the opportunity to request and then receive the data used and the beneficiary names relevant to any measure or results the provider wishes to appeal.[17] CMS did not define what aspects of the proposed report could be appealed or give any examples in the Final Rule.[18] CMS also did not mandate a timeframe for the appeal process to be completed, stating only that they hope 60 days would give providers "ample opportunity to resolve the appeals process."[19] Further, CMS declined to establish a uniform appeal process.[20] According to CMS, it would not be appropriate for "CMS to become involved in the appeals and error correction process or to offer a public forum for providers and suppliers to defend themselves," instead citing only the "rigorous application process" and agency monitoring.[21] CMS noted that it lacks the authority to mandate that qualified entities share claims data from non-Medicare sources, which may be subject to limitations imposed by the non-Medicare source, but nevertheless "encouraged" qualified entities to share such data where possible.[22]

In strong terms, CMS says that a qualified entity *must* publicize the report on the date it told the provider that publication would occur, notwithstanding the fact that a provider has an appeal request outstanding.[23] CMS declared that this requirement would "prevent providers or suppliers from making spurious requests for error correction to prevent the publication of measure results."[24] But in such a situation, the qualified entity must "if feasible, post publicly the name of the appealing provider … and the category of the appeal request."[25] Notably, although qualified entities will be required to report detailed information and statistics regarding provider appeals and requests for error correction, no remedy is prescribed for affected providers.[26] CMS *may* impose sanctions ranging from a warning notice to termination of a qualified entity that violates any provisions related to data sharing, fails to report to CMS, or fails to correct errors in a timely manner.[27]

Impact on LTACHs and Other Providers. The Final Rule and new regulations give LTACHs and other providers no input in the identification and approval of qualified entities. Providers will have some input in the approval of alternative measures, either through the submission of comments during notice-and-comment rulemaking or the stakeholder consultation process.[28] Further, the appeal and error correction process in the regulations afford providers little protection, and no defined remedy, in the event that damaging or inaccurate information is published. CMS has tried to address these concerns by stating that it will monitor qualified entities. However, providers will need to be diligent in reviewing proposed reports from qualified entities and the underlying

data and measures for accuracy. Since there are no restrictions on how the reports may be used once they are in the public domain, providers will also need to monitor how non-regulated third parties use the information in these reports.

---

1. Medicare Program; Availability of Medicare Data for Performance Measurement, 76 Fed. Reg. 76542 (Dec. 7, 2011).
2. 42 C.F.R. § 401.701 *et seq.* (effective Jan. 6, 2012).
3. 76 Fed. Reg. at 76,544.
4. 42 C.F.R. § 401.705.
5. *Id.*
6. 76 Fed. Reg. at 76,545-46 (though conditional approval is available for qualified entities that do not possess sufficient other-payer data per 42 C.F.R. § 401.707.).
7. *Id.*
8. 42 C.F.R. § 401.707.
9. *Id.* at § 401.709.
10. *Id.* at § 401.715(a).
11. 76 Fed. Reg. at 76,547.
12. *Id.*
13. 42 C.F.R. § 401.715(b).
14. *Id.*
15. 76 Fed. Reg. at 76,449-50.
16. *Id.* at § 401.717.
17. 42 C.F.R. § 401.717.
18. *See* 76 Fed. Reg. at 76,556-58.
19. *Id.* at 76,557.
20. *Id.*
21. 76 Fed. Reg. at 76,558.
22. *Id.*
23. In the preamble to the Final Rule, 76 Fed. Reg. at 76,557, CMS said "the qualified entity **must** publicly release reports on the specified date regardless of the status of any requests for error correction." This directive was repeated and defended by CMS in the preamble, *Id.* at 76,557-58; however, the regulations published do *not* include this mandate.
24. 76 Fed. Reg. at 76,557.
25. 42 C.F.R. § 401.717.
26. *Id.* at § 401.419.
27. *Id.* at § 401.721.
28. 76 Fed. Reg. at 76,550

About Us

The Law Offices of Jason M. Healy PLLC is a health care law firm that focuses exclusively on legal issues affecting health care providers. We help health care providers and their trade associations understand Medicare and Medicaid laws and regulations. We also represent health care providers in reimbursement audits, appeals, and litigation. Located in Washington, DC, 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.

Please feel free to reach us at the phone number or email address above if we can be of assistance. We look forward to working with you and your company.