



“COPS – PLANNING FOR SUCCESS”

Medicare Hospice Conditions of Participation (Cops) and Preamble Series

SUBPART C—Conditions of Participation: § 418.58 Condition of Participation: Quality Assessment and Performance Improvement

This information sheet includes the Centers for Medicare and Medicaid Services’ (CMS) regulatory language for 418.58 and the accompanying language from the preamble. The preamble language provides questions about the regulation responses to the questions, and CMS’s rationale for the final language in the regulation.

The regulation - § 418.58 Condition of Participation: Quality assessment and performance improvement.

The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice’s governing body must ensure that the program: Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) Standard: Program scope.

- (1) The program must at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.
- (2) The hospice must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations.

(b) Standard: Program data.

- (1) The program must use quality indicator data, including patient care, and other relevant data, in the design of its program.
- (2) The hospice must use the data collected to do the following:
 - (i) Monitor the effectiveness and safety of services and quality of care.
 - (ii) Identify opportunities and priorities for improvement.
- (3) The frequency and detail of the data collection must be approved by the hospice’s governing body.

(c) Standard: Program activities.

- (1) The hospice’s performance improvement activities must:
 - (i) Focus on high risk, high volume, or problem-prone areas.

- (ii) Consider incidence, prevalence, and severity of problems in those areas.
- (iii) Affect palliative outcomes, patient safety, and quality of care.
- (2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.
- (3) The hospice must take actions aimed at performance improvement and, after implementing those actions, the hospice must measure its success and track performance to ensure that improvements are sustained.

(d) Standard: Performance improvement projects. Beginning February 2, 2009 hospices must develop, implement, and evaluate performance improvement projects.

- (1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.
- (2) The hospice must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) Standard: Executive responsibilities. The hospice's governing body is responsible for ensuring the following:

- (1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained, and is evaluated annually.
- (2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness.
- (3) That one or more individual(s) who are responsible for operating the quality assessment and performance improvement program are designated.

Preamble language for § 418.58 Condition of Participation: Quality assessment and performance improvement.

II. Provisions of the Proposed Regulations and the Analysis and Responses to Public Comments

On May 27, 2005, we set forth proposed rules for hospices that choose to participate in Medicare and Medicaid. We proposed to revise all of the existing conditions of participation (CoPs), and to add several new CoPs to address aspects of hospice care that we believe need attention. This section will briefly describe the content of each CoP in the proposed rule.

We proposed no changes to Subparts B (Eligibility, Election and Duration of Benefits), G (Payment for Hospice Care), or H (Coinsurance) of 42 CFR part 418.

We received 205 timely items of correspondence that raised numerous issues. These Comments, detailed below, came from accrediting bodies, consumer advocacy organizations, hospices, individuals, national health care provider organizations, State agencies, and State health care provider organizations.

Condition of Participation: Quality Assessment and Performance Improvement (Proposed §418.58)

The existing § 418.66, “Condition of participation-Quality assurance,” relies on a problem-oriented approach to identify and resolve patient care issues. Failure to meet the quality assurance condition is consistently one of the top 10 deficiencies cited by Medicare surveyors nationwide. During the last decade the health care industry, including the hospice industry, has moved beyond the problem-oriented, after-the-fact corrective approach of quality assurance to an approach that focuses on a preemptive plan that continuously addresses QAPI. Hospice industry associations have indicated that the upgraded QAPI approach used by many hospice providers is incompatible with the existing quality assurance condition. On the other end of the spectrum some providers do not have any quality program.

The proposed QAPI requirement would raise the performance expectations for hospices seeking entrance into the Medicare and Medicaid programs, as well the expectations of those currently participating in Medicare and Medicaid. We proposed that each hospice would develop, implement, and maintain an effective, continuous quality assessment and performance improvement program that stimulates the hospice to constantly monitor and improve its own performance, and to be responsive to the needs, desires, and satisfaction levels of the patients and families it serves. The desired overall outcome of this proposed CoP would be that the hospice would drive its own quality improvement activities and improve its provision of services. With an effective quality assessment and performance improvement program in place and operating properly, a hospice can better identify and reinforce the activities it is doing well, identify its activities that are leading to poor patient outcomes, and take actions to improve performance. A hospice would be free to develop a program that meets its needs. As proposed, a provider’s QAPI program would not be judged against a specific model.

The proposed QAPI CoP was divided into five standards. Under standard § 418.58(a), “Program scope,” a hospice’s quality assessment and performance improvement program would include, but not be limited to, an ongoing program that would be able to show measurable improvement in indicators that were linked to improving palliative outcomes and end-of-life support services. We expect that a hospice would use standards of care and the findings made available in current literature to select indicators to monitor its program. The hospice would measure, analyze, and track these quality indicators, including areas such as adverse patient events and other aspects of performance that assess processes of care, hospice services, and operations. (“Adverse patient events,” as used in the field, generally refer to occurrences that are harmful or contrary to the targeted patient outcomes.)

The second proposed standard at § 418.58(b), “Program data,” would require the hospice program to incorporate quality indicator data, including patient care, administrative, and other relevant data, into its QAPI program. This would include data that were received from or submitted to hospice professional organizations. We did not propose to require that hospices use any particular process or outcome measures. However, a hospice that would choose to use the available quality measures would be able to expect an enhanced degree of insight into the quality of its services and patient satisfaction, compared to beginning the outcome-measure

development process anew because currently existing measures have already been tested to some degree for reliability and validity.

Proposed standard (b) also would require that data collected by the hospice, regardless of the source of the data elements, would be collected in accordance with the detail and frequency specifications established by the hospice's governing body. Once collected, hospices would use the data to monitor the effectiveness and safety of services, and to identify opportunities for improvement.

The third standard under the quality assessment and performance improvement program at proposed § 418.58(c), "Program activities," stated that the hospice would set priorities for its performance improvement activities that focused on high risk, high volume and problem-prone areas, considered the prevalence and severity of identified problems' and gave priority to improvement activities that affected palliative care, patient safety, and quality of care outcomes. In § 418.58(c) we also proposed to require the hospice to track adverse patient events, analyze their causes, and implement preventive actions that would include feedback and learning throughout the hospice.

We proposed at § 418.58(d), "Performance improvement projects," that the number and scope of improvement projects conducted annually would reflect the scope, complexity, and past performance of the hospice's services and operations. The hospice would document what improvement projects were being conducted, the reasons for conducting them, and the measurable progress achieved on them.

In the final proposed standard at § 418.58(e), "Executive responsibilities," a hospice's governing body would be responsible and accountable for ensuring that the ongoing quality improvement program was defined, implemented, and maintained. The governing body would ensure that the program addressed priorities for improved quality of care and patient safety. The governing body would also specify the frequency and detail of the data collection and ensure that all quality improvement actions were evaluated for effectiveness. The governing body's most important role would be to ensure that staff were furnishing, and patients were receiving, safe, effective, quality care. Therefore, it would be incumbent on the governing body to lend its full support to agency quality assessment and performance improvement efforts.

Comment: A few commenters stated that the phrases "measurable improvement," "palliative outcomes," "end of life support systems," and "quality indicators" as they were used in the QAPI CoP, were vague.

Response: We agree that the phrase "end of life support systems" is vague, and we have removed it in the opening paragraph and standard (a) because it is duplicative of the requirement that a hospice's QAPI program must involve all hospice services, including those services furnished under contract or arrangement. In § 418.58(a)(1) we have replaced the term "end of life support systems" with "hospice services" to correspond with the "hospice services" described in the opening paragraph. We do not agree that the phrase "palliative outcomes" is

vague. Outcomes are the results of care provided; therefore palliative outcomes are the results of palliative care provided. Since hospices primarily furnish palliative care to patients and respond to the results of the care furnished, we believe that it is reasonable to expect hospices to include palliative outcomes, gathered as part of the comprehensive and updated comprehensive assessments in accordance with final § 418.54(e), as part of their QAPI programs. We replaced the phrase “indicators for which there is evidence that improvement in those indicators will improve palliative outcomes” in § 418.58(a)(1) with the phrase “indicators related to palliative outcomes.” We believe that this revised language is clearer and more precise. Therefore, revised § 418.58(a)(1) now reads, “[t]he program must at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.” We do not agree that the phrase “measurable improvement” is vague. Hospices are required to have data-driven QAPI programs. Through these data, hospices measure their current performance, implement performance improvement projects, and measure their changes in performance after implementing the performance improvement project. Based on an analysis of the data, we believe that hospices will be able to measure the amount of improvement, stagnation, or decline in their performance and adjust their activities accordingly.

Comment: Numerous commenters asked for more clarification of the term “adverse event” as it is used in § 418.58(a) and § 418.58(c) of this Condition of Participation. Other commenters asked for a delay in the proposed requirement that hospices must collect and analyze adverse event data.

Response: We do not define the term “adverse event” because we believe that, as part of their QAPI programs, hospices should be free to define and implement the term in the manner that fits their needs. Hospices may choose to develop their own definition or use a definition developed by an accrediting body or industry organization. Once a hospice has identified the definition of an adverse event, it is responsible for adhering to the definition when tracking and analyzing these events and when implementing preventive actions. In general, an adverse event would be any action or inaction by a hospice that caused harm to a hospice patient. However, hospices are not bound to use this generic description.

We believe that it is essential to a hospice’s QAPI program to begin tracking and analyzing adverse events at the same time that it begins collecting patient level outcome measure data elements and hospice-wide measures. Since adverse events generally result in harm to a patient, they serve as important indicators of areas for potential improvement. If hospices do not collect adverse event information, they may be missing important data from which to assess their performance. Therefore, we are not delaying the adverse event requirements in this final rule.

Comment: Many commenters submitted suggestions for what hospices may want to consider when selecting the elements of their QAPI program. Commenters suggested that hospices may

want to examine such issues as pharmacy services, bar coding, electronic prescribing, clinical decision support programs, adverse event reporting systems, provider education efforts, patient and family education efforts, pain, nausea, shortness of breath, skin integrity, constipation, the appropriateness of emotional and spiritual interventions, and the timeliness of meeting patient needs at the start of care.

Response: We appreciate all of the suggested areas that hospices may choose to examine when developing their QAPI programs. In addition to these suggested domains, hospices may also want to consider issues surrounding patient transitions. Transitions from one care setting/provider to a hospice, or from a hospice to another care setting/provider, are an opportunity for hospices to improve their relationships with their referral sources while improving patient care and safety. Hospices may want to consider the use of shared protocols, agreements to honor advance directives, medication reconciliation processes, caregiver training and support systems, communication arrangements, and feedback systems, all related to patient transitions, as areas to examine in their QAPI programs. We are not requiring hospices to use any of the suggested domains identified above at this time because there is no currently available set of standardized measures.

Comment: A few commenters requested clarification about when and where patient care measures will be documented.

Response: Different patient care measures require different data collection timeframes. While some measures may require data collection only once, other measures may require data collection every few days or weeks. The nature of the patient care measure will determine the timeframe for collecting and updating. We expect hospices to establish their data collection timeframes within the specific context of the measures used, the available literature, any nationwide data collection projects they may participate in, their own data collection needs and goals, as well as the needs of their patients.

We require in § 418.104(a)(4) that the patient care outcome measure data be included in the patient's clinical record because hospices must use such data for individual care planning and coordination of services (§ 418.54(e)(2)). Hospices are free to document the patient care measure data in other locations as well in order to meet their needs. All documentation must be in accordance with the data collection policies and procedures established by the hospice to ensure consistency and retrievability.

Comment: Many commenters requested clarification on the role of national standardized patient outcome measures and their relationship to standardized benchmarks. Specifically, commenters noted that, while some national measures are currently available, there is still work to be done in this area. A commenter suggested that any measures developed should relate to providing physical and emotional support, promoting shared decision-making, individualizing care, and attending to the needs of families. In addition, commenters expressed uncertainty about how

national benchmarks may be used to measure patient outcomes. Some commenters suggested that we should work with the hospice industry and quality improvement organizations (QIOs) to establish such benchmarks while other commenters stated that benchmarking is not necessary because the variances between hospices put the validity of the benchmarks into question.

Response: We agree that more work is needed to establish a wide variety of valid patient outcome measures that hospices may choose from. We commissioned a special study, the PEACE project, conducted by the North and South Carolina QIO. This study created a quality-focused self-audit tool for hospices to use, and identified quality measures that focus on the quality of clinical care furnished to hospice patients. Results of the study are available at <http://medqic.org/dcs/ContentServer?pagename=Medqic/MQPage/Homepage>.

In addition, the National Hospice and Palliative Care Organization launched a National Quality Initiative and Quality Collaborative to improve hospice and palliative care outcomes. This initiative is helping hospices develop functional QAPI programs, including patient outcome measures.

Furthermore, the National Quality Forum has issued voluntary consensus standards for end-of-life care of cancer patients, who comprise approximately 50 percent of the hospice patient population (*National Voluntary Consensus Standards for Symptom Management and End-of-Life Care in Cancer Patients*, December 2006, www.qualityforum.org/publications/reports/palliative.asp).

The National Quality Forum also issued the “National Framework and Preferred Practices for Palliative and Hospice Care Quality” (2006, www.qualityforum.org). This report identified eight domains of quality care as follows: Structures and processes of care; physical aspects of care; psychological and psychiatric aspects of care; social aspects of care; spiritual, religious, and existential aspects of care; cultural aspects of care; care of the imminently dying patient; and ethical and legal aspects of care. Using the structure of these domains, the report identifies 38 preferred practices that have been endorsed as suitable for implementation in hospice programs.

Furthermore, the agency for Healthcare Quality and Research (AHRQ) issued an evidence-based review of end-of-life care and outcomes (www.ahrq.gov/clinic/epcsums/eolsums.htm) that may also assist hospices.

We believe that these efforts, combined with the measures already identified by the NHPCO and Brown University (Time Toolkit, www.chcr.brown.edu/pcoc/toolkit.htm), are sufficient to provide hospices with patient outcome measure options that suit their needs. Some of the measures that already have been or are being developed relate to comfortable dying, self-determined life closure, and family satisfaction with care.

We do not believe that these efforts are sufficient to establish nationwide benchmarks that are appropriate for inclusion in this rule. More time is needed to test, refine, and collect further data related to any specific measure before we could establish a nationwide benchmark that all hospices should be required to meet. The necessary information is simply not available at this

time to establish mandatory benchmarks, although hospices are free to use existing benchmarks to measure their own performance against that of other similar hospices who use the same measures.

In order to further the process of establishing widely-accepted, valid, benchmarked quality measures, CMS is actively pursuing additional research on selected quality measures. This research will help identify and refine measures that are valid, meaningful, and reliable for hospices. It will also help establish benchmarks for hospices to attain.

Following publication of this final rule, CMS will issue further sub-regulatory guidance on QAPI.

Comment: A few commenters questioned the ability or appropriateness of using the same outcome measures for each patient within a hospice. Some commenters noted that not all measures may apply to all patients. Likewise, the commenters noted that certain patients may need individualized measures unique to the patient's needs and goals. Other commenters noted that measures may be different based on the location in which care is provided (that is, in the patient's home or in an in-patient facility). Still other commenters noted that outcome measure data may not be statistically significant when the data are collected from extremely small samples due to a low patient census.

Response: A variety of hospice-specific patient outcome measures are currently available. Many of these measures capture data about universal issues such as patient pain or discomfort. We believe that these universal measures can be successfully applied to all of a hospice's patients, regardless of their diagnosis or care location. At the same time, we agree that hospices may need to add specific outcome measures for specific patients in order to gather data related to the individual's needs and goals. Hospices may add patient-specific measures to the core set of standard measures that they choose to collect data on for all patients. As with the core set of standardized patient data, patient-specific data must be gathered and documented in a consistent, systematic and retrievable manner.

When analyzing data on a patient level, sample size does not matter. To use the patient outcome measure of pain controlled within 48 hours of admission discussed above in the patient assessment section, a hospice would need to document for a patient the presence or absence of uncontrolled pain upon the patient's admission to hospice. If a patient has uncontrolled pain, the hospice would then reassess his or her pain 48 hours after the patient's admission to hospice and document the presence or absence of uncontrolled pain at that time. This does not mean that the hospice does not assess the patient's pain between the initial pain assessment and the 48 hour pain assessment. Indeed, the hospice may need to assess the patient's pain far more frequently in order to adjust the treatments being provided to control the patient's pain. In completing a patient-level analysis of the patient's data, the hospice would be able to judge the effectiveness of the initial care furnished in controlling the patient's pain.

In completing the hospice-wide analysis, this patient's pain control data would be aggregated with the pain control data of the other patients that the hospice cared for. This aggregated data

would allow the hospice to look for patterns such as a high level of pain control success for patients with cancer diagnoses and lesser levels of success for congestive heart failure patients. Identifying patterns, areas of strength, and areas of weakness allows the hospice to reaffirm promising practices that lead to positive patient outcomes and re-examine practices that lead to inadequate or negative patient outcomes.

Aggregation of data must be done in accordance with the policies and procedures established by the hospice. If a hospice has an extremely small average monthly census, then it may make sense for that hospice to aggregate several months of data. Likewise, if a hospice has an extremely large average monthly census, then it may make sense for them to aggregate the data more frequently to ensure that the amount of data does not become overwhelming to those analyzing it. The flexible nature of the patient outcome measure standard and the quality assessment and performance improvement CoP allow hospices to adapt data collection and analysis to their needs and goals.

Comment: A few commenters expressed enthusiastic support for the requirement that hospices collect patient outcome measure data, noting that other health care providers have been collecting this data for several years. Other commenters, while expressing support for the overall goals of data collection and QAPI, expressed concern about the potential costs. Commenters cited the potential cost and availability of software to aid in data collection as the single largest concern.

Response: We appreciate the overall support for data collection and QAPI. At the same time, we understand the concerns that some hospices have about implementing these new requirements. We note that the new regulation does not require hospices to use electronic health records or any specific software for data collection. Hospices are free to choose the data collection methods and tools that best suit their needs. We do not believe that this rule is imposing a burden on hospices by requiring them to obtain sophisticated data collection and analysis computer programs. Analysis of patient outcome measures, as well as administrative data, will allow hospices to determine objectively what care results in the best outcomes for a particular patient or subset of patients. This will help hospices identify best practices and avoid ineffective practices, which may reduce hospice expenditures in the future. We believe these benefits will outweigh any costs associated with the process.

Comment: A commenter suggested that, in § 418.58(b)(2)(ii), hospices should be required to use quality indicator data that they collected to identify priorities, as well as opportunities, for improvement.

Response: We agree that hospices should use data to prioritize their areas for improvement, and we have incorporated this suggestion into the final rule. Section 418.58(b)(2)(ii) now reads, “[i]dentify opportunities and priorities for improvement.”

Comment: In proposed § 418.58(b)(3), a commenter suggested that the governing body should approve, rather than specify, the frequency and detail of data collection.

Response: We agree that the governing body's general QAPI oversight responsibility would be more appropriately described by the term "approved" than the proposed term "specified," and we have made this change.

Comment: Some commenters suggested that the requirement for hospices to conduct performance improvement projects should be phased in.

Response: In accordance with this rule, hospices are required to identify opportunities and priorities for improvement based on the data that they have collected. We agree that it would be appropriate to delay implementation of the performance improvement projects requirement to allow hospices time to develop and implement a data collection program, and actually amass several months of data. For this reason, we have added a 240 day phase-in period. This phase-in period will allow hospices to gather several months of data before being required to develop and implement their data-driven performance improvement projects. Once the 240 day phase-in period is complete, we expect hospices to begin developing and implementing their data-driven performance improvement projects, with evaluation of those performance improvement projects to follow thereafter.

Comment: A commenter asked us to specify, in § 418.58(d)(1), that the number and scope of performance improvement projects that a hospice undertakes should be based on the needs of the hospice's population and its own internal organizational needs. Another commenter asked us to clarify our proposed requirement that performance improvement projects must reflect a hospice's past performance.

Response: While we understand that some hospices may want additional guidance on the number and scope of projects that must be undertaken, we believe that a hospice's performance improvement projects should be required to reflect the needs of its patient population as well as its own needs, and this requirement is included in the final rule. We also believe that hospices must examine their past performance when developing performance improvement projects. If a hospice is aware that it had issues in a particular area in the past, then we believe that it is appropriate to reexamine that issue to assure that it has been remedied. Hospices should conduct these performance improvement projects that focus on previously existing concerns in concert with performance improvement projects that focus on more recently occurring issues, to ensure that they are consistently furnishing quality services to patients. Revised § 418.58(d)(1) reads, "The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations."

Comment: A commenter suggested that, in § 418.58(d)(2), hospices should be specifically required to document any national quality improvement projects they are participating in. Other commenters questioned whether or not participation in national quality improvement projects would satisfy the QAPI requirement.

Response: Section 418.58(d)(2) requires hospices to document all performance improvement projects they are conducting, including national performance improvement projects. There is no need to single out national performance improvement projects as needing to be documented separately because they are one part of a hospice's larger performance improvement project plan, which must be documented. Hospices are free to participate in such national projects. We would caution however, that participation in such projects does not guarantee that hospices are in compliance with this requirement. As required by § 418.58(b)(2)(ii), hospices must use the quality indicator data that they have gathered to identify and prioritize opportunities for improvement. In addition, § 418.58(a)(1) requires a hospice's QAPI program to be able to show measurable improvement in areas related to improved palliative outcomes and hospice services. Furthermore, § 418.58(d)(1) requires that the scope and number of a hospice's performance improvement projects are to be based on the needs of the hospice and its patient population. Read together, these requirements require hospices to develop, implement, and assess performance improvement projects that reflect their areas of weakness, as identified through the data that they have collected, and the needs of their organizations. If a hospice participates in a national performance improvement project that does not address one or more of its areas of weakness, or if that performance improvement project will not enable the hospices to demonstrate measurable improvement in areas identified as needing to be addressed, then participation in the national performance improvement project would not meet the QAPI requirements of this rule.

Comment: Numerous commenters stated that the proposed QAPI requirement at § 418.58(e) assigned a hospice's governing body too much responsibility for the hospice's QAPI program. Commenters believed that the hospice IDG or a professional advisory committee would better fulfill the executive responsibilities described in this paragraph. One commenter suggested that the role of the governing body should be augmented by requiring it to monitor the QAPI program rather than simply ensuring that it is functioning. Another commenter suggested that the role of the governing body should be further clarified by adapting leadership standards for home care agencies established by the Joint Commission.

Response: Section 418.100(b) of this rule requires the hospice's governing body to assume full legal authority and responsibility for the management of the hospice, including its QAPI program. Section 418.58(e) of the proposed rule specified the QAPI responsibilities of the governing body. It would require the hospice's governing body to ensure that a QAPI program is defined, implemented, and maintained. In addition, the rule proposed that the governing body must ensure that the QAPI program addresses the hospice's quality priorities and that its effectiveness is evaluated. As the entity that is legally responsible for the hospice, we believe

that it is essential that the hospice governing body ensures that the hospice's QAPI program is meeting the requirements of this rule.

We believe that our governing body requirements meet the intent of the Joint Commission leadership standards. Therefore we are setting forth this requirement as final. The governing body may assume hands-on control of the QAPI program to ensure that the program is in compliance with this rule, or it may choose to appoint one or more individuals to handle the structure and administration of the QAPI program while the governing body retains ultimate responsibility for the actions of the designated individual(s).

As many commenters noted, the individuals who compose the governing body may not have significant experience in a hospice QAPI program and would therefore not be the best candidates to actively supervise or direct its activities. For this reason, it may not be appropriate to require the governing body to actively monitor the QAPI program if this function can be managed by others more knowledgeable in clinical and/or related fields of endeavor. A new provision has been added at § 418.58(e)(3) explicitly requiring the governing body to appoint QAPI leaders.

Comment: A commenter asked us to delete the proposed § 418.58(e)(3) which required the governing body to ensure that clear expectations for patient safety are established. The commenter stated that patient safety is already addressed throughout the regulations, and that it is redundant to include this requirement in the QAPI CoP.

Response: We agree that patient safety is already addressed throughout the rule and does not need to be separately included in the QAPI section.

Comment: The majority of commenters that submitted comments on the proposed quality assessment and performance improvement CoP supported its overall goals. The commenters appreciated our recognition of the role that QAPI now plays in the hospice industry as well as its current limitations. The commenters requested assistance from CMS in implementing some aspects of the proposed QAPI requirement. Commenters sought additional CMS involvement in developing measures that hospices may choose to use. Commenters also sought assistance from the QIOs that CMS contracts with to provide quality assistance for other provider types.

Response: In August 2006 CMS contracted with the North and South Carolina QIO to conduct a special study on hospice quality measures. This study created a quality-focused self-audit tool for hospices to use and identified quality measures that focus on the quality of clinical care furnished to hospice patients. Results of the study are available at <http://medqic.org/dcs/ContentServer?pagename=Medqic/MQPage/Homepage>.

In addition to this completed project, CMS plans to sponsor additional research that will examine the validity, reliability, appropriateness, and usefulness of select quality measures. Furthermore,

CMS plans to sponsor work that will develop a method for QIOs to actively assist interested hospices in developing and implementing QAPI programs.

Comment: Many commenters made general statements in support of the broad framework adopted by the proposed QAPI requirement. These commenters liked the fact that we did not propose that hospices use any specific quality measures, data elements or benchmarks. Commenters voiced approval that they would be permitted to identify their own quality goals, measures and elements, and that they would be permitted to identify how many performance improvement projects they undertook and what those projects would focus upon. Conversely, other commenters specifically asked for the regulation to detail the quality measures and data elements that must be collected, the number and topics of performance improvement projects that must be undertaken, and the exact benchmarks or results that must be achieved.

Response: The two diametrically opposed viewpoints expressed by commenters are difficult to reconcile. Our intent in developing the QAPI CoP was to ensure that hospices would develop a data-driven program for continuous quality improvement that reflects the needs of patients and hospices alike. We believe that prescribing specific data measures and improvement projects is not appropriate at this time because there is no currently available, valid, reliable, widely applied set of clinical and/or administrative quality measures. As hospice quality measurement and best practices continue to evolve, we believe that a set of measures and practices may be identified, and that such measures and practices may be appropriate for inclusion in the hospice rules.

At the same time, we are sensitive to the concerns of hospice providers who are wary of the new and unknown. As described above, we conducted a special study through the Carolina QIO to identify hospice measures focusing on the quality of clinical care furnished to hospice patients. These measures are publicly available at no cost to hospice providers. In addition, the largest hospice industry group, the National Hospice and Palliative Care Organization, has launched a major quality initiative to provide hospices with the tools they need to begin collecting and analyzing QAPI data and to develop, implement, and analyze performance improvement projects. Furthermore, Brown University has made available the TIME Toolkit, which contains quality measures and related data elements that hospices may use in their QAPI programs. We are confident that these efforts, and others that may arise in the future, will help hospices transition from the quality assurance approach to the QAPI approach. For additional discussion of the former quality assurance requirements and the new QAPI requirements, see pages 30847–30849 of the May 27, 2005 hospice proposed rule (70 FR 30840).

Comment: Many commenters expressed general concern about the cost of implementing a QAPI program. Several of these commenters suggested that implementing a QAPI program will require more staff hours and money than estimated in the impact analysis section of the proposed rule.

Response: We recognize that moving from the basic QA approach to a QAPI approach will require some hospices to reallocate funds to expand and evolve their existing quality programs. However, an effective QAPI program will allow hospices to identify areas for improvement. The analysis of patient care and administrative data for the QAPI program may help hospices identify ineffective therapies, opportunities for staff improvement, low performing contracts for services, etc., and allow hospices the chance to improve services and efficiency. A vigorous QAPI program will benefit hospices and patients, and will help ensure that hospice resources are being used in the most effective and efficient manner possible. While we have adjusted the cost estimate for this CoP in the impact analysis section, we have not factored in the cost savings that hospices may achieve.

Comment: Several commenters stressed the importance of ensuring that all hospice employees are involved in the QAPI program. Of these commenters, a few highlighted the need for board certified chaplain involvement in QAPI.

Response: We agree that it is important to involve employees, both paid and volunteer, as well as individuals furnishing services under contract, in the hospice's QAPI program. In order to ensure such involvement, we require in § 418.62, that all licensed professionals furnishing services on behalf of the hospice must actively participate in the hospice's QAPI program. Hospices have the flexibility, within the licensed professional requirement, to determine which individuals will lead QAPI efforts based on their own needs and goals. Hospices may choose to use the services of board certified chaplains in developing and implementing their QAPI program.

Comment: A few commenters suggested that we should require hospices to publicly report the results of their data collection, while other commenters expressed concern that we may require hospices to use a data collection tool such as OASIS, which would enable public reporting of hospice data. Similarly, commenters expressed concern that we would expect hospices to use computerized systems in implementing the QAPI requirement.

Response: Quality assessment and performance improvement is a fast growing approach to quality improvement in the hospice industry. However, there is no nationally standardized and accepted set of measures that could be used at this time to develop an OASIS-like tool that would enable public reporting. The intent of this rule is to establish the framework of QAPI in hospice, not to prescribe specific measures or tools. As such, we are not requiring hospices to use specific outcome or process measures, data elements, forms, or computer systems. These decisions are at the discretion of each hospice based on its own needs and goals. We caution that we cannot, at this time, predict with any certainty the future of hospice data collection and its relationship to the public reporting of data.

Comment: Many commenters asked for more information about how State surveyors will survey hospices for compliance with the QAPI requirements. Commenters sought more information about how hospice surveyors will use hospice data and how they will determine a QAPI program's scope, complexity and adequacy of improvement projects.

Response: Hospices are required to collect and analyze patient care and administrative quality data and to use that data to identify, prioritize, implement, and evaluate performance improvement projects to improve the quality of services furnished to hospice patients. In order to assess compliance with the QAPI requirements, hospice surveyors will need to access, upon request, a hospice's aggregated data and its analysis of that data. Surveyors will also need access to the hospice's QAPI plan, any meeting minutes or notes for meetings concerning the development and implementation of the hospice's QAPI program, those individuals responsible for the QAPI program, and any other necessary resources needed to assess a hospice's compliance. This information will allow surveyors to match the data provided by the hospice with the actual experiences of hospice employees and patients to ensure that the QAPI program is prevalent throughout the hospice's operations and services, and that it is positively influencing patient care. Furthermore, this information will enable surveyors to assess the adequacy and appropriateness of a hospice's QAPI program. Surveyors will focus on areas such as how and why a hospice chose its quality measures, how it ensures consistent data collection, how it uses data in patient care planning, how it aggregates and analyzes data, how it uses the data analysis to select performance improvement projects, how it implements such projects, and its use of data to evaluate the effectiveness of those projects. We will include more detailed information about the QAPI survey process and goals in future sub-regulatory guidance such as the State Operations Manual and Interpretive Guidelines.

We note that hospitals are currently required to comply with a very similar performance improvement project regulation and have successfully determined their performance improvement project needs and goals without prescribed minimums. Likewise, hospital surveyors have successfully assessed hospital compliance with the performance improvement project regulation without such minimums. We will use the knowledge gained through the hospital survey process to guide our understanding and implementation of surveys for hospices complying with this performance improvement project regulation.

III. Provisions of the Final Regulations

In this final rule we are adopting the provisions as set forth in the May 27, 2005 proposed rule with the following revisions. We have—

Condition of Participation: Quality Assessment and Performance Improvement (§ 418.58)

Removed the phrase “focuses on the end-of-life support services provided” from § 418.58.

Replaced the phrase “end-of-life support services” with “hospice service” in § 418.58(a). In addition, we replaced the phrase “for which there is evidence that improvement in those

indicators will improve palliative outcomes” with the phrase “related to improved palliative outcomes.”

Revised § 418.58(b) to clarify our intent. In § 418.58(b)(2)(ii), we incorporated a requirement that quality indicator data must be used to identify priorities, as well as opportunities, for improvement. In § 418.58(b)(3), we replaced the term “specified” with the term “approved” to clarify that the governing body is not necessarily the entity that establishes data collection specifications.

Added a 240-day phase-in period to § 418.58(d) to allow hospices more time to collect the initial program data.

Revised § 418.58(e) by adding a requirement that the governing body annually evaluates the hospice’s QAPI program. We also added a requirement that the hospice governing body must identify at least one individual who is responsible for operating the QAPI program. Deleted proposed § 418.58(e)(3) regarding expectations for patient safety.

V. Collection of Information

Condition of Participation: Quality Assessment and Performance Improvement (§ 418.58)

Section 418.58 states that a hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement (QAPI) program. In addition, the hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

Section 418.58(a) describes the required scope of the QAPI program. Specifically, § 418.58(a)(1) discusses the documentation requirements. The QAPI program must be able to demonstrate measurable improvement in indicators related to improved palliative outcomes and hospice services. Section 418.58(a)(2) states that the hospice must measure, analyze, and track quality indicators.

Section 418.58(b)(2) states that a hospice must use the data to monitor the effectiveness and safety of services and quality of care. As part of the monitoring process, the data must be used to identify improvement opportunities. The data must also be used to assist in the prioritization of the aforementioned opportunities for improvement.

Section 418.58(c)(2) states that as part of performance improvement activities, a hospice must track adverse patient events, analyze their causes, and implement preventative actions and mechanisms that include feedback and learning throughout the hospice. Section 418.58(c)(3) requires a hospice to measure its success and track performance in its performance improvement initiatives to ensure that the improvements are continuous.

Section 418.58(d) discusses that standard for performance improvement projects. Hospices are responsible for developing, implementing, and evaluating performance improvement projects.

Section 418.58(d)(2) requires hospices to document their performance improvement projects, the reason for conducting each project, and the measurable progress achieved as a result of the projects.

The burden associated with the requirements contained in § 418.58 is the time and effort necessary to develop, draft, and implement a QAPI program. As part of the QAPI program, there is also burden associated with recording quality data for performance improvement initiatives. We estimate that for all 2,872 hospices, 1 hour per hospice will be required to comply with the documentation of the domains and measures, 91 hours per hospice for data entry and 48 hours to aggregate the data. This is an annual burden of 140 hours per hospice to meet the requirement of this section. The estimated annual burden associated with the requirements in § 418.58 is 402,080 hours annually.