

HEALTH LAW NEWS

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CMS FINALIZES NEW CONDITIONS OF PARTICIPATION FOR HOME HEALTH: PART 1

Review of the New Quality Assessment and Performance Improvement Condition

This is the first article in a series discussing CMS's pre-publication copy of the Final Revised Home Health Conditions of Participation ("Final CoPs"). With the release of the Final CoPs, CMS is finalizing, with only a few changes, the significant changes they proposed to make to the home health CoPs in October 2014. Although the major revisions are mostly adopted as proposed, a number of "clarifying changes" introduced in the final rule are substantive.

Since the Final CoPs impose numerous requirements, Hall Render will issue a series of articles summarizing various components. Last week, Hall Render published an article that contained a brief analysis of the Final CoPs.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT - SECTION 484.65

The new Home Health Agency ("HHA") Conditions of Participation ("CoPs") remove two old CoPs (Group of Professional Personnel and Evaluation of the Agency's Program) and replace them with a single new CoP: Quality Assessment and Performance Improvement ("QAPI"). This change is part of the overall quality focus of the new HHA CoPs. It is also part of CMS's "effort to reduce medical errors, and improve the quality of health care in all settings." CMS acknowledged commenters' concerns that preparing for the QAPI CoP will take significant effort. CMS amended the regulation so that HHAs do not need to begin conducting performance improvement projects until January 13, 2018.

DETAILED SUMMARY

The Final QAPI CoP contains five standards: Program Scope; Program Data; Program Activities; Performance Improvement Projects; and Executive Responsibilities. The final regulation states that "[t]he HHA must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program." The regulation specifically cites the HHA's governing body's involvement in QAPI. The regulation does not define a "one-size-fits-all" program, but rather requires an HHA's QAPI program to: 1) reflect the complexity of the HHA's organization and services; 2) include all HHA services; 3) focus on indicators related to improved outcomes, including use of emergency services, hospital admissions and hospital readmissions; and 4) take action to improve HHA performance across the spectrum of care. The final regulation added emergency services as an indicator of HHA quality.

For HHAs that are part of a larger provider entity/health system, the larger entity's QAPI program may not suffice for compliance with this requirement. CMS stated that "this rule requires the QAPI program to be individualized to the HHA." Because of this requirement that the program be individualized, "[p]articipation in a larger, system-based improvement program may or may not satisfy the requirements of this rule." Whether it would depends upon "whether the larger, system-based improvement program addresses the specific areas of concern or weakness within the HHA component of the system." HHAs must ensure their program is specific to their needs. For example, if the health system's QAPI program was focused on infection control, but the HHA's area of concern was OT achieving desired outcomes, the parent QAPI program would not suffice. The HHA would need to have its own QAPI on OT in place of or in addition to the parent's program.

The program scope standard requires the QAPI program to be "capable of showing measureable improvement in indicators" that are linked to improvement in patient outcomes, safety and care quality. The program must "measure, analyze and track quality indicators." Quality indicator is a defined term in the final CoPs. CMS included a definition in the proposed CoPs in 2014. This definition received significant support from commenters and was included without any changes. A quality indicator is a "specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care." CMS does not specify what constitutes a quality indicator, but the QAPI CoP includes a standard regarding Program Data. Under this standard, an HHA's QAPI program must "utilize quality indicator data, including measures derived from OASIS..." CMS also commented when it proposed this definition and related standard that "surveyors would expect HHAs to demonstrate, with the objective data from the OASIS data set and other sources available to the HHA, that improvements had taken place with respect to actual care outcomes, processes of care, patient satisfaction levels and/or other quality indicators." HHAs will definitely need to consider data from OASIS as part of their QAPI program.

The HHA's QAPI program must use this data to monitor the effectiveness and safety of services as well as the quality of care provided and to



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identify opportunities for improvement.

This condition also includes a standard describing the QAPI program activities. An HHA's QAPI program must: "(i) Focus on high risk, high volume, or problem-prone areas; (ii) Consider incidence, prevalence, and severity of problems in those areas; and (iii) Lead to an immediate correction of any identified problem that directly or potentially threatens the health and safety of patients." The HHA must track adverse patient events, analyze their cause and implement preventive actions. This standard not only requires HHA to take action to improve performance but also measure its success and track performance after taking action to ensure the improvements are sustained.

The QAPI CoP includes a standard describing HHA Performance Improvement Projects. These are the discrete efforts to measure, analyze and improve performance. This standard has been modified to include a later compliance deadline. All other provisions of the proposed CoPs take effect on July 13, 2017, but this standard states that HHAs are not required to undertake any performance improvement projects until January 13, 2018. CMS received many comments seeking a "phased-in" compliance approach for the QAPI CoP because this is a major substantive change. In response to the commenters' concerns, CMS stated:

"[W]e agree that a phased-in implementation time frame is appropriate for the requirement that HHAs must conduct performance improvement projects because it will take additional time to collect the data necessary to identify areas for improvement that are appropriate for performance improvement. We have added a phase-in to allow HHAs the time necessary to collect data prior to implementing performance improvement projects. This allows for a full 12 month time period between the time that this final rule is published and the time that HHAs must begin conducting performance improvement efforts."

Although HHAs will have until January 13, 2018 to begin pursuing performance improvement projects, they should begin working on implementing QAPI now. This will allow time not only to develop the necessary policies, procedures and tools but to test their programs and ensure they are achieving the requirements of the regulation.

An HHA's performance improvement projects must reflect the "scope, complexity and past performance of the HHA." The HHA must document the projects undertaken, the reasons for choosing these projects and the progress achieved.

The last standard that is part of this CoP is the standard for Executive Responsibilities. This standard imposes a number of specific requirements on the governing body. Although the governing body was involved in the old HHA evaluation efforts, this standard will require more understanding and involvement from the governing body. The governing body must ensure that: (1) an ongoing QAPI program is defined, implemented and maintained; (2) the QAPI program addresses priorities for improved quality of care and patient safety and that all improvement actions are evaluated for effectiveness; (3) the clear expectations for patient safety are established, implemented and maintained; and (4) any fraud or waste identified by the QAPI program is appropriately addressed. In addition, the program data standard requires the HHA's governing body to approve the frequency and detail of the HHA's data collection. HHAs will need to implement policies and procedures to ensure communication with the board, documentation of decision-making by the board and similar issues. This will likely include the use of dashboards to report on QAPI efforts, suggestions from the QAPI program to the board for future projects, reports of identified waste or fraud to the board and similar matters. The governing body's minutes/agenda ought to include, at least annually, a QAPI discussion and related decision-making.

CMS estimates that in year one, HHAs will spend 81 hours annually on QAPI and that in future years, HHAs will spend 75 hours annually on QAPI. This seems weefully insufficient for the scope of QAPI program envisioned by the regulations.

Overall, the proposed QAPI CoP provides HHAs with a significant degree of flexibility to implement QAPI, or modify a current QAPI program, in a manner that fits with the HHA's operations. Regardless of the specifics of an HHA's implementation, the proposed QAPI standard will require a detailed, objective, ongoing and well-documented QAPI effort. QAPI will no longer just be about the group of professional personnel, but it will be HHA-wide and go all the way up to the governing body and/or health system partners. HHAs will need to thoroughly document their efforts from the initiation of the QAPI program through selection of ongoing efforts, monitoring improvements, reporting to the governing body, etc.

PRACTICAL TAKEAWAYS

Unlike the rest of the rule, HHAs have until January 13, 2018 to comply with the QAPI CoP. This gives HHAs additional time, but they should be sure to use it wisely.



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- HHAs should review current QAPI efforts to identify what components can be utilized in their efforts to prepare for this new condition.
- HHAs should begin to educate their governing body on QAPI and this condition.
- HHAs should begin to consider how they will connect their governing body to the QAPI process and document the governing body's involvement.

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¹ 42 C.F.R. 484.65.

² Pre-Publication Copy, pp. 159.

³ Id.

⁴ Pre-Publication Copy, pp. 155.