

January 19, 2011

Barbara Edwards
Director
Disabled and Elderly Health Programs Group
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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Dear Ms. Edwards,

We are writing in regard to the Centers for Medicare and Medicaid Services (CMS) recent developments in the Continuous Quality Improvement strategy for the 1915(c) Home- and Community-Based Waiver program.

Quality is a dimension of service delivery in home and community programs that has rightly become a prominent focus of consumers, elected officials, the public, the Centers for Medicare and Medicaid Services and the state agencies managing service systems. The development and adoption of the Quality Framework by CMS in 2002 provided a solid foundation for CMS and state agencies to collaborate in the development of an approach to assuring and improving quality that was relevant, practical, and accountable.

In 2003, CMS responded to media reports about serious problems in home- and community-based services and demands for improvement from Congress by developing a set of strategies to improve services provided by the states and the federal government's oversight of state programs. Those strategies included: a series of letters to State Medicaid Directors disseminating information on quality practices, the provision of technical assistance to states, and the redesign of the processes for approving state applications to provide home- and community-based waiver services and for conducting federal oversight of state programs.

Recognizing that home- and community-based services are operated and also funded by state governments, CMS made an important decision to initiate a working relationship with state agencies to develop these strategies. State Medicaid agencies, developmental disability agencies and state aging agencies were involved. This unique and positive federal/state collaboration produced the key component of the new CMS quality strategy – the 1915(c) waiver application. In line with the Quality Framework, the waiver application focused attention on the design of state service systems. It required states to describe, in considerable detail, the structure and functioning of the overall program and especially the state's approach to assuring and improving quality utilizing the core functions outlined in the Quality Framework – discovery, remediation and improvement.

Accompanying the development of the waiver application was the adoption of the Interim Procedural Guidance (IPG) which changed the federal approach to oversight of the program. Prior to the IPG, CMS regional staff routinely conducted site visits to state programs, visiting a handful of consumers receiving services in an effort to evaluate the extent to which state agencies were meeting CMS assurances. Recognizing the ineffectiveness of inspection strategies in such large state systems and the need for an evidence-based approach, CMS revamped its oversight protocol to obligate states to provide data to CMS measuring the state's performance in meeting the waiver assurances. The data provided by the states would enable CMS to determine if the state had a credible quality management strategy, and over time, whether states were effectively identifying and acting upon areas that needed remediation and improvement.

As the waiver application has been modified since its adoption in 2003, there has been considerable growth in the requirements for states to both collect data and report to CMS. Assurances have expanded to include subassurances, states are being required to identify performance measures for each assurance and subassurance with considerable specificity, remediation is not only required but states must now report on remediation activities with person specific detail.

It is these more recent developments in the implementation of the CMS Quality Strategy that are problematic.

Performance Measures and Compliance

The number of performance measures: An effective quality management system is one that focuses on a limited number of important, critical, and strategic problems. It engages all those involved in the delivery of service in the design and implementation of remedies as well as the evaluation of whether the remedy has been effective. This requires a longitudinal view of systems to determine whether systems improvements are having an effect over time.

Currently, states are being required to provide detailed information on the performance measures for each assurance and subassurance, including the sampling methodology, the frequency of data collection, the data sources, and the entity gathering the data. The number of performance measures in waiver applications now ranges from 35 to 70.

Nowhere else in the Medicaid or Medicare programs is this number of performance measures being required. Such a significant number of performance measures creates an extraordinary data collection burden and overwhelms state agency staff. It is a standard rule in the field of Quality Management that "if you measure everything, you measure nothing." Overwhelmed by data, managers become paralyzed.

100% compliance: Presentations by the National Quality Enterprise make it clear that the only acceptable level of performance across all assurances and subassurances is 100%. This requirement has the inevitable consequence of compelling states to report on every measure every year in perpetuity, since 100% compliance in any system of any size is impractical and virtually unachievable. Such a requirement also eliminates consideration of a test of substantial compliance or the use of a measurement threshold that would

determine that a finding is systemic rather than idiosyncratic. The 100% standard is unreasonable, particularly in large waiver programs serving several thousand beneficiaries. The requirement also impedes the ability of a state to carry out true quality management practice because it requires resources to be directed to issues that may be incidental at the expense of issues that have a substantial impact on the quality of services and people's lives.

Remediation at the Individual Level

An essential aspect of quality management is remediation of serious issues. While a state must describe its method for prompt follow up and remediation of identified problems at the individual level in its 1915(c) waiver application, the focus of remediation, as conceptualized in the Quality Framework and the initial discussions between CMS and the states, was to be on provider and systems level improvements. That is, when an area of program management was found to be deficient and out of compliance, the state was expected to analyze the root cause of the systems performance failure and institute a system wide remedy. Systems remedies could include new policies, new business practices, and changes in the design of the program. On going performance measurement would determine whether the system remedy was effective over time.

Guidance provided by CMS regarding the development, implementation and monitoring of the 1915(c) Medicaid waiver programs does not require or even reference the development of Quality Improvement Strategies to assure and report on 100% compliance at the individual level. The HCBS Waiver Application Version 3.5 (Appendix H, Section b (i)), requires only that a state identify its "method for addressing individual problems as they are discovered" and to "include information regarding responsible parties and GENERAL methods for problem correction." The detailed Instructions, Technical Guide and Review Criteria (2008) for Waiver Application Version 3.5 emphasize in Appendix H Systems Improvement that the process must include: "the measures and processes employed to correct identified problems;" "aggregate and analyze trends in the identification and remediation of problems and establish priorities for, and assess the implementation of, systems improvements (p. 242)." The focus on systems improvement is additionally reflected in the CMS Interim Procedural Guidance for Conducting Quality Reviews of Home- and Community-Based Services (HCBS) issued February 6, 2007, Guide on Assessing Annual State 372 Reports, which focuses on the state's submission of timely and accurate data, compliance with approved cost and utilization limits, and the documentation of problem resolution, both in terms of individuals affected and systemic modifications to prevent problem recurrence in the future (p. 12).

The recently instituted practice of requiring states to report remediation at the individual level in every performance area deviates significantly from the concept of improving systems. While findings that the health and safety of any individual is in jeopardy must be remedied quickly, findings in many areas of performance such as untimely plan authorization, late eligibility determinations, or failure to deliver services authorized in the plan cannot be remedied after the fact. The bigger and more important issue is whether the number of times these things occur is significant rather than occasional, whether the state has identified the systemic reason for the performance shortfall and has instituted a meaningful remedy. The final question is whether performance improves over time as a result of the systemic remedy.

The current practice of requiring states to report remediation for each individual and whether action was taken within 30, 60, and 90 days is a survey and certification practice, practical at the provider level but highly impractical in systems that serve as many as 25,000 people or more. With 35-70 performance measures and hundreds of individuals sampled, it is highly likely that there will be many hundreds of issues to be tracked and reported whether or not there was substantial compliance with the assurance or whether or not the health and welfare of any individual is jeopardized. In many cases the finding may be based simply on missing documentation; for many it will be failure to provide a unit of service on a timely basis – a common occurrence at least once for every individual.

More importantly, focusing on remediation at the individual level is at the expense of determining whether the overall system is designed and operated adequately. Some states report that they are now struggling to maintain two reporting systems – one to provide CMS with individual remediation information and one to actually measure and improve the quality of the system.

Data Collection and State Resources

The new data collection expectations are unreasonable and appear to be escalating. Most recently, one state was required to track the training of all direct care staff which involves 10,000 employees of hundreds of private provider agencies. This mandate is necessitating the development of additional information technology and a new requirement that provider agencies routinely report the training completed by each employee.

The only alternative to the development of an information technology system is additional staff to receive reports from provider agencies, enter it into a data base, track provider reporting and analyze the data for compliance.

States do not have resources for additional employees or to develop information technology systems.

Building a quality management system that is dependent on people to manually collect data separate from everyday business practices is impractical, unreliable and during these times, simply impossible. The only viable tool for collecting and analyzing data efficiently and reliably is Information technology (IT). However, it has been difficult to identify resources for IT development during good financial times; today it is near impossible.

While a few states have succeeded in obtaining enhanced federal financial participation (FFP) to support contracting with Quality Improvement Organizations and developing information technology systems to manage service delivery and quality, doing so has been arduous and approval has often come after implementation. Initial outlays of funding by states with the hope of obtaining enhanced FFP for these necessary system components is no longer an option for any state. Reductions in the number of state personnel limit the states' ability to navigate the rules and application process for obtaining approval for enhanced FFP. Increased expectations of states to improve quality must be accompanied by increased resources and assistance.

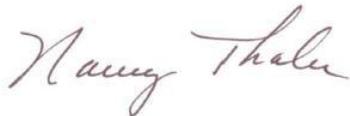
In Summation

The growing demands on states to implement increasingly complex quality management systems and improvement strategies are problematic because they: (a) deviate significantly from the original intent of the quality initiative, i.e. that CMS would review state systems of quality rather than monitor activities at the level of the individual beneficiary, (b) extend beyond the expectations specified in the HCBS Waiver Application Version 3.5 and related guidance, and (c) are being placed on states at a time when their fiscal and human resources are diminishing.

Our members fully appreciate the need to both assure and monitor quality and the necessity of CMS to have confidence that states are in fact doing so. However, the current growth in performance measures and reporting requirements significantly exceeds the level of measurement and reporting necessary for CMS to have such confidence.

We would respectfully request that actions to further expand waiver application requirements and reporting requirements be suspended and that CMS use it's working relationship with state agencies to develop expectations that are time and resource efficient and achieve the outcomes we all desire.

Sincerely,



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