

Protection of QAPI Materials

I Thought My Quality Assurance Documents Were Protected?

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One of the more confusing elements of the Quality Assurance and Performance Improvement (QAPI) process is the mistaken belief that all documents that may fall under the QAPI process or reviewed by the QAPI committee cannot be reviewed by surveyors and are not subject to disclosure to attorneys in a personal injury/wrongful death lawsuit against a nursing facility.

ACCESS OF QAPI MATERIALS BY A DIA OR CMS SURVEYOR

The basis for the requirement for a facility to maintain an active QAPI program is found in F865.

The rule provides in relevant part:

§483.75(a) Quality assurance and performance improvement (QAPI) program.

Each long-term care facility, including a facility that is part of a multi-unit chain, must develop, implement and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must:

§483.75(a)(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include, but is not limited to, systems and reports demonstrating systematic identification, reporting, investigation, analysis and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

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§483.75(a)(3) Present its QAPI plan to a state survey agency or federal surveyor at each annual recertification survey, upon request during any other survey and to CMS upon request; and

\$483.75(a)(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a state survey agency, federal surveyor or CMS, upon request.

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§483.75(h) Disclosure of information.

A state or the secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

The GUIDANCE contained in the State Operations Manual provides helpful information relating the interpretation of QAPI requirements relating to limitations on providing documents under §483.75(a)(2)-(3), and (h)-(i) relating to the QAPI Plan

<u>Disclosure of Information and Good Faith Attempts</u>

The survey process is intended to be an objective assessment of facility compliance with the Requirements of Participation. This assessment is guided by facility performance and outcomes as reported by Quality Measures (QMs) and Minimum Data Set (MDS) data, as well as complaints and surveyor observations, interviews, and record reviews. The surveyor task to review the QAPI Plan/QAA is intended to occur at the end of the survey, after completion of investigation into all other requirements to ensure that concerns are identified by the survey team independent of the QAPI Plan/QAA review. Surveyors must use critical thinking and investigatory skills to identify noncompliance, rather than using information provided during the QAA review as a source to identify deficiencies.

The intent of §483.75(h), (i) is to:

- Ensure information obtained from QAA committee documents that is related to the committee's good faith attempt to identify and correct quality deficiencies are not used by surveyors to identify additional concerns not previously identified during the survey; and
- Foster a culture where nursing homes can openly conduct their internal QAA investigations and performance improvement efforts.

Surveyors may only require facilities to disclose QAA committee records if they are used to determine the extent to which facilities are compliant with the provisions for QAA.

Protection from disclosure is generally afforded documents generated by the QAA committee, such as minutes, internal papers, or conclusions. However, if those documents contain the evidence necessary to determine compliance with QAPI/QAA regulations, the facility must allow the surveyor to review and copy them. The key point is that the facility must provide satisfactory evidence that it has, through its QAA committee, identified its own high risk, high volume, and problem-prone quality deficiencies, and are making a "good faith attempt" to correct them. Information gleaned from disclosure of QAA committee documents will not be used to cite new issues (not already identified by the survey team) or to expand the scope or severity of concerns identified on the current survey.

NOTE: Prior to conducting the QAA review, the survey team must conduct a thorough investigation of all issues identified, including expanding the sample as necessary to determine the scope of the issue.

Reports and Logs

Incident and accident reports, wound logs, or other reports or records used to track adverse events are not protected from disclosure. Surveyors may request these documents as part of their normal investigation of other areas of concern throughout the survey to support their findings.

As an example, if a surveyor identifies an issue with pressure sores or call light response, or is investigating a complaint involving these areas, the surveyor is allowed to ask for QA documentation to see if the facility's QAPI program identified the issue and implemented interventions to address the issue. The facility is obligated to provide information relating to this issue but does not need to provide other QA material relating to other areas. The surveyor is not supposed to request QA materials for the purpose of conducting a "fishing expedition."

The surveyors are only supposed to inquire about the facility's QAPI program at the end of the survey, after survey findings have already been identified by the surveyor. It is proper to remind surveyors of this guidance to this rule if a surveyor seeks QA information prior to the end of the survey process.

One advantage of a well-documented QAPI process is that the rules reward effective quality assurance. As noted above, good faith attempts by a facility to identify and correct quality deficiencies are not supposed to be used as a basis for sanctions. Facilities that correct a problem that is later discovered by the Iowa Department of Inspections and Appeals (DIA) is likely to be considered "corrected past noncompliance" which may result in less punitive actions by DIA or CMS.

QAPI DOCUMENTATION DISCLOSURE WITHIN MALPRACTICE LAWSUITS

When a nursing facility is sued by a resident or a family on the resident's behalf, the rules allow for broad discovery by both parties which often includes requests for all QAPI materials maintained by a facility over a multi-year period. Attorneys seek these documents because they want to establish that a facility was aware of a particular problem but took inadequate steps to correct the issue. This assists in establishing the elements of negligence as well as punitive damages. If a facility is aware that it has an identified problem with pressure sores, but does not move to diligently correct the issue, an attorney can argue that the facility acted in a reckless manner or with wanton disregard for a resident health or safety.

Unfortunately, neither federal or Iowa state law offers a privilege that would prohibit or limit disclosure of QAPI materials, and facilities should presume that those records will be handed over to the attorney for a resident/family. The limitations that apply to surveyor review of QAPI materials does not apply to civil litigation. Keeping this in mind is important when preparing QAPI materials. Be objective in documentation measuring improvement or decline in quality measures and implement new interventions if improvement is not shown. Avoid inflammatory language (e.g. – "screwed up "botched"). Documentation of monitoring and an audit of identified problems is crucial to show a jury that a facility remained on top of an identified problem,.

The QAPI Process is an important part of any health care provider's ongoing risk management and avoidance process. While certain protections may apply during the survey recess, QAPI materials may not remain confidential and should be prepared with this understanding in mind.