Healthcare Law

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CMS Releases Final Rule to Allow Access to Medicare Claims Data

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On December 5, 2011, the Centers for Medicare & Medicaid Services (CMS) released a Final Rule to implement a provision of the Affordable Care Act ("ACA") giving qualified entities access to Medicare claims data for use in evaluating the performance of health care providers.

This Final Rule incorporates changes based on public comments to the Notice of Proposed Rulemaking ("NPRM") published on June 8, 2011. In our report on the NPRM we described how the rule sets forth guidelines on how an organization that meets extensive qualification requirements may pay an annual fee to access patient-level Medicare Parts A, B, and D data. These entities will combine Medicare data with private-sector claims data that they already have access to in order to prepare public reports measuring the performance of physicians, other providers, and suppliers. The goal is to help consumers and payers make informed decisions about their health care by selecting the highest-quality providers in their areas.

The following update highlights the key changes between the NPRM and the Final Rule released by CMS and presents key takeaways from the Final Rule.

What Are the Key Changes and Additions in the Final Rule?

Eligibility Process for Qualifying Entities

As we described in our earlier report, in order to be eligible to receive Medicare Parts A, B, and D data for purposes of measuring provider and supplier performance, an entity must meet specific criteria, including: (1) ability to prove it can keep the data secure; (2) access to at least one other source of non-Medicare commercial payer data; (3) ability to produce accurate performance reports; and (4) development of a review and grievance procedure for providers.

Key Changes and/or Additions

- The Final Rule revised the eligibility criteria to allow potential participants in the program to receive a conditional acceptance as a qualified entity if the entity does not currently have another source of claims data at the time of application, but meets all the other eligibility requirements.
- The Final Rule clarified that entities seeking to be part of the evaluative process do not need to be single organizations; subcontracting with other private or public entities to demonstrate competence in measuring provider quality is permitted.

Standard and Alternative Quality Measures

Qualifying entities must use a standard performance measure or an

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approved alternative measure. The NPRM defined a "standard measure" as one that can be calculated using *only* claims data and that is endorsed by the National Quality Forum. Standard measures also included any claims-based measure of provider performance that has been adopted through rulemaking and that is currently used in a CMS program that involves performance measurement.

As formerly proposed and retained by the Final Rule, an entity may suggest use of an "approved alternative measure" for evaluating performance even if a standard measure already exists. Public comment may be sought by CMS through notice and comment rulemaking, so it may determine if the alternative measure is more valid, reliable, and responsive to consumer preferences.

Key Changes and/or Additions

- Based on Public Comment, the Final Rule allows qualifying entities to utilize measures that are not fully calculated using only claims data, thus allowing for use of clinical data in performance measurement, which is intended to ensure reliability of reports on specific performance measures.
- The Final Rule adds measures endorsed by a CMS-approved, consensus-based entity to the list of standard measures. CMS will approve organizations as consensus-based upon review of the entity's criteria for approval of the performance measurement standard.
- The Final Rule retains the NPRM guidelines for approval of a proposed alternative measure but implements a secondary process by which entities may seek approval to use alternative measures. This process allows a qualified entity to receive approval upon the submission of documentation evidencing consultation (and ultimate agreement) by the entity with stakeholders in the geographic region pertaining to the extracted data and scientific, technical evidence that the measure is indeed more valid, reliable, and responsive to consumer preferences.

Dissemination of Medicare Data By CMS

The NPRM sought comment on whether Medicare claims data should be released to qualified entities on both a regional and national basis. CMS proposed releasing nationwide claims data only if a qualified entity reached a particular threshold of non-Medicare data to match with the Medicare data released. The NPRM also sought comment on how to improve efficiency and timeliness in release of such data to qualified entities for use in performance evaluation.

Key Changes and/or Additions

- CMS estimates that the cost of releasing Medicare data will be substantially lower than previously predicted. The average cost for a qualified entity for the first year of the program is $40,000, down from $200,000. This estimate is based on the assumption that there will be 25 qualified entities and on average each entity will request data for approximately 2.5 million beneficiaries. Medicare has embedded efficiencies into the process, such as access to more "timely" Medicare claims data, so as to alleviate the burden of synthesizing information from such a large beneficiary population.
- In response to public comment concerning the benefit of using

national data by agencies engaged in performance measurement and data aggregation, the Final Rule permits any entity to purchase a five percent national sample of Medicare claims data for purposes of calculating national benchmarks for performance measures.

Provider Grievance Procedures

The NPRM emphasizes the importance of the establishment of a confidential review and grievance procedure by the qualifying entity to allow providers and suppliers to review reports, measurement methodologies, and the actual data relied upon, prior to publication of measure reports. This ensures an opportunity to correct measurement errors where necessary and a greater degree of accuracy and consistency.

Key Changes and/or Additions

- In anticipation of increased costs and a significant investment of resources by providers in the measure report review process, the Final Rule lengthens the time allotted to providers for review of performance reports from 30 days to 60 days to allow for more comprehensive review.

How Does the Final Rule Improve Upon the Existing Landscape for Provider Performance Appraisal?

- **Increased Reliability Through Changes to Data Dissemination and Allowable Quality Measures:** By allowing data dissemination on both a regional and a nationwide basis the Final Rule ensures that a broader sampling of Medicare data is combined with data from other commercial payers to provide for increased reliability of results. Likewise, by allowing the potential for a broader subset of standard and alternative measures to be used (including measures that utilize clinical data), the Final Rule takes into account the potential for unfair representations of providers where the validity of statistical measures is called into question. The Final Rule also considers the environment in which providers operate by allowing the use of different kinds of data in performance calculation.
- **Retention of Data Privacy and Security Requirements:** The Final Rule reinforces the ongoing obligation that qualified entities apply privacy and security protections to the released data (e.g., execution of a Data Use Agreement, which contains significant penalties—civil monetary and criminal penalties—for inappropriate disclosures of data). The close monitoring of a rigorous privacy program implemented by the qualifying entity will hopefully minimize such inappropriate disclosures, but at the very least the Data Use Agreements ensure that individuals who are affected by disclosures of individually identifiable data are promptly notified.
- **Increased Transparency and Provider Accountability:** Performance reporting is instrumental in helping consumers make informed decisions about providers and reinforces the concept of value-based purchasing and accountability by providers and suppliers alike.

What Are Potential Pitfalls and Questions Left Unanswered by the Final Rule?

- While the Final Rule makes it clear that extracted Medicare data and

any derivative data thereof may be used only for purposes of creating such reports, it does not address the use of the public reports post-publication. As noted by CMS in the preamble, the reports themselves can be utilized by any party, including the qualified entity, for activities such as internal analysis, quality assurance, pay-for-performance initiatives, or provider tiering. Since there are no limitations as to how these reports may be used downstream, there should be particular interest by providers in how this initiative unfolds and in closely monitoring the release of such reports. The reports have the potential to impact consumer purchasing decisions and to alter the provider landscape accordingly.

- The Final Rule has modified the eligibility process so as to require only that qualifying entities document and demonstrate expertise in the areas of measurement particular to their measurement methodologies, rather than in all four areas of quality measurement (i.e., quality, efficiency, effectiveness, and resource use). Thus, for example, according to CMS an entity does not need to be familiar with risk-adjustment activities if it is not utilizing a measure that adjusts for risk. This raises concerns about the comprehensiveness of the expertise base of potential qualifying entities and about the measures themselves. A permitted lack of knowledge about risk adjustment signals concerns about the impact of sample size and other factors (such as resource-intensive provider specialties) on particular provider performance measurements.
- Rather than adding a restriction to the amount of claims data applicants must possess to address concerns about sample size and reliability, the Final Rule refrains from instituting an absolute threshold for a minimum amount of non-Medicare claims data measuring entities must possess. Instead, applicants are asked to explain why their other payer source data is sufficient to control for issues of sample size, for example, when there is only a single payer source. There is still a question of how the lack of restriction will translate into effective comparison reporting where the raw data utilized by entities in producing the prescribed reports is not standardized.

The Final Rule is available here.

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