M. Medicare Shared Savings Program

Under section 1899 of the Act, CMS has established the Medicare Shared Savings program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in health care costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule implementing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by ACOs, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization such as rates of hospital admission for ambulatory sensitive conditions. Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for ACOs to report to evaluate the quality of care furnished by ACOs. Section 1899(b)(3)(C) of the Act requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs, and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for the purposes of assessing the quality of care. Additionally, section 1899(b)(3)(D) of the Act gives the Secretary authority to incorporate reporting requirements and incentive payments related to the PQRS, EHR Incentive Program and other similar initiatives under section 1848 of the Act. Finally, section 1899(d)(1)(A) of the Act states that an ACO is eligible to receive payment for shared savings, if they are generated, only after meeting the quality performance standards established by the Secretary.

In the November 2011 final rule establishing the Shared Savings Program, we established the quality performance standards that ACOs must meet to be eligible to share in savings that are generated (76 FR 67870 through 67904). Quality performance measures are submitted by ACOs through a CMS web interface, currently the group practice reporting option (GPRO) web interface, calculated by CMS from internal and claims data, and collected through a patient and caregiver experience of care survey.

Consistent with the directive under section 1899(b)(3)(C) of the Act, we believe the existing Shared Savings Program regulations incorporate a built in mechanism for encouraging ACOs to improve care over the course of their 3-year agreement period, and to reward quality improvement over time. During the first year of the agreement period, ACOs can qualify for the maximum sharing rate by completely and accurately reporting all quality measures. After that, ACOs must meet certain thresholds of performance, which are currently phased in over the course of the ACO's first agreement period, and are rewarded for improved performance on a sliding scale in which higher levels of quality performance translate to higher rates of shared savings (or, for ACOs subject to performance-based risk that demonstrate losses, lower rates of shared losses). In this way, the quality performance standard increases over the course of the ACO's agreement period.

Additionally, we have made an effort to align quality performance measures, submission methods, and incentives under the Shared Savings Program with the PQRS. Eligible professionals participating in an ACO may qualify for the PQRS incentive payment under the

Shared Savings Program or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO measures on their behalf using the GPRO web interface.

Since the November 2011 final rule establishing the Shared Savings Program was issued, we have revisited certain aspects of the quality performance standard in the annual PFS rulemaking out of a desire to ensure thoughtful alignment with the agency's other quality incentive programs that are addressed in that rule. Specifically, we have updated our rules to align with PQRS and the EHR Incentive Program, and addressed issues related to benchmarking and scoring ACO quality performance (77 FR 69301 through 69304; 78 FR 74757 through 74764). This year, as part of the CY 2015 Physician Fee Schedule proposed rule, we addressed several issues related to the Shared Savings Program quality performance standard and alignment with other CMS quality initiatives. Specifically, we revisited the current quality performance standard, proposed changes to the quality measures, and sought comment on future quality performance measures. We also proposed to modify the timeframe between updates to the quality performance benchmarks, to establish an additional incentive to reward ACO quality improvement, and to make several technical corrections to the regulations in subpart F of Part 425.

1. Existing Quality Measures and Performance Standard

As discussed previously, section1899(b)(3)(C) of the Act states that the Secretary may establish quality performance standards to assess the quality of care furnished by ACOs and "seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both...." In the November 2011 Shared Savings Program final rule, we established a quality performance standard that consists of 33 measures. These measures are submitted by the ACO through the GPRO web interface, calculated by CMS from administrative and claims data, and collected via a patient experience of care survey based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) survey. Although the patient experience of care survey used for the Shared Savings Program includes the core CG-CAHPS modules, this patient experience of care survey also includes some additional modules. Therefore, we will refer to the patient experience of care survey that is used under the Shared Savings Program as CAHPS for ACOs. The measures span four domains, including patient experience of care, care coordination/patient safety, preventive health, and at-risk population. The measures collected through the GPRO web interface are also used to determine whether eligible professionals participating in an ACO qualify for the 2013 and 2014 PQRS incentive payment or avoid the PQRS payment adjustment for 2015 and subsequent years. Eligible professionals in an ACO may qualify for the PQRS incentive payment or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports all of the ACO GPRO measures on their behalf using the GPRO web interface.

In selecting the 33 measure set, we balanced a wide variety of important considerations. Given that many ACOs were expected to be newly formed organizations, in the November 2011 Shared Savings Program final rule (76 FR 67886), we concluded that ACO quality measures should focus on discrete processes and short-term measurable outcomes derived from administrative claims and limited medical record review facilitated by a CMS-provided web interface to lessen the burden of reporting. Because of the focus on Medicare FFS beneficiaries, our measure selection emphasized prevention and management of chronic diseases that have high impact on these beneficiaries such as heart disease, diabetes mellitus, and chronic obstructive pulmonary disease. We believed that the quality measures used in the Shared Savings Program should be tested, evidence-based, target conditions of high cost and high prevalence in the Medicare FFS population, reflect priorities of the National Quality Strategy, address the continuum of care to reflect the requirement that ACOs accept accountability for their patient populations, and align with existing quality programs and value-based purchasing initiatives.

At this time, we continue to believe it is most appropriate to focus on quality measures that directly assess the overall quality of care furnished to FFS beneficiaries. The set of 33 measures that we adopted in the November 2011 Shared Savings Program final rule includes measures addressing patient experience, outcomes, and evidence-based care processes. Thus far, we have not included any specific measures addressing high cost services or utilization since we believe that the potential to earn shared savings offers an important and direct incentive for ACOs to address utilization issues in a way that is most appropriate for their organization, patient population, and local healthcare environment. We note that while the quality performance standard is limited to these 33 measures, the performance of ACOs is measured on many more metrics and ACOs are informed of their performance in these areas. For example, an assessment of an ACO's utilization of certain resources is provided to the ACO via quarterly reports that contain information such as the utilization of emergency services or the utilization of CTs and MRIs.

As we have stated previously (76 FR 67872), our principal goal in selecting quality measures for ACOs was to identify measures of success in the delivery of high-quality health care at the individual and population levels. We believe endorsed measures have been tested, validated, and clinically accepted, and therefore, selected the 33 measures with a preference for NQF-endorsed measures. However, the statute does not limit us to using endorsed measures in the Shared Savings Program. As a result we also exercised our discretion to include certain

measures that we believe to be high impact but that are not currently endorsed, for example, ACO#11, Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment.

In selecting the final set of 33 measures, we sought to include both process and outcome measures, including patient experience of care (76 FR 67873). Because ACOs are charged with improving and coordinating care and delivering high quality care, but also need time to form, acquire infrastructure and develop clinical care processes, we continue to believe it is important to have a combination of both process and outcomes measures. We note, however, that as other CMS quality reporting programs, such as PQRS, move to more outcomes-based measures and fewer process measures over time, we may also revise the quality performance standard for the Shared Savings Program to incorporate more outcomes-based measures over time.

Therefore, we viewed the 33 measures adopted in the November 2011 Shared Savings Program final rule as a starting point for ACO quality measurement. As we stated in that rule (67 FR 67891), we plan to modify the measures in future reporting cycles to reflect changes in practice and improvements in quality of care and to continue aligning with other quality reporting programs and will add and/or retire measures as appropriate through the rulemaking process. In addition, we are working with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date. We note that we must balance the timing of the release of specifications so they are as up-to-date as possible, while also giving ACOs sufficient time to review specifications. Our intention is to issue the specifications annually, prior to the start of the reporting period for which they will apply.

In the November 2011 Shared Savings Program final rule (76 FR 67873), we combined care coordination and patient safety into a single domain to better align with the National Quality

Strategy and to emphasize the importance of ambulatory patient safety and care coordination. We also intended to continue exploring ways to best capture ACO care coordination metrics and noted that we would consider adding new care coordination measures for future years (67 FR 67877).

2. Changes to the Quality Measures Used in Establishing Quality Performance Standards that ACOs must meet to be Eligible for Shared Savings

a. Background and Proposal.

Since the November 2011 Shared Savings Program final rule, we have continued to review the quality measures used for the Shared Savings Program to ensure that they are up to date with current clinical practice and are aligned with the GPRO web interface reporting for PQRS. Based on these reviews, in the CY 2015 Physician Fee Schedule proposed rule, we proposed a number of measure additions, deletions and other revisions that we believed would be appropriate for the Shared Savings Program. An overview of changes we proposed is provided in Table 50 of the proposed rule (79 FR 40479 through 40481) which lists the measures that we proposed would be used to assess ACO quality under the Shared Savings Program starting in 2015. To summarize, we proposed to add 12 new measures and retire eight measures. We also proposed to rename the EHR measure in order to reflect the transition from an incentive payment to a payment adjustment under the EHR Incentive Program and to revise the component measures within the Diabetes and CAD composites. In total, we proposed to use 37 measures for establishing the quality performance standard that ACOs must meet to be eligible for shared savings. Although the total number of measures would increase from the current 33 measures to 37 measures under this proposal, we stated we did not anticipate that this would increase the reporting burden on ACOs because the increased number of measures is accounted for by

measures that would be calculated by CMS using administrative claims data or from a patient survey. The total number of measures that the ACO would need to directly report through the CMS website interface would actually decrease by one, in addition to removing redundancy in measures reported.

Finally, as part of the proposed changes, we proposed to replace the current five component diabetes composite measure with a new four component diabetes composite measure. In addition, we proposed to replace the current two component coronary artery disease composite measure with a new four component coronary artery disease composite measure. Under this proposal, 21 measures would be reported by ACOs through the GPRO web interface and scored as 15 measures.

Below, we summarize and group comments received on these proposals by first responding to general comments on our proposals and then by the method of data submission for the measure as listed in Table 50 of the proposed rule (79 FR 40479 through 40481) (that is, survey, claims, EHR incentive program, and the CMS web interface). In order to align the measures submitted through the CMS web interface with the PQRS and VM programs, we discuss specific comments in response to the proposed changes to the measures submitted through the CMS web interface for these same measures for the PQRS and the VM programs. See Tables 79 and 80 in section III.K., for a discussion of and response to these comments.

<u>General Comment</u>: In addition to the comments that focus on individual measures, we received many general comments about the quality performance measures used in the Shared Savings Program. For example, we received many comments supporting the alignment between ACO, PQRS and VM quality measures and an increased focus on outcomes-based quality measures. Some commenters objected to the net increase in measures, believing there is underlying burden for providers even for claims-based measures. Additionally, many ACOs did not support the proposed new measures, suggesting, for example, they would be unnecessary because of the incentives inherent to the Shared Savings Program, or that, in general, the new proposed measures are inadequately defined, tested or benchmarked. These ACOs believed that many of the proposed new measures address clinical issues beyond an ACO's control and therefore should not be added. Other concerns about the new measures were that they would require substantial change in clinical practice, would substantially add to the reporting burden, and/or are questionably related to improving care quality and/or patient outcomes.

Other commenters supported adding the new measures. One commenter, for example, stated that "the expanded measures are important utilization and management measures that our developing ACO would have likely considered and built into our ACO Cost, Utilization, and Risk dashboard anyway. From a clinical and system standpoint, these additions are key components of better managing avoidable utilization and costs. They are measures we would want to know regardless of the Proposed Rule." MedPAC suggested that CMS move quality measurement for ACOs, MA plans, and FFS Medicare in the direction of a small set of population-based outcome measures, such as potentially preventable inpatient hospital admissions, emergency department visits, and readmissions.

<u>Response</u>: We continue to believe it is appropriate to add, remove, and modify quality measures for the Shared Savings Program to reflect changes in clinical practice and for other program needs. We want to minimize any additional burdens this could create for ACOs and their ACO participants and ACO providers/suppliers. Therefore, we agree with the comments in support of the alignment between ACO, PQRS and VM for the quality measures submitted through the CMS web interface, and an increased focus on outcomes-based quality measures. We disagree with those ACOs that suggested certain proposed new measures would be unnecessary because of the incentives inherent to the Shared Savings Program. Instead, we agree with the commenter who noted that such measures can be important utilization and management tools that many ACOs may consider and build into their own internal monitoring systems as a way to help manage avoidable utilization and costs. Further, we believe certain proposed new measures highlight the value of discussions with patients about their care. b. Survey based measure:

• <u>CAHPS Stewardship of Patient Resources</u>. This measure is one of the unscored survey measures currently collected in addition to the seven scored survey measures that are already part of the current set of 33 measures under the Shared Savings Program. Information on the unscored survey measure modules is currently shared with the ACOs for informational purposes only. The Stewardship of Patient Resources measure asks the patient whether the care team talked with the patient about prescription medicine costs. The measure exhibited high reliability during the first two administrations of the CAHPS survey, and during testing, the beneficiaries that participated in cognitive testing said that prescription drug costs were important to them. We proposed to add Stewardship of Patient Resources as a scored measure in the patient experience domain because we believe, based on testing, that this is an important factor for measuring a beneficiary's engagement and experience with healthcare providers. We also proposed that the measure would be phased into pay for performance as we plan to do for other new measures, using a similar process to the phase in that was used for the scored measure modules in the survey that are currently used to assess ACO quality performance.

Comment: Some commenters supported the proposed addition of this measure, agreeing

that discussing the cost of medications is important to assess the possibility that medication costs may be a barrier to care or that the measure may be an indicator of a patient's satisfaction with the care he or she is receiving. Other commenters questioned how this discussion leads to a plan of action or a modified plan of treatment to improve care if the patient is unable to pay for the medication. These commenters asked us to further explain how we envision this measure improving patient care. Some believe it would be reasonable to include this measure under pay for reporting, but that additional discussions with the community would be needed in order to establish an appropriate benchmark for this measure, as this is a relatively new measure. Some thought that physician discussions with patients regarding medication cost would be appropriate for "high tier," costly medications, but would be of questionable value relative to measuring patient-centered, quality care delivery for more frequently prescribed, lower cost, generic medications and/or the extent to which patients take medications as prescribed. Some commenters suggested that it would be unnecessary and/or burdensome to add this measure. For example, commenters indicated that physicians do not and cannot know the co-pays for each drug under each insurance plan and product and that there would be tremendous patient dissatisfaction when inaccurate pricing or cost information is provided to the patient by the provider. Some commenters believe this measure is unnecessary since encouraging adherence to medications is a key strategy for ACOs to reduce avoidable costs, and inability to afford medications is a key barrier to adherence, so ACOs already have an incentive to discuss the cost of medications with their patients.

<u>Response</u>: This measure asks patients whether any health care provider spoke to them about their prescription medication costs and does not require that physicians know the co-pays for each drug under each insurance plan and product. Additionally, discussing this topic with beneficiaries can lead a clinician to understand whether and how the beneficiary may struggle with payment for medications, a factor that can affect adherence to prescribed regimens. We can therefore envision a scenario where, once the issue is identified, a clinician participating in an ACO could inform and educate the beneficiary about less expensive options, such as the use of generic medications, or about available community resources, as part of the ACO's care coordination processes required under §425.112(b)(4). This in turn could directly improve the quality of care the beneficiary receives by improving medication adherence and leading to greater beneficiary engagement. Because this measure is already part of the CAHPS survey, we do not believe it will increase reporting burden for the ACO. The CAHPS survey question is available in the CAHPS Survey for ACOs Quality Assurance Guidelines on the CAHPS for ACOs website. As discussed below, because this is a new measure, the measure will be pay-for-reporting for the first two reporting periods it is in use for all ACOs, regardless of the phase-in schedule to pay-for-performance, in order to provide time for the development of an appropriate benchmark.

<u>Final Decision</u>: We are finalizing our proposed addition of the CAHPS: Stewardship of Patient Resources measure. After the measure has been used in the program under pay for reporting for two reporting periods, it will be pay-for-reporting for the first performance year of an ACO's first agreement period and pay-for-performance for the ACO's second and third performance years. We continue to believe that it is important for physicians and others to discuss the beneficiary's perspective on the cost of medications because is important to assess the possibility that medication costs may be a barrier to care. The measure exhibited high reliability during the first two administrations of the CAHPS survey, and during testing, the beneficiaries that participated in cognitive testing said that prescription drug costs were important to them.

c. Claims Based Measures to be Computed by CMS

• Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM). We proposed to add a 30-day all cause skilled nursing facility (SNF) readmission measure. CMS is the measure steward for this claims-based measure, which is under review at NQF under NQF #2510. This measure estimates the risk-standardized rate of all-cause, unplanned, hospital readmissions for patients who have been admitted to a SNF within 30 days of discharge from a prior inpatient admission to a hospital, CAH, or a psychiatric hospital. The measure is based on data for 12 months of SNF admissions. We believe this measure would help fill a gap in the current Shared Savings Program measure set and would provide a focus on an area where ACOs are targeting care redesign. ACOs and their ACO participants often include post-acute care (PAC) settings and the addition of this measure would enhance the participation of and alignment with these facilities. Even when the ACO does not include post-acute facilities formally as part of its organization, ACO providers/suppliers furnish other services that have the potential to affect PAC outcomes. Thus, this measure would emphasize the importance of coordinating the care of beneficiaries across these sites of care. Additionally, because this measure would be calculated from claims, there would not be a burden on ACOs to collect this information.

Comment: A number of commenters supported including the measure and/or the concept to align the incentives of ACOs and SNFs to lower their readmission rates. Some provided suggestions to further refine the measure, such as to use a risk-adjusted measure of potentially avoidable readmissions for SNFs. Although MedPAC recommended that CMS consider a risk-

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adjusted, potentially avoidable readmission measure for SNFs, they did support the addition of a SNF readmission measure because of the importance of post-acute care management and care transitions between settings in improving beneficiary care. Another commenter supported the measure but encouraged delay until such time as Medicare readmission policy links a portion of SNF payments to their readmission rates so that SNFs would bear risk/penalty equal to that of other providers in order to incent readmissions reduction. Some commenters believe that it is unnecessary and duplicative to add this quality measure since it is an inherent part of the Shared Savings Program that an ACO will be penalized through a reduction in shared savings if it has a high rate of readmissions. They also argue that ACOs that use SNFs for higher-acuity patients could see an increase in SNF readmission rates and thus be inappropriately penalized. A commenter suggested ACO scores will be inappropriately affected when beneficiaries return to an ACO participant hospital after being discharged to a SNF that is not participating in the ACO. In such cases, an ACO may be unable to achieve the same level of collaboration needed to affect change as compared to ACOs that include one or more SNFs as ACO participants or ACO providers/suppliers. Concern was also expressed regarding the ability of ACOs to consistently monitor psychiatric hospital discharges since federal laws limit the use and disclosure of documentation regarding drug and substance abuse as well as mental health therapies. These commenters recommend removing psychiatric hospital admissions from this measure since ACOs currently do not receive mental health claims data and should not be held accountable for measures for which they are not able to collect and monitor data over the performance period. Operational concerns were also raised including data lags and that ACOs can only derive raw admissions/readmission rates from the monthly claims files and the commenters believe these rates are not useful for improving performance against benchmarks unless CMS provides the

algorithm to apply the appropriate risk adjustment. These commenters indicate that ACOs face significant challenges in monitoring performance when reliable risk-adjusted rates of admissions and readmissions are not provided on a regular basis.

Response: We appreciate the numerous thoughtful comments. We disagree with commenters that this measure is unnecessary and duplicative because we continue to believe that including this measure would reinforce the importance of coordinating the care of beneficiaries across hospital and SNF sites of care. We have previously expressed our expectation that ACOs coordinate the care of beneficiaries across these sites regardless of whether there are any postacute care (PAC) providers participating in the ACO (§425.112(b)(4)). Even when the ACO does not include post-acute facilities formally as ACO participants or ACO providers/suppliers, ACO providers/suppliers furnish other services that have the potential to affect PAC outcomes. Thus, this measure would emphasize the importance of coordinating the care of beneficiaries across these sites of care. Additionally, because this measure is calculated from claims, there would not be a reporting burden on ACOs to collect this information. We appreciate the recommendations that we use a risk-adjusted, potentially avoidable SNF readmission measure, however, there is currently no such measure available for use. We note that the SNF 30-day allcause readmission measure does exclude planned readmissions using a similar methodology to ACO-8 Risk-Standardized, All Condition Readmission. Unplanned readmission rates do provide ACOs with useful information to better coordinate care and work toward reducing the risk of readmissions for all patients, including patients coming from a SNF. Further, contrary to the assertion of some commenters, we note that the HIPAA Privacy Rule generally provides the same protections for mental health information as it does for all protected health information (with the exception of psychotherapy notes). See the Department's guidance on the HIPAA

Privacy Rule and sharing information related to mental health, available at

http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/mhguidance.html. Thus, ACOs that request claims data under §425.704 for purposes of their own health care operations or the health care operations of their covered entity ACO participants and ACO providers/suppliers, in accordance with HIPAA requirements, already receive information about mental health therapies as part of those data sets.

<u>Final Decision</u>: We are finalizing our proposal to add this 30-day all-cause SNF readmission measure. After the measure has been used in the program under pay for reporting for two reporting periods, the measure will be pay-for-reporting in the first two performance years of an ACO's first agreement period and will transition to pay-for-performance in the final year of the ACO's agreement period. We believe this measure will help fill a gap in the current Shared Savings Program measure set and will provide a focus on an area where ACOs are targeting care redesign.

• <u>All-Cause Unplanned Admissions for Patients with Diabetes Mellitus (DM), Heart</u> <u>Failure (HF) and Multiple Chronic Conditions</u>. We proposed to add three new measures to the Care Coordination/Patient Safety domain. The three new measures are for: all-cause unplanned Admissions for Patients with Diabetes Mellitus (DM), all-cause unplanned Admissions for Patients with Heart Failure (HF) and all-cause unplanned Admissions for Patients with Multiple Chronic Conditions (MCC). These three measures are under development through a CMS contract with Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (CORE) to develop quality measures specifically for ACO patients with heart failure, diabetes, and multiple chronic conditions. We believe that these measures are important to promote and assess ACO quality as it relates to chronic condition inpatient admission because these chronic conditions are major causes for unplanned admissions and the addition of these measures will support the ACOs' efforts to improve care coordination for these chronic conditions. These measures are claims-based, and therefore, we do not expect that they would impose any additional burden on ACOs.

The following is a summary of the comments we received regarding our proposal to add these three new claims-based measures for All-Cause Unplanned Admissions for Patients with DM, HF and MCC.

Comment: We received a wide variety of comments in response to the proposal to add these claims-based measures. Many commenters supported the use of claims-based outcome measures to reduce reporting burden for providers, however, concerns were raised regarding the lack of NQF endorsement. Some commenters supported adding one or more of these measures, agreeing that chronic condition inpatient admissions are major causes for unplanned admissions and that the addition of one or more of these measures would support the ACOs' efforts to improve care coordination. For example, a few commenters supported the addition of a measure for All Cause Unplanned Admission for Patients with Multiple Chronic Conditions as all efforts to manage chronic disease may help lead to better patient outcomes and control cost. Another commenter supported the measures but preferred collapsing them into one measure of potentially avoidable hospitalizations, because of concern that the proposed condition-specific measures will be statistically unreliable and subject to random variation that will limit their usefulness in distinguishing ACOs' actual performance. In addition, some commenters urged CMS to ensure the measures are adjusted for planned readmissions, unrelated readmissions and sociodemographic status. Other commenters supported applying these measures in the Shared Savings Program as pay for reporting only at this time since these measures are still under

development, accepted target rates are not available and the measures are not yet endorsed by NQF. Commenters requested additional definition of what "other multiple chronic conditions" would be measured. MedPAC supported an increase of outcome measures. Finally, some commenters believe it is not possible to comment on measures that are still under development, and questioned the added benefit of including these measures since ACOs have an inherent incentive to avoid or reduce unplanned hospital admissions.

Response: We continue to believe that these measures are important to promote and assess ACO quality because these chronic conditions are major causes for unplanned admissions and the addition of these measures will support the ACOs' efforts to improve care coordination for beneficiaries with these chronic conditions. These measures are claims-based, and therefore, we do not expect that they would impose any additional reporting burden on ACOs. Many concerns were raised regarding the lack of NQF endorsement, but CMS intends on submitting all three measures to NQF for review in the future. Draft measure specifications were made available to the public during the measure development comment period during the spring and summer of 2014. CMS will provide final measure specifications to the public when available (typically in the early part of the performance year). The MCC measure cohort definition aligns with the NQF MCC Measurement Framework, which defines patients with MCCs as people "having two or more concurrent chronic conditions that…act together to significantly increase the complexity of management, and affect functional roles and health outcomes, compromise life expectancy, or hinder self-management."¹¹ The MCC measure cohort of chronic conditions

¹¹ National Quality Forum (NQF). Multiple Chronic Conditions Measurement Framework. 2012; <u>http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71227</u>

includes conditions such as, but not limited to, Acute Myocardial Infarction, Stroke, and Chronic Obstructive Pulmonary Disease.

Final Decision: After considering the comments received in response to our proposal to add these three measures, we will add the All-Cause Unplanned Admissions for Patients with MCC, HF, and DM measures as pay-for-reporting for two performance years. After this time, the measure will be pay-for-reporting for the first two performance years for new ACOs in their first agreement period before transitioning to pay for performance in performance year three. We believe that it is important to include these measures in the Shared Savings Program measure set since they were specifically developed for ACO populations and move the quality performance standard under the Shared Savings Program toward more outcome-based measures. DM, HF, and MCCs affect a large volume of Medicare beneficiaries and can result in high costs due to poorly coordinated care. As a result, these chronic conditions are a focus of many ACO care redesign activities. Finally, these measures are claims-based and therefore do not impose an additional burden on ACOs for data reporting.

d. Measure submitted through the EHR incentive program:

• Percent of PCPs who Successfully Meet Meaningful Use Requirements.

Because downward adjustments to Medicare payments will begin in 2015 under the EHR Incentive Program, we proposed to modify the name and specifications for ACO #11 Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment so that it more accurately depicts successful use and adoption of EHR technology in the coming years. We note this measure would continue to be doubly weighted.

Comment: We received a range of comments regarding this proposal. Some agreed that it is necessary to rename the measure given that the EHR Incentive Program begins its transition

to a payment adjustment effective in 2015. Some of the commenters, while agreeing with the proposed change, also provided additional specification suggestions such as to exclude certain physicians, such as hospitalists, from the denominator of this measure, stating that hospitalists are not PCPs when providing observation services. Another commenter requested that CMS clarify "the interaction of the Medicaid Meaningful Use program and the MSSP" and "the impact to non-PCP EPs". Another commenter requested that CMS make the list of EPs available to ACOs intermittently throughout the performance year to aid ACOs in ensuring that all EPs attest in a timely manner. A commenter questioned why this measure in its current form is limited only to PCPs, as opposed to all EPs that are ACO providers/suppliers. Others were concerned that there appeared to be no opportunity to exclude physicians such as those who retired, died, moved out the country, from the denominator of this measure. Finally, there were a number of commenters that suggested the measure should be dropped and not renamed, since it is a process measure and the commenters believe that this measure has no direct relationship to the quality of patient care.

Response: We continue to believe, as do a number of commenters, that this is an important measure that should be retained and renamed given that downward adjustments to Medicare payments will begin in 2015 under the EHR Incentive Program. We appreciate the suggestions from commenters that agree with the proposed change and provided additional specification suggestions. We are not persuaded by commenters that suggest this measure should be removed from the quality performance standard for the Shared Savings Program. On the contrary, we believe the measure directly supports the adoption and meaningful use of certified EHR technology, which is an important tool to support change in the health care delivery system including the steps being taken by ACOs to improve the quality and efficiency

of care. The measure specifications will continue to align with the EHR Incentive Program definitions of hospital-based providers and will exclude observation services, accordingly. The measure specifications include Medicare and Medicaid eligible PCPs. Practitioners other than PCPs are not included in the measure at this time in efforts to focus on the meaningful use of certified EHRs in the provision of primary care services. This measure aligns with other HHS initiatives that support the adoption and meaningful use of certified EHR technology. For example, the HHS Office of the National Coordinator for Health Information Technology and CMS are managing \$27 billion in funding from the American Recovery and Reinvestment Act of 2009 and other sources to promote the adoption of electronic health records (EHR) in hospitals and doctor's offices¹². More than 75 percent of eligible health care professionals, and over 90 percent of eligible hospitals, have already qualified for EHR incentive payments for using certified EHR technology. Retaining this measure in the quality performance standard for the Shared Savings Program will help provide an additional and appropriate incentive to reinforce the adoption and meaningful use of certified EHR technology. Finally, performance on this measure is determined using EHR Incentive Program data and due to the EHR Incentive Program timelines and data collection, CMS will not be able to provide lists of EPs to ACOs throughout the performance year.

Final Decision: After consideration of the comments received, we are finalizing the proposal to modify the name and specifications of ACO-11 to the Percent of PCPs who successfully meet MU requirements.

e. Measures submitted through the CMS web interface

¹² http://www.hhs.gov/news/press/2014pres/09/20140916a.html

To align with PQRS, we proposed to add several measures submitted through the CMS web interface that we believed were appropriate for the ACO quality performance standard. The measures we proposed to add were:

- Depression Remission at Twelve Months (NQF #0710).
- Diabetes Measures for Foot Exam and Eye Exam (NQF #0056 and #0055).
- Coronary Artery Disease (CAD): Symptom Management.
- <u>Coronary Artery Disease (CAD): Beta Blocker Therapy—Prior Myocardial Infarction</u> (<u>MI) or Left Ventricular Systolic Dysfunction (LVEF<40%) (</u>NQF #0070).
- Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF #0067).
- Documentation of Current Medications in the Medical Record (NQF #0419).

Additionally, we identified a number of the existing measures submitted through the CMS web interface that have not kept up with clinical best practice, are redundant with other measures that make up the quality performance standard, or that could be replaced by similar measures that are more appropriate for ACO quality reporting. For the reasons specified in the proposed rule, we proposed to no longer collect data on the following measures, and these measures would no longer be used for establishing the quality performance standards that ACOs must meet to be eligible to share in savings:

- ACO #12, Medication Reconciliation after Discharge from an Inpatient Facility.
- ACO #22, Diabetes Composite measure: Hemoglobin A1c control (<8 percent).
- ACO #23, Diabetes Composite: Low Density Lipoprotein (<100) (NQF #0729).
- ACO #24, Diabetes Composite: Blood Pressure (<140/90) (NQF #0729).
- ACO #25, Diabetes Composite: Tobacco Non-use (NQF #0729).

• ACO #29, <u>Ischemic Vascular Disease: Complete Lipid Profile and LDL Control (<100</u> mg/dl) (NQF #0075).

• ACO #30, <u>Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF</u> #0068).

• ACO #32, Coronary Artery Disease (CAD) Composite: Drug Therapy for Lowering

LDL Cholesterol (NQF #74).

Finally, given these proposed changes, we also proposed updates and revisions to the Diabetes and CAD Composite measures. We proposed that the Diabetes Composite include the following measures:

• ACO #26: Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for

Patients with Diabetes Mellitus and Ischemic Vascular Disease.

- ACO #27: Diabetes: Hemoglobin A1c Poor Control.
- ACO #41: Diabetes: Foot Exam.
- ACO #42: Diabetes: Eye Exam.

We further proposed that the CAD Composite include the following measures:

• ACO #33: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor

Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%).

- ACO #43: Antiplatelet Therapy.
- ACO #44: Symptom Management.
- ACO #45: Beta-Blocker Therapy Prior Myocardial Infarction (MI) or Left

Ventricular Systolic Dysfunction (LVEF<40%).

We solicited comment on these composite measures and whether there are any concerns regarding the calculation of a composite score. Given the general concerns around composite

measures and their use, we also solicited comment on how we combine and incorporate component measure scoring for the composite.

<u>Comment</u>: Most commenters supported the proposed removal and replacement of measures that may not align with current clinical guidelines or that appear to overlap with other measures currently in the measure set. At least one commenter specifically opposed removal of ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068) and the LDL measures, stating that there is disagreement on guidelines among professional organizations. Others expressed concern about the number of proposed changes that will require ACOs, in turn, to make changes to their internal processes and their EHRs to facilitate data collection. Some commenters raised general clinical or other methodological concerns about individual proposed measures submitted through the CMS web interface. Our detailed responses to those comments can be found in Table 79 of section III.K. of this final rule with comment period.

We do, however, wish to note some specific comments relevant to our final policy decisions with respect to the quality performance measures used in the Shared Savings Program: (1) Commenters noted that the Patient Health Questionnaire 9 (PHQ-9) is specified for use in the Depression Remission measure (proposed ACO # 40), and that this tool is only one of several options available to practitioners. These commenters suggested not adding this measure until ACOs have had the opportunity to uniformly phase in the use of the PHQ-9 in order to meet the measure specification requirements. Additionally, commenters suggested that their ability to perform well on this measure may be limited if they cannot access the PHQ-9 score data from mental health care providers. (2) Many commenters did not support the proposed addition of the CAD: Symptom Management measure (proposed ACO # 44), stating they believe the measure

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lack primary care focus and that there are potential challenges in data collection. CMS also received a comment supporting the proposed addition of the CAD: Antiplatelet Therapy measure (proposed ACO # 43), however, this commenter recommended that if added, the measure only be used for pay-for-reporting. (3) Some commenters did not support the retirement of the 4 Diabetes Composite measures and 1 CAD Composite measure proposed to be removed due to the resources already invested in reporting these 5 measures. (4) CMS received comments suggesting that the quality performance standard under the Shared Savings Program should focus on broader categories of measures (such as preventive health measures) that are generalizable across providers and care settings, rather than measures that target specific providers or care settings.

<u>Response</u>: We continue to believe that the quality performance measures used in the Shared Savings Program should reflect current clinical guidelines. We appreciate the commenters' agreement with our proposed changes to remove and replace measures that are not in adherence with current clinical guidelines. In response to comments, included in Table 79 in section III.K, we will retain ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068). We note that we erroneously made the assertion that this measure conflicts with current clinical guidelines. Therefore, due to the clinical importance of the measure, the measurement gap it addresses, and its alignment with the Million Hearts Campaign and PQRS, we will retain this measure.

Given the concerns raised by commenters, included in Table 80 of section III.K, regarding our proposal to use PHQ-9 for the Depression Remission measure, we will not finalize our proposal that the measure would be phased-in to pay-for-performance during the second and third performance years of an ACO's first agreement period. We will, however, finalize our proposal to use the measure to assess ACO quality, but only as pay-for-reporting for all three performance years of an ACO's first agreement period. We believe this approach will provide flexibility for ACOs to continue to use tools other than the PHQ-9, while providing the opportunity for ACOs to begin adopting this tool without harming their ability to achieve full points on the measure. Additionally, as noted above, the HIPAA Privacy Rule generally provides the same protections for mental health information as it does for all protected health information (with the exception of psychotherapy notes). We therefore do not believe there would be any unusual impediments to accessing the information required for reporting of this particular measure.

After consideration of the comments received and in order to align with the final measures that will be used in the PQRS program, we will not finalize the CAD: Symptom Management (proposed ACO – 44) and CAD: Antiplatelet Therapy (proposed ACO – 43) measures for the Shared Savings Program. See section III.K, Table 79, for comment discussion and response.

We believe it is important to make changes in the measures used to assess ACO quality to address the statutory mandate in section 1899(b)(3)(A) of the Act which requires the Secretary to determine appropriate measures to assess the quality of care furnished by the ACO, reflect current clinical practice, promote high quality care, and alignment with PQRS and National Quality Strategy. We therefore disagree with commenters that internal operational challenges that arise from changes in the measure set outweigh the benefit of such changes.

After considering the comments received regarding the proposed new measures, we are finalizing our proposal to add the following new measures that will be submitted by the ACO through the CMS web interface:

- Documentation of Current Medications in the Medical Record (NQF #0419).
- Depression Remission at Twelve Months (NQF #0710).
- <u>Diabetes Measures for Eye Exam (NQF #0055)</u>.

For the reasons stated in section III.K., we decline to finalize our proposals to add the following measures:

- Diabetes: Foot Exam (NQF #0056)
- CAD: Antiplatelet Therapy (NQF #0067)
- CAD: Symptom Management
- CAD: Beta-Blocker Therapy Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVSD) (NQF #0070)

We are not finalizing our proposal to add the CAD: Antiplatelet Therapy (NQF #0067) measure and instead will keep the measure it was designed to replace, ACO #30, <u>Ischemic</u> <u>Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068)</u> because we have determined that it does not conflict with clinical guidelines, remains clinically important, addresses a measurement gap, and aligns with the Million Hearts Campaign and PQRS. We believe that retention of this measure in lieu of the proposed Antiplatelet Therapy measure will additionally reduce burden on ACOs that would otherwise need to revise their data collection processes to accommodate this change.

Additionally, we are finalizing our proposal to remove certain measures from the ACO quality performance standard including the following:

- ACO #12, Medication Reconciliation after Discharge from an Inpatient Facility
- ACO #22, Diabetes Composite measure: Hemoglobin A1c control (<8 percent).
- ACO #23, Diabetes Composite: Low Density Lipoprotein (<100) (NQF #0729).

- ACO #24, Diabetes Composite: Blood Pressure (<140/90) (NQF #0729).
- ACO #25, Diabetes Composite: Tobacco Non-use (NQF #0729).
- ACO #29, <u>Ischemic Vascular Disease: Complete Lipid Profile and LDL Control (<100</u> mg/dl) (NQF #0075).

• ACO #32, <u>Coronary Artery Disease (CAD) Composite</u>: <u>Drug Therapy for Lowering</u> <u>LDL Cholesterol (NQF #74)</u>.

Finally, given these changes, we are revising the Diabetes Composite to include the following measures:

- ACO #27: Diabetes: Hemoglobin A1c Poor Control (NQF #0059).
- ACO #42: Diabetes: Eye Exam (NQF #0055).

Although not previously proposed, in order to align with PQRS and in response to commenter concerns about using this measure outside the composite, we are removing ACO #26, Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease. While we believe the measure may be valid apart from the composite, we are swayed by the concerns raised by commenters as discussed in Table 79 in section III.K. We believe removing ACO-26 is consistent with our proposals to align with the PQRS program and remove redundancy of measures within the Shared Savings Program measure set. In addition, we believe removing this measure will reduce reporting burden for ACOs and may also help to improve performance on the diabetes composite. We also note that the removal of this measure would additionally alleviate some redundancy with ACO #30 Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068) which we are retaining for the reasons discussed above.

The CAD Composite will be removed since there is only one CAD measure remaining.

We believe that the final measure set as adopted in this final rule is appropriate for purposes of the ACO quality performance standard and in order to align with changes being made to the PQRS for the reasons specified above and in Tables 79 and 80 in section III.K. Additionally, we believe that our final decision to remove certain measures will improve alignment with best practices and reduce reporting burden for ACOs.

f. Summary of Changes to the ACO Quality Measures

We are finalizing the ACO quality performance measures as follows. In total, we will use 33 measures to establish the quality performance standards that ACOs must meet to be eligible for shared savings. Although the number of measures in the measure set remains at 33, we are reducing the number of measures reported through the CMS web interface by 5 to reduce burden. In addition, as discussed in section III.K., we are also reducing the number of patients ACOs are required to report on for each measure. This change will also reduce the burden of quality reporting for ACOs. The new measures will be pay for reporting for the first two performance years for all ACOs. After this initial period, the measures will be phased in to payfor-performance over the course of an ACO's first agreement period with the exception of Depression Remission at 12 Months which will stay at pay-for-reporting for all three performance years.

Specifically, we are finalizing the following changes to the Shared Savings Program quality measure set (see Table 81 for a list of the final measures and for further details of phase in to pay-for-performance during the agreement period):

• Add the CAHPS: Stewardship of Patient Resources measure as pay-for-reporting in the first performance year of an ACO's first agreement period and pay-for-performance in the second and third performance years.

• Add SNF 30-Day All-Cause Readmission measure and All-Cause Unplanned Admissions measures for Patients with Multiple Clinical Conditions, Heart Failure, and Diabetes as pay-for-reporting for the first two years of an ACO's first agreement period before

transitioning to pay for performance in performance year three.

• Add Depression Remission at 12 Months (NQF #0710) measure as pay-for-reporting for all three performance years of an ACO's first agreement period.

• Replace ACO-12 Medication Reconciliation (NQF #0097) with "Documentation of Current Medications in the Medical Record" (NQF #0419).

• Add Diabetes: Eye Exam (NQF #0055)

• Modify name and specifications of ACO-11 from Percent of PCPS who successfully Qualify for an EHR Incentive Program Payment to the Percent of PCPs who Successfully Meet MU Requirements.

In addition, we are finalizing the retirement of 6 of the 7 measures we proposed to delete because they do not align with updated clinical guidelines or are similar to existing measures (ACO-22, 23, 24, 25, 29, and 32). We are not finalizing our proposal to remove ACO-30 Ischemic Vascular Disease: Use of Aspirin or Another Antithrombotic and are removing ACO-26 Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease due to comments received and for the reasons discussed above and in section III.K, Table 79.

We are also not finalizing the following proposed measures, but instead will continue to consider them for the future given the measurement gaps and high-cost, high-volume conditions these measures address for the quality performance standard as discussed in Table 79 in section III.K:

- Diabetes: Foot Exam (NQF #0056)
- CAD: Antiplatelet therapy (NQF #0067)
- CAD: Symptom management
- CAD: Beta-blocker therapy prior Myocardial Infarction (MI) or LVSD (NQF #0070)

As a result, we will no longer have a CAD composite in the measure set and will only have 1 CAD measure in the Clinical Care in the At-Risk Population domain (ACO# 33: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%)).

An overview of the changes we are finalizing is provided in Table 81, which lists the measures that will be used to assess ACO quality under the Shared Savings Program starting with the 2015 performance year.

TABLE 81: Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings

						·	Performance	
Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	R – Reporting P – Performance		
						PY1	PY2	PY3
		AIM: Better Care	e for Individuals	-				
	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF #0005, AHRQ	Survey	R	Р	Р
	ACO - 2	CAHPS: How Well Your Doctors Communicate		NQF #0005 AHRQ	Survey	R	Р	Р
	ACO - 3	CAHPS: Patients' Rating of Doctor		NQF #0005 AHRQ	Survey	R	Р	Р
Patient/Caregiver	ACO - 4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ	Survey	R	Р	Р
Experience	ACO - 5	CAHPS: Health Promotion and Education		NQF #N/A CMS/AHRQ	Survey	R	Р	Р
	ACO - 6	CAHPS: Shared Decision Making		NQF #N/A CMS/AHRQ	Survey	R	Р	Р
	ACO – 7	CAHPS: Health Status/Functional Status		NQF #N/A CMS/AHRQ	Survey	R	R	R
	ACO - 34	CAHPS: Stewardship of Patient Resources	Х	NQF #N/A CMS/AHRQ	Survey	R	Р	Р
	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	Р
	ACO - 35	Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)	Х	NQF #TBD CMS	Claims	R	R	Р
	ACO - 36	All-Cause Unplanned Admissions for Patients with Diabetes	Х	NQF#TBD CMS	Claims	R	R	Р
	ACO -37	All-Cause Unplanned Admissions for Patients with Heart Failure	Х	NQF#TBD CMS	Claims	R	R	Р
Care Coordination/ Safety	ACO -38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions	Х	NQF#TBD CMS	Claims	R	R	Р
	ACO - 9	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease or Asthma in Older Adults (AHRQ Prevention Quality Indicator (PQI) #5)		Adapted NQF #0275 AHRQ	Claims	R	Р	Р
	ACO - 10	Ambulatory Sensitive Conditions Admissions: Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8)		Adapted NQF #0277 AHRQ	Claims	R	Р	Р
	ACO - 11	Percent of PCPs who Successfully Meet Meaningful Use Requirements		NQF #N/A CMS	EHR Incentive Program Reporting	R	Р	Р

Domain	ACO Measure #	Measure Title		NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase In R – Reporting P – Performance		
						PY1	PY2	PY3
	ACO -39	Documentation of Current Medications in the Medical Record	Х	NQF #0419 CMS	CMS Web Interface	R	Р	Р
	ACO - 13	Falls: Screening for Future Fall Risk		NQF #0101 NCQA	CMS Web Interface	R	Р	Р
		AIM: Better Healt	h for Populations					
	ACO - 14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI	CMS Web Interface	R	Р	Р
	ACO – 15	Pneumonia Vaccination Status for Older Adults		NQF #0043 NCQA	CMS Web Interface	R	Р	Р
	ACO – 16	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up		NQF #0421 CMS	CMS Web Interface	R	Р	Р
	ACO – 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	Р	Р
Preventive Health	ACO – 18	Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	Р	Р
	ACO – 19	Colorectal Cancer Screening		NQF #0034 NCOA	CMS Web Interface	R	R	Р
	ACO – 20	Breast Cancer Screening		NQF #NA NCOA	CMS Web Interface	R	R	Р
	ACO - 21	Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented		CMS	CMS Web Interface	R	R	Р
Clinical Care for At Risk Population - Depression	ACO – 40	Depression Remission at Twelve Months	Х	NQF #0710 MNCM	CMS Web Interface	R	R	R
• •		Diabetes Composite (All or Nothing Scoring):		CMS Composite				
Clinical Care for At Risk Population - Diabetes	ACO -27	ACO - 27: Diabetes Mellitus: Hemoglobin Ale Poor Control		NQF #0059 NCQA (individual component)	CMS Web Interface	R	Р	Р
Topulation Diabetes	ACO - 41	ACO - 41: Diabetes: Eye Exam	Х	NQF #0055 NCQA (individual component)	CMS Web Interface	R	Р	Р
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension (HTN): Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	Р	Р
Clinical Care for At Risk Population - Ischemic Vascular Disease	ACO-30	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic		NQF #0068 NCQA	CMS Web Interface	R	Р	Р
Clinical Care for At Risk Population - Heart Failure	ACO - 31	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)		NQF #0083 AMA-PCPI	CMS Web Interface	R	R	Р

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	ŀ	Performance R – Reportin – Performar	g
						PY1	PY2	PY3
Clinical Care for At Risk Population – Coronary Artery Disease	ACO - 33	Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%)		NQF # 0066 ACC	CMS Web Interface	R	R	Р

The current quality scoring methodology is explained in the regulations at §425.502 and in the preamble to the November 2011 final rule (76 FR 67895 through 67900). As a result of the additions, deletions, and revisions to the quality measure set being made in this final rule, each of the four domains will include the following number of quality measures (See Table 82 for details.):

- Patient/Caregiver Experience of Care 8 measures
- Care Coordination/Patient Safety 10 measures
- Preventive Health 8 measures
- At Risk Population 6 measures (including 5 individual measures and a 2-

component diabetes composite measure)

Table 82 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes under these changes. Otherwise, the current methodology for calculating an ACO's overall quality performance score will continue to apply. Table 83 provides the measures that are retired/replaced.

Domain	Number of Individual Measures	Total Measures for Scoring Purposes	Total Possible Points	Domain Weight
Patient/Caregiver Experience	8	8 individual survey module measures	16	25%
Care Coordination/ Patient Safety	10	10 measures. Note that the EHR measure is double-weighted (4 points)	22	25%
Preventive Health	8	8 measures	16	25%
At-Risk Population	7	5 individual measures, plus a 2- component diabetes composite measure, scored as one.	12	25%
Total in all Domains	33	32	66	100%

 TABLE 82: Number of Measures and Total Points for Each Domain within the Quality

 Performance Standard

Notes	Domain	Measure Title	NQF Measure #/ Measure Steward	Method of Data Submission	Pay for Performance Phase In R = Reporting P=Performance Performance Performance Performance			
					Year 1	Year 2	Year 3	
ACO #12 Replaced	Care Coordination/ Patient Safety	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility	NQF #97 AMA- PCPI/NCQA	GPRO Web Interface	R	Р	Р	
ACO #22 Retired	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (<8 percent)	NQF #0729 MN Community Measurement	GPRO Web Interface	R	Р	Р	
ACO #23 Retired	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Low Density Lipoprotein (<100)	NQF #0729 MN Community Measurement	GPRO Web Interface	R	Р	Р	
ACO #24 Retired - Redunda nt Measure	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Blood Pressure <140/90	NQF #0729 MN Community Measurement	GPRO Web Interface	R	Р	Р	
ACO #25 Retired - Redunda nt measure	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Tobacco Non Use	NQF #0729 MN Community Measurement	GPRO Web Interface	R	Р	Р	
ACO # 26 Retired - redundan t measure	At Risk Population – Diabetes	Diabetes Composite: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease		GPRO Web Interface	R	Р	Р	
ACO #29 Retired	At Risk Population – Ischemic Vascular Disease	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control <100 mg/dl	NQF #75 NCQA	GPRO Web Interface	R	Р	Р	
ACO #32 Retired	At Risk Population – Coronary Artery Disease	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Drug Therapy for Lowering LDL- Cholesterol	NQF #74 CMS (composite) / AMA-PCPI (individual component)	GPRO Web Interface	R	R	Р	

TABLE 83:	Shared Savings	Program	Measures	Retired/Replaced
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We believe that these modifications to the quality measure set for the Shared Savings Program will further enhance the quality of care patients receive from ACO participants and ACO providers/suppliers, better reflect clinical practice guidelines, streamline measures reporting, and enhance alignment with PQRS and the EHR Incentive Program.

g. Effective date and phase in of quality measures.

<u>Proposal</u>: We proposed that these measures changes would become effective beginning with the 2015 reporting period, and the 2015 performance year (PY). We also proposed that all quality measures would be phased in for ACOs with 2015 start dates according to the phase-in schedule in Table 81. We proposed that ACOs with start dates before 2015 would be responsible only for complete and accurate reporting of the new measures for the 2015 performance year and then responsible for either reporting or performance on measures according to the phase in schedule.

<u>Comment</u>: Most commenters did not separately provide comments on this specific proposal regarding the effective date for measure changes but addressed the general issue as part of their comments on individual measures or related issues, especially with respect to the effective date for benchmarking purposes. However, a number of commenters disagreed with the proposal to move certain new measures to pay for performance after only one year of pay for reporting. They suggested that an additional year of pay for reporting would be needed in order to adequately and fairly set benchmarks for pay for performance, especially for measures that have not been previously tested in any large scale health system and may be newly or not yet accredited by the National Quality Forum (NQF).

<u>Response</u>: We are finalizing our proposal that quality measures will become effective for the Shared Savings Program quality performance standard beginning in 2015 and the phase-in schedule indicated in Table 81. Additionally, we are convinced by commenters that believe that an additional year of pay for reporting is needed by CMS and ACOs to fully implement new measures. Therefore, each new measure will be pay-for-reporting for its first two reporting

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periods in use. This additional time will help to ensure that ACOs have adequate time to phase in their own care processes and infrastructure before they are held accountable for performance and that CMS has adequate data to set benchmarks for new measures before they transition to pay for performance according to the phase-in schedule in Table 81. In other words, the phase-in schedule indicated in Table 81 applies to a measure after it has been pay-for-reporting for the first two reporting periods it is in use. In this case, the new measures we are finalizing will be pay-for-reporting for the 2015 and 2016 reporting periods, which will take precedence over the phase-in schedule for ACOs that are currently participating in the Shared Savings Program. Using new measures as pay-for-reporting for the first two reporting periods they are in use will provide adequate time and data necessary to set the benchmarks for the 2017 reporting period when the measures will transition to pay for performance under the phase in schedule indicated in Table 81.

For example, assume a new measure is scheduled to phase in with reporting in PY1, reporting in PY2, and performance in PY3. Further assume that an ACO with a 2014 start date will be in its second performance year (PY2) when the measure becomes effective. In this example, according to the performance year phase-in schedule, the ACO would be responsible for complete and accurate reporting of the new measure in PY2 and for performance on the measure in PY3. However, because the measure is new and will be pay-for-reporting for the 2015 and 2016 reporting periods, this overrides the phase-in schedule because we would not have benchmark information for this ACO's PY3. In this example, if the ACO renews its participation agreement for a new agreement period then the ACO would be responsible for performance on the measure in PY1 of its new agreement period, because the measure was scheduled to be pay-for-performance in PY3 of the previous agreement period. If we change the assumptions in the example to an ACO with a start date of 2015, under the phase-in schedule the

ACO would be responsible for performance in PY3 which corresponds with the 2017 reporting period, the first year in which the measure is available to be used for pay-for-performance. In other words, each new measure is pay-for-reporting until it is possible to use it as pay-for-performance, and whether the ACO is subject to pay-for-performance at that time is determined by the phase-in schedule in Table 81.

We are also revising §425.502(a)(4) to provide that the quality performance standard for a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measure is required. For subsequent reporting periods, the quality performance standard for the measure will be assessed according to the phase-in schedule for the measure.

h. Aligning with PQRS sampling methodology

Proposal: As noted in the November 2011 Shared Savings Program final rule (76 FR 67900), the Shared Savings Program uses the same sampling method used by PQRS GPRO. Specifically, the sample for the ACO GPRO must consist of at least 411 assigned beneficiaries per measure set/domain. If the pool of eligible, assigned beneficiaries is less than 411, the ACO must report on 100 percent, or all, of the assigned beneficiaries sampled. In the proposed rule, we stated that to the extent that PQRS modifies and finalizes changes in the reporting requirements for group practices reporting via the GPRO web interface, we proposed to make similar modifications to ACO reporting through the GPRO web interface. Specifically, as discussed in section III.K. of this final rule with comment period, we proposed to reduce the GPRO web interface minimum reporting requirements for PQRS reporting from 411 to 248 consecutively ranked and assigned patients for each measure or 100 percent of the sample for each measure if there are less than 248 patients in a given sample. We proposed that the reduced sample for each measure for reporting through the GPRO web interface would also apply to ACOs. We stated that we believe that a reduction in the number of sampled beneficiaries would reduce reporting burden for ACOs while maintaining high statistical validity and reliability in results.

<u>Comment</u>: We received relatively few comments on this proposal, but most of those that commented supported the proposal. A majority of commenters also supported the PQRS proposal to reduce the reported sample size for groups of 100 or more EPs, and agreed that this smaller sample size would reduce reporting burden (please refer to section III.K.). However, a few commenters were concerned that a sample size of 248 may not adequately or accurately represent the diversity of an ACO's providers and suppliers, especially for larger ACOs. These ACOs can include mixed models of employed and independent-affiliated provider practices. Therefore, these commenters support reducing the sample size requirement only for smaller ACOs, such as those ACOs with 5,000 to 10,000 assigned beneficiaries. Alternatively, these commenters request that ACOs be given the option to continue to report a larger sample size if they prefer. A commenter also asked that CMS publish results that support the statistical validity and reliability of the proposed reduction of the sample from 411 to 248.

<u>Response</u>: Specific responses to comments on this proposal can be found in section III.K.4.a. of this final rule with comment period. We appreciate the comments from stakeholders that support the proposal to reduce the sample size and agree that this change will reduce reporting burden for ACOs. Moreover, commenters agreed that a reduction in the sample size to 248 would continue to be statistically valid and reliable. As discussed in section III.K.4.a, our internal assessments performed for PQRS confirm this conclusion. Additionally, we clarify that the GPRO web interface tool will continue to contain an oversample of 616 patients at it has previously, however, the number required for reporting is being reduced from 411 to 248. Because we have concluded that a sample of 248 is statistically valid and reliable, we disagree that the reduced sample size will not adequately represent the diversity of the ACO's providers and suppliers. Further, we do not have a mechanism that would allow us to deviate from the established methodology used by the GPRO web interface, and therefore cannot offer an option at this time for ACOs to choose to be assessed on more than 248 patients. As noted above, the tool oversamples up to 616 patients, and ACOs may choose, but are not required, to report on all 616. We oversample to allow ACOs to include beneficiaries for quality reporting to replace beneficiaries ACOs are unable to report on, due to exclusions, so they can complete the minimum required number of patients. However, in accordance with the methodology previously adopted under PQRS, the ACO would only be assessed based on reporting for 248 patients using the existing sampling methodology that otherwise has been previously established.

In order to align with the policy being finalized for PQRS, we are reducing the required number of consecutively ranked patients reported for each measure module through the CMS web interface from 411 to 248. Because ACOs report using the same web interface tool used by PQRS, this reduction in the required sample size for reporting will reduce burden, while ensuring statistical validity and reliability is maintained. It also ensures consistency and equal treatment for all groups reporting through the GPRO web interface.

3. Request for Comments for Future Quality Measures

In the proposed rule (79 FR 40483), we indicated that in addition to the changes to the current set of measures for the Shared Savings Program discussed above, we were interested in public comment on additional measures that we may consider in future rulemaking. We particularly welcomed comments regarding the following issues:

• <u>Gaps in measures and additional specific measures</u>: We solicited comments on specific measures or measure groups that may be considered in future rulemaking to fill in gaps that may exist for assessing ACO quality performance.

• <u>Caregiver experience of care</u>: We solicited comment on additional specific caregiver experience of care measures that might be considered in future rulemaking.

• <u>Alignment with Value-Based Payment Modifier (VM) measures</u>: We solicited comment on whether there are synergies that can be created by aligning the ACO quality measure set with the measures used under the VM. Although we did not propose any changes to align with the measures used under the VM, we did seek comment on whether the VM composites should be considered in the future as a replacement for the two ACO claims-based ambulatory sensitive conditions admissions (ASCA) measures.

• <u>Specific measures to assess care in the frail elderly population</u>: We welcomed comments with suggestions of new measures of the quality of care furnished to the frail elderly population that we may consider adopting in future rulemaking.

• <u>Utilization</u>: We welcomed comments on whether it is sufficient for utilization information to be included in the aggregate quarterly reports to ACOs or whether utilization measures should also be used to assess the ACO's quality performance as an added incentive to provide more efficient care. If commenters were interested in having utilization measures included in the quality performance standard, we welcomed specific comments on what utilization measures would be most appropriate for future consideration and suggestions for how to risk adjust these measures.

• <u>Health outcomes</u>: We welcomed suggestions as to whether and when it would be appropriate to include a self-reported health and functional status measure in the quality performance standard. We specifically welcomed comments on the appropriateness of using a tool such the Health Outcomes Survey for health plans which assesses changes in the physical and mental health of individual beneficiaries over time. We also welcomed suggestions for alternatives to self-reported measures that may be considered in the future. • <u>Measures for retirement</u>: We solicited input from commenters on any measures that should be considered for retirement in future rulemaking. We welcomed comments on whether to continue to require 'topped out" measures be included as pay for reporting measures. In addition, we noted that we were proposing changes to the benchmarking methodology for topped out measures.

• Additional public health measures: In the proposed rule, we noted that we may propose to include an additional preventive health measure in the quality measure set under the Shared Savings Program in future rulemaking. Specifically, we indicated that we were considering adding "Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling" (NQF #2152). This measure would reflect screening of Medicare beneficiaries covered under the existing Medicare benefit referred to as the "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse" benefit. We welcomed comments on the potential addition of this measure and noted that we would consider any comments received in developing any future proposal with respect to this measure.

<u>Comment</u>: Commenters identified a wide variety of specific measure gap areas that we should address, such as COPD, care coordination, medication management and adherence, preventive care/adult immunizations, pain, malnutrition, wounds, bladder control, outcome measures and cost/efficiency/utilization related measures. Some commenters provided suggestions for specific measures that we should consider in future rulemaking while other commenters provided more general suggestions about the types of additional measures that we should consider. For example, some commenters suggested that quality measures should be primarily designed to protect beneficiaries from inappropriate reductions in services by ACOs. Other commenters noted that to improve care for beneficiaries, the measures should focus on areas where: (a) CMS believes Medicare beneficiaries are receiving poor care today; and (b) it is

feasible for an ACO to make changes in care that would improve care in those areas using the limited resources available in the Shared Savings Program. Others opposed utilization measures, believing these types of measures are not necessary within the Shared Savings Program because of the inherent incentive for ACOs participating in the program to reduce unnecessary services and achieve savings. A commenter supported adding public health measures "...to help overcome the difficulties inherent in procedure-based measures that capture limited volumes of experience in rural settings." This commenter provided additional suggestions, such as that we exercise caution in interpreting results from self-reported measures, because of a tendency of rural respondents to understate the true burden of chronic illness and travel. Another commenter emphasized that measure development should not entirely focus on outcomes measures because process measures can also improve outcomes. Some measures without clear clinical evidence (that is, lacking NOF endorsement) should be avoided. Furthermore, survey measures should be minimal (and not heavily weighted) due to subjectivity, cost of collection, and risk of inaccurate representation based on response rate. This commenter also recommended that the number of measures required to be reported should be realistic and CMS should move toward the use of composites and outcome measures. Refining the measurement strategy in this way over time will allow for ACOs to mature in function, which takes a few years, and CMS should structure measure selection and performance measurement to reflect growth from fledgling ACO to a mature ACO. CMS should set up data reporting to be automated as much as possible. Finally, a commenter suggested that complementing the measurement strategy should be a forum for communication among ACO participants to share best practices and lessons learned. Comments regarding "topped out" measures for retirement are included in the discussion below regarding the adjustment of the benchmarks for "topped out" measures.

Response: We appreciate receiving the many thoughtful suggestions. We will consider

these suggestions further as we develop any future proposals for additional measures for the Shared Savings Program, which we would implement through rulemaking.

4. Electronic Reporting of Quality Measure Data

We believe that certified EHR technology used in a meaningful way is one piece of a broader health information technology infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. Through our programs such as the Medicare and Medicaid EHR Incentive Programs and the Stage 2 meaningful use (MU) requirements we seek to expand the meaningful use of certified EHR technology (CEHRT). Adoption of CEHRT by ACO participants and ACO providers/suppliers may help support efforts to achieve improvements in patient care and quality, including reductions in medical errors, increased access to and availability of records and data, improved clinical decision support, and the convenience of electronic prescribing. Additionally, we believe that the potential for the Shared Savings Program to achieve its goals could be further advanced by direct EHR-based quality data reporting by ACOs and their ACO participants and ACO providers/suppliers. This could help reinforce the use of CEHRT, reduce errors in quality measure submission, and achieve data submission efficiencies. We believe ACOs and their providers should be leaders in encouraging EHR adoption and should be using CEHRT to improve quality of care and patient safety and to reduce errors.

Furthermore, beginning in 2015, eligible professionals that do not successfully demonstrate meaningful use of CEHRT will be subject to a downward payment adjustment under Medicare that starts at -1 percent and increases each year that an eligible professional does not demonstrate meaningful use, to a maximum of -5 percent. A final rule establishing the requirements of Stage 2 of the Medicare EHR Incentive Program appeared in the September 4, 2012 **Federal Register** (Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule) (77 FR 53968). Included in this final rule are the meaningful use and other requirements that apply for the payment adjustments under Medicare for covered professional services provided by eligible professionals failing to demonstrate meaningful use of CEHRT, including the CQM reporting component of meaningful use. As previously discussed in section III.M.2, we are finalizing a proposal to revise the name and the specifications for the quality measure regarding EHR adoption to take the changing incentives into account. Specifically, we are changing the name of ACO #11 from "Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment" to "Percent of PCPs Who Successfully Meet Meaningful Use Requirements" to more accurately reflect what is being measured.

Additionally, under a group reporting option established for the Medicare EHR Incentive Program (77 FR 54076 through 54078), EPs participating in an ACO under the Shared Savings Program who extract the data necessary for the ACO to satisfy the quality reporting requirements of the Shared Savings Program from CEHRT would satisfy the CQM reporting component of meaningful use as a group for the Medicare EHR Incentive Program. In addition to submitting CQMs as part of an ACO, EPs have to individually satisfy the other objectives and associated measures for their respective stage of meaningful use.

However, we clarified that if an EP intends to use this group reporting option to meet the CQM reporting component of meaningful use, then the EP would have to extract all of its CQM data from a CEHRT and report it to the ACO (in a form and manner specified by the ACO) in order for the EP to potentially qualify for the Medicare EHR Incentive Program. The ACO must also report the GPRO web interface measures and satisfy the reporting requirements under the Shared Savings Program in order to its EPs to satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program.

Although these group reporting requirements were established under the Medicare EHR Incentive Program, the Shared Savings Program regulations were not amended to reflect these reporting requirements. Therefore, we proposed to amend the regulations governing the Shared Savings Program to align with the requirements previously adopted under the Medicare EHR Incentive Program in order to provide that EPs participating in an ACO under the Shared Savings Program can satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the ACO reports GPRO web interface measures by adding new paragraph (d) to §425.506. We proposed that this new paragraph would provide that EPs participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when: (1) the eligible professional extracts data necessary for the ACO to satisfy its quality reporting requirements from CEHRT; and (2) the ACO satisfactorily reports the ACO GPRO measures through a CMS web interface.

Although we did not propose any new requirements regarding EHR based reporting under the Shared Savings Program, we welcomed suggestions and comments about issues which we would consider in developing any future proposals. We especially solicited comment on the feasibility of an ACO to be a convener and submitter of quality measures through an EHR or alternative method of electronically reporting quality measures to us. We indicated our interest in the opportunities and barriers to ACO EHR quality measure reporting, as well as ways to overcome any barriers. We also welcomed suggestions on alternative ways that we might implement EHR-based reporting of quality measures in the Shared Savings Program, such as directly from EHRs or via data submission vendors. We solicited comment on whether EHR reporting should be a requirement for all Shared Savings Program ACOs or if the requirement for EHR reporting should be phased in gradually, for instance through a separate risk track or by the establishment of a "core and menu" quality measure set approach in which we would establish a core set of required quality measures and then supplement these required measures with a menu of additional measures (such as EHR-based reporting) from which an ACO could choose. This approach could provide ACOs with additional flexibility and allow them to report on quality measures that better reflect any special services they provide. As an alternative, we also solicited comment on whether ACO providers/suppliers could use a local registry-like version of the GPRO web interface to capture relevant clinical information and to monitor performance on all Medicare patients throughout the year and to more easily report quality data to CMS annually.

Comment: We received a wide variety of suggestions from ACOs and other stakeholders. Most ACOs support CMS's decision not to propose any new requirements at this time regarding EHR based reporting, and they agree with aligning the Shared Savings Program with the EHR Incentive Program whereby EPs participating in an ACO can satisfy the CQM reporting component of meaningful use when the EP extracts data necessary for the ACO to satisfy its quality reporting requirements using a CEHRT and the ACO satisfactorily reports the GPRO measures through the CMS web interface. Some commenters believe the technical and operational barriers outlined in the proposed rule were severely understated. Healthcare Information and Management Systems Society (HIMSS) considered requiring EHR-based reporting of quality measures in the Shared Savings Program to be premature. Commenters raised concerns that the current lack of interoperability capabilities for ACOs that are formed by disparate organizations, often hospitals and physician groups coming together, but using differing EHR platforms that do not communicate electronic data sufficiently to centralize data for quality reporting would limit the ability of ACOs to successfully report quality through an EHR. They state it will take significant resources and time to ensure that interoperability is

achieved. Rather than requiring EHR-based reporting, some commenters suggested that CMS should give providers the option to report through EHRs.

<u>Response</u>: We appreciate the comments recommending that we not establish any new requirements at this time regarding EHR based reporting under the Shared Savings Program. We also appreciate the comments supporting aligning the Shared Savings Program with the EHR Incentive Program whereby EP participating in an ACO can satisfy the CQM reporting component of meaningful use when the EP extracts data necessary for the ACO to satisfy its GPRO reporting requirement using a CEHRT and the ACO satisfactorily reports the GPRO measures through the CMS web interface.

We will continue to work toward electronic reporting of quality measures, keeping in mind the unique relationship ACOs have with their ACO participants and ACO providers/suppliers. We understand and appreciate the feedback from those stakeholders who raised important concerns about the readiness of ACOs and EHR systems to report quality electronically under the Shared Savings Program. We will use the information provided by commenters to work with ACOs and other stakeholders to develop possible ways to encourage EHR adoption taking into account input from ACOs on challenges for ACO electronic collection and submission of measures. In addition, we will consider the input we have received from stakeholders when deciding what additional requirements should be proposed in future rulemaking to encourage EHR adoption and use by ACOs and their ACO participants and ACO providers/suppliers.

After consideration of the comments received regarding this proposal, we are finalizing our proposal to codify in the Shared Savings Program rules for 2015 and beyond that an eligible professional that is an ACO provider/supplier can satisfy the CQM reporting component of meaningful use when the eligible professional extracts data from CEHRT necessary for the ACO

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to satisfy its quality reporting requirements under the Shared Savings Program and the ACO reports the GPRO measures through the CMS web interface. This policy will be codified at § 425.506(d) of the Shared Savings Program regulations. We emphasize that if an EP intends to use this group reporting option to meet the CQM reporting component of meaningful use, then the EP would have to extract all its CQM data from a CEHRT and report it to the ACO (in a form and manner specified by the ACO) in order for the EP to potentially qualify for the Medicare EHR Incentive Program. The ACO must also report the GPRO measures through the CMS web interface in order for its EPs to satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program.

Although this amendment to the regulations will align the Medicare Shared Savings Program regulations with the existing requirements under the Medicare EHR Incentive Program, we intend to take steps in the future to better align and integrate EHR use into quality reporting under the Shared Savings Program.

5. Quality Performance Benchmarks

a. Overview of Current Requirements

Section 1899(b)(3)(C) of the Act directs the Secretary to "establish quality performance standards to assess the quality of care furnished by ACOs" and to "seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care." Under the current Shared Savings Program regulations at §425.502, the following requirements with regard to establishing a quality performance benchmark for measures apply: (1) during the first performance year of an ACO's agreement period, the quality performance standard is set at the level of complete and accurate reporting; (2) during subsequent performance years, the quality performance standard will be phased in such that ACOs will be assessed on their performance on certain measures (see Table 1 of the November 2011 Shared Savings Program final rule (76 FR 67889 through 67890), for details of the transition for each of the 33 measures); (3) we designate a quality performance benchmark and minimum attainment level for each measure, and establish a point scale for the level of achievement on each measure; and (4) we define quality performance benchmarks using FFS Medicare data or using flat percentages when the 60th percentile is equal to or greater than 80.00 percent.

Section 425.502(b)(2) governs the data that CMS uses to establish the quality performance benchmarks for quality performance measures under the Shared Savings Program. Consistent with section 1899(b)(3)(C) of the Act, which requires CMS to seek to improve the quality of care furnished by ACOs participating in the Shared Savings Program over time, §425.500(b)(3) states that in establishing the measures to assess the quality of care furnished by an ACO, CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

Subsequently, we discussed several issues related to the establishment of quality performance benchmarks in the CY 2014 PFS final rule with comment period (78 FR 74759 through 74764). In that rule (78 FR 74760), we finalized a proposal to combine all available Medicare FFS quality data, including data gathered under PQRS (through both the GPRO web interface tool and other quality reporting mechanisms) and other relevant FFS quality data reported to CMS (including data submitted by Shared Savings Program and Pioneer ACOs) to set the quality performance benchmarks for 2014 and subsequent reporting periods. In establishing this policy, we determined that it was appropriate to use all FFS data rather than only ACO data, at least in the early years of the program, to avoid the possibility of punishing high performers where performance is generally high among all ACOs. We did not finalize a proposal to use Medicare Advantage (MA) data alone or in combination with FFS data in the

short-term. Instead, we stated in the CY 2014 PFS final rule with comment period (78 FR 74760) that we intended to revisit the policy of using MA data in future rulemaking when we have more experience setting benchmarks for ACOs.

Additionally, in the CY 2014 PFS final rule with comment period, we retained the ability to use flat percentages to set benchmarks when many reporters demonstrate high achievement on a measure, so that ACOs with high performance on a measure are not penalized (78 FR 74760). More specifically, we will now use all available FFS data to calculate benchmarks, including ACO data, except where performance at the 60th percentile is equal to or greater than 80 percent for individual measures. In these cases, a flat percentage will be used to set the benchmark for the measure. This policy allows ACOs with high scores to earn maximum or near maximum quality points while still allowing room for improvement and rewarding that improvement in subsequent years.

As previously discussed, the first performance year of an ACO's agreement period is pay for reporting only, so ACOs earn their maximum sharing rate for completely and accurately reporting all 33 quality measures. Quality performance benchmarks are released in subregulatory guidance prior to the start of the quality reporting period for which they apply so that as we phase in measures to pay for performance, ACOs are aware of the actual performance rates they will need to achieve to earn the maximum quality points under each domain. In the November 2011 Shared Savings Program final rule, we indicated our intent to gradually raise the minimum attainment level to continue to incentivize quality improvement over time and noted that we would do so through future rulemaking after providing sufficient advance notice with a comment period to allow for industry input (76 FR 67898). In the CY 2014 PFS final rule with comment period, we reiterated our policy of setting quality performance benchmarks prior to the reporting year for which they would apply (78 FR 74759). Specifically, we use data submitted in

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2013 for the 2012 reporting period to set the quality performance benchmarks for the 2014 reporting period. However, we recognize that in the first few years of the Shared Savings Program, we will only have a limited amount of data for some measures, which may cause the benchmarks for these measures to fluctuate, possibly making it difficult for ACOs to improve upon their previous year's performance. Stakeholders have also told us that they prefer to have a stable benchmark target so that they can be rewarded for quality improvement from one year to the next. Therefore, instead of modifying quality performance benchmarks annually, in the CY 2014 PFS final rule with comment period (78 FR 74761) we stated that we would set the benchmarks for the 2014 reporting year in advance using data submitted during 2013 for the 2012 reporting year, and continue to use that benchmark for 2 reporting years (specifically, the 2014 and 2015 reporting years). We further indicated our intention to revisit this issue in future rulemaking to allow for public comment on the appropriate number of years that a benchmark should apply before it is updated.

b. Revisions for Benchmarking Measures That Are "Topped Out"

In the discussion of measures in the CY 2015 Physician Fee Schedule proposed rule, we indicated that some measures may be topped out, meaning that all but a very few organizations achieve near perfect performance on the measure. Since publication of the quality performance benchmarks for the 2014 and 2015 quality reporting years, a number of ACOs have noted that using available national FFS data has resulted in some benchmarks where the 80th or 90th percentiles approach 100 percent performance on the measure. Stakeholders have suggested it is unreasonable to hold organizations, especially very large organizations such as ACOs to this high standard and that it may be easier for smaller and medium size physician practices to achieve higher levels of performance given their smaller patient populations. We believe these concerns have merit because we have looked at the FFS data submitted to CMS and agree it is

possible that smaller practices or practices with smaller populations may be able to achieve these higher levels of performance more easily than larger practices or organizations with larger patient populations. Therefore, we proposed certain modifications to our benchmarking methodology to address the way that such "topped out" measures are treated for purposes of evaluating an ACO's performance. Specifically, when the national FFS data results in the 90th percentile for a measure are greater than or equal to 95 percent, we would use flat percentages for the measure, similar to our policy under (425.502(b)(2)(ii)) of using flat percentages when the 60th percentile is greater than 80 percent to address clustered measures. We believe this approach would address concerns about how topped out measures affect the quality performance standard while continuing to reward high performance, and being readily understandable to all. We proposed to revise §425.502(b)(2)(ii) to reflect this policy. We invited comments on this proposal. We also invited comments on other potential approaches for addressing topped out measures. We indicated that we would use any comments received to help develop any future proposals regarding topped out measures. For example, we welcomed comments on whether we should drop topped out measures from the measures set, fold them into composites, or retain them but make them pay for reporting only.

<u>Comment</u>: Commenters were generally in agreement with our proposal to use flat percentages for topped out measures, which is consistent with our policy of using flat percentages when the 60th percentile is greater than 80 percent to address clustered measures. We received a wide variety of responses to our request for comment on what should be done with topped out measures through future rulemaking. Many commenters supported retaining such measures with the view that quality measures are intended to protect Medicare beneficiaries from receiving inappropriate care. If all but a few organizations achieve near perfect performance, the commenters believe it would be important to retain that measure to encourage better performance from the low performing organizations, and to prevent backsliding by the high performers. Other commenters, including MedPAC, suggested removing topped out measures to reduce reporting burden. Others suggested that topped out measures could be dropped or moved from being process-based to clinical outcome-based and be folded into composites to prevent "back sliding," or that they could be considered "deemed met" without a reporting requirement but available for audit if so chosen.

<u>Response</u>: We appreciate the commenters' support for the proposal to use flat percentages when the national FFS data results in the 90th percentile performing at greater than or equal to 95 percent. We also appreciate the additional suggestions regarding treatment of topped out measures and intend to consider this issue further in future rulemaking.

<u>Final Decision</u>: After consideration of the comments received on this issue, we are finalizing our proposal to use flat percentages when the national FFS data results in the 90th percentile for a measure are greater than or equal to 95 percent. We are also finalizing our proposed revisions to §425.502(b)(2)(ii) to reflect this policy. Although this final policy is similar to our current policy for setting benchmarks based on flat percentages when the 60th percentile is equal to or greater than 80.00 percent, we clarify that this methodology would apply to all measures, including measures whose performance rates are calculated as ratios, for example, measures such as the ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measure. We believe it is appropriate to apply this methodology to all topped out measures, including measures whose performance rates are calculated as ratios. Measures calculated and reported as ratios may also become topped out and we believe it is important to keep a consistent approach for addressing all Shared Savings Program measures that become topped out.

c. Quality Performance Standard for Measures that Apply to ACOs that Enter a Second or Subsequent Participation Agreement

As discussed previously, during an ACO's first participation agreement period, the quality performance standard during the first performance year is initially set at the level of complete and accurate reporting, and then, during performance years 2 and 3 within the ACO's first agreement period, the quality performance standard is phased in such that the ACO is assessed on its performance on selected measures. We did not directly indicate the quality performance standard that would apply if an ACO were to subsequently enter into a second or subsequent participation agreement. However, §425.502(a)(1) provides that during the first performance year of an ACO's agreement period, CMS will define the quality performance standard at the level of complete and accurate reporting of all quality measures. As drafted, this regulation could be read to imply that the quality performance standard for ACOs in the first performance year of a subsequent agreement period would also be set at the standard of full and accurate reporting. We do not believe it is appropriate for an ACO in a second or subsequent agreement period to report quality measures on a pay-for-reporting basis if they have previously reported these measures in a prior agreement period. The ACO would have gained experience reporting the quality measures during the earlier agreement period, and as a result, we do not believe it would be necessary to provide any further transition period. Rather, we believe it would be appropriate to assess the ACO's actual performance on measures that have been designated as pay for performance during all 3 years of the second or subsequent participation agreement period.

Accordingly, we proposed to revise our regulations to expressly provide that during a second or subsequent participation agreement period, the ACO would continue to be assessed on its performance on each measure that has been designated as pay for performance. That is, the

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ACO would continue to be assessed on the quality performance standard that would otherwise apply to an ACO if it were in the third performance year of the first agreement period. We will do this by modifying §425.502(a)(1) and (a)(2) to indicate that the performance standard will be set at the level of complete and accurate reporting of all quality measures only for the first performance year of an ACO's first agreement period, and that during subsequent agreement periods, pay for performance will apply for all three performance years.

<u>Comment</u>: We received relatively few comments on this proposal. A number of those that responded supported the proposal. A few were hesitant to support it, suggesting that a performance standard for a quality measure should not be continued into a second or a subsequent participation agreement period if there have been any significant changes in the measure set and/or in the specifications used to calculate performance on the measures. In such cases, those measures that have changed should follow the same schedule as would apply to an ACO in its first agreement period. Another example of a concern these commenters raised is if an ACO with a 2013 start date (three year agreement for 2013 through 2015) chooses to sign a subsequent three year agreement (for 2016 through 2018), that requires it to accept risk, then the ACO would possibly be facing new benchmarks beginning in PY 2016 and would not be afforded a one year pay for reporting transition period to gain experience with the new benchmarks.

<u>Response</u>: We appreciate the comments in support of this proposal. We believe that concerns that were expressed by some commenters about changes in the measure set are addressed through the phase-in schedule for new measures, as outlined in Table 81, and our policy, finalized above, that all new measures will be pay-for-reporting for all ACOs for the first two reporting periods in which they are in use, regardless of the phase-in schedule. This will permit time for CMS to gather data for benchmarking and publish benchmarks prior to the start of the third reporting period in which a new measure is in use. This two year grace period will also permit ACOs to become accustomed to the measure before it becomes pay-for-performance. So in the example given by the commenter, the ACO with a 2013 start date would not be subject to pay-for-performance in its first year of the subsequent agreement period (starting in 2016) for any of the new measures finalized in this rule. The first opportunity for the new measures to be used as pay-for-performance would be for the 2017 reporting period, which would correspond to this ACO's second performance year of its subsequent agreement period. Because the ACO would be in its subsequent agreement period, all measures would be pay-for-performance at that time, with the exception of measures that remain pay-for-reporting in all years, according to the phase-in schedule indicated in Table 81. For example, the Depression Remission at 12 Months measure (ACO# 40) is pay-for-reporting for all three years of an ACO's first agreement period. In a subsequent agreement period, ACOs will continue to be assessed on this measure as pay-for-reporting, which corresponds to the level of performance required in PY3 of the first agreement period.

<u>Final Decision:</u> We are finalizing our proposal to modify §425.502(a) to indicate that for ACOs in a second or subsequent agreement period, all measures will be pay for performance for all three performance years unless the measure is designated as pay-for-reporting for all three years, as indicated in Table 81. We clarify that, as discussed in more detail above, this policy applies only to measures that have been in use for two years or more, for which benchmarks are available, and thus, would not apply to new measures, which are designated as pay-for-reporting during the first two reporting periods they are in use.

d. Timing for Updating Benchmarks

As discussed in the CY 2014 PFS final rule with comment (78 FR 74761), we have further considered suggestions from ACOs regarding the appropriate number of years that a benchmark should apply before it is updated. ACOs suggested that there be a longer period of time to gain experience with the performance measure, before the benchmark is further updated. ACOs also indicated that it would be desirable to set and leave benchmarks static for additional performance years so that they have a quality improvement target to strive for that does not change frequently. ACOs believe that a stable benchmark would enhance their ability to be rewarded for quality improvement, as well as quality achievement, from one year to the next. We recognize, however, that there could be some concerns about lengthening the period between updates to the quality performance benchmarks. The current benchmarks as discussed previously, for example, are based on a combination of all available Medicare FFS quality data, including data gathered under PQRS, the Shared Savings Program and Pioneer ACO Model, but not MA quality data. To the extent that the benchmarks are based on quality data reported by a large number of ACOs and other FFS entities, we believe it is reasonable to use them to assess the quality performance of ACOs. Furthermore, as discussed in the 2014 PFS final rule with comment period (78 FR 74761), we are also persuaded that we should establish a longer period between updates to the benchmarks in order to provide ACOs with a more stable target for measuring quality improvement. In the absence of this stability, it could be very difficult to assess quality improvement from year to year.

In the 2014 PFS final rule with comment period, we noted that we intended to address the number of years between updates to the benchmarks again in future rulemaking in order to allow for public comment. Therefore, we considered how long benchmarks should be in place before they are updated. We considered a range of options, from setting benchmarks every 2 years to setting benchmarks every 5 years. For example, we considered the option of setting benchmarks every 3 years. However, we note that ACO agreement periods are 3 years long and a new cohort of ACOs enters the program each year. As a result, setting benchmarks every 3 years might

advantage some ACOs over others, particularly ACOs that have an agreement period during which benchmarks are not updated. Therefore, we proposed to update benchmarks every 2 years. We believe 2 years is an appropriate amount of time because the Shared Savings Program is relatively new and we do not have extensive experience in setting benchmarks under the Shared Savings Program. Updating the benchmarks every 2 years would enable us to be more flexible and give us the ability to make adjustments more frequently if appropriate. We note, however, that we may revisit this policy as more ACOs enter the program, more FFS data is collected which could help us better understand to what extent benchmarks should vary from year to year, or if we make any future proposals regarding the use of MA quality data for setting benchmarks.

Accordingly, we proposed to revise §425.502(b) to add a new paragraph (b)(4)(i), which would provide that CMS will update benchmarks every 2 years. To illustrate this proposed policy, the existing quality performance benchmarks, which are based on data submitted in 2013 for the 2012 reporting period would apply for a total of 2 performance years (the 2014 and 2015 performance years) after which we would reset the benchmarks for all ACOs based on data for the 2014 reporting period that is reported during 2015. These updated benchmarks would apply for the 2016 and 2017 performance years. This timeline is summarized in Table 85. Under this proposal, ACOs would have a stable target for quality achievement for 2 years, which should improve the opportunity for ACOs to be rewarded for improvement from year to year compared to that benchmark. We also proposed to revise §425.502(b) to add a new paragraph (b)(4)(ii), which would provide that for measures introduced in the first year of the 2-year benchmarking cycle, the benchmark will be established in the second year and updated along with the other measures at the start of the next 2-year benchmarking cycle.

We solicited comment on this proposal. We specifically solicited comment on the appropriate number of years that a benchmark should remain stable before it is updated. We also welcomed comments about when annual updates might be appropriate such as when there is a substantive specification change to a measure between years. For instance, the age range used for the breast cancer screening measure is different in 2014 than in 2013, or when the measure owner modifies or retires a measure. Additionally, although we proposed to retain our current policy of using the most recent available data to set the quality performance benchmarks, we also solicited comment on whether data from other reporting periods should also be considered in establishing benchmarks that will apply for 2 performance years. Specifically, we sought input on whether data from multiple years should be used to help provide more stable benchmarks. For example, should data submitted for the 2013 and 2014 reporting periods be combined to set benchmarks for the 2016 and 2017 performance years?

<u>Comment</u>: We received a wide range of comments in response to this proposal. In general most commenters supported setting benchmarks for at least two years but many, including some ACOs, supported a longer period of at least three years to align with the Shared Savings Program agreement period to provide more stability for ACOs. There were some commenters that suggested more frequent adjustment of benchmarks under certain situations, suggesting that more frequent benchmark updates may be necessary whenever there are substantive specification changes for a measure, such as changes in the dominator or frequency. For example, a commenter stated that even slight modifications to a measure specification could eliminate any opportunity to establish a valid benchmark and that CMS must therefore consider establishing new benchmarks when even "non-substantive" changes are made to measure. A commenter suggested that instead of the proposed two year interval, benchmarks should be adjusted annually if there is a statistically significant performance change across all organizations. Some commenters suggested the use of multiple years of data to set benchmarks, suggesting, for example, that some measures could be susceptible to year specific events that could skew results.

<u>Response</u>: We are finalizing our proposal to set benchmarks for two years to provide ACOs with stable quality improvement targets. We believe that setting benchmarks for two years provides ACOs with stable quality improvement targets while not advantaging some ACOs over others by setting them for three years. We also agree with commenters who suggested the use of multiple years of data to set benchmarks to reduce the effect that year to year variation might have on the benchmarks. Therefore, we will use up to 3 years of FFS data to set benchmarks, if available. This should provide sufficient stability to minimize year to year variation while also representing reasonably current practices, if the data is available. The use of multiple years of FFS data to set benchmarks will apply to all newly established benchmarks, but will not affect existing benchmarks, which apply to the 2014 and 2015 performance years.

We are finalizing our proposal to set benchmarks for two years to provide ACOs with stable targets for quality improvement. In addition, we will use up to three years of FFS data to set benchmarks, if available. The use of multiple years of FFS data to set benchmarks will apply to all newly established benchmarks, but will not affect existing benchmarks, which apply to the 2014 and 2015 performance years. We are finalizing our proposal to revise §425.502(b) to add a new paragraph (b)(4)(i) providing that CMS will update benchmarks every 2 years. In light of our decision to set the quality performance standard for a newly introduced measure at the level of complete and accurate reporting for the first two reporting periods for which the measure is in use, we are revising proposed §425.502(b)(4)(ii) to provide that for newly introduced measures that transition to pay for performance in the second year of the 2-year benchmarking cycle, the benchmark will be established in that year and updated along with the other measures at the start

of the next 2-year benchmarking cycle. For example, if a new measure is scheduled to become pay for performance in 2017 after being used for pay-for-reporting for 2015 and 2016, it will be set for the 2017 performance year and subsequently reset at the beginning of the next 2-year benchmarking cycle (2018-2019). In other words, such a measure would have its benchmark set for a single year before phasing into the biennial benchmarking schedule outlined in Table 84.

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Reporting period for data used to set benchmark	Year data is analyzed, and benchmark is published	Performance year and reporting period to which benchmark applies	
2012	2013	2014 & 2015	
2012, 2013, 2014	2015	2016 & 2017	
2014, 2015, 2016	2017	2018 & 2019	

TABLE 84: Timeline for Setting and Updating Quality Performance Benchmarks

6. Rewarding Quality Improvement

a. Current Approach to Rewarding ACOs for Both Quality Attainment and Quality Improvement

ACOs must meet a CMS-specified quality performance standard in order to be eligible to share in savings. The Shared Savings Program quality performance standard currently consists of a set of quality measures spanning four domains that are collected via the patient and caregiver experience of care survey, calculated by CMS from internal administrative and claims data, and submitted by the ACO through the CMS web interface. The four domains include patient/caregiver experience of care, care coordination/patient safety, preventive health, and atrisk populations. The measures collected through the CMS web interface are also used to determine whether eligible professionals that bill through the TIN of an ACO participant qualify for the PQRS incentive payment or avoid the downward PQRS payment adjustment. Eligible professionals that bill through the TIN of an ACO participant may qualify for the PQRS incentive payment or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO quality measures on their behalf. Under current policy, the quality performance standard is defined at the level of full and complete reporting for the first performance year of an ACO's agreement period. After that, an ACO must meet certain thresholds of performance and is rewarded on a sliding scale in which higher levels of quality performance translate to higher rates of shared savings. This scale, therefore, rewards improvement over time, since higher performance translates to higher shared savings. For example, an ACO that performs at the 80th percentile one year and then at the 90th percentile the next year would receive a higher level of shared savings in its second year than its first year, based on its improved quality performance. In this way, ACOs are rewarded for both attainment and improvement. This is particularly true when benchmarks are stable for more than one year, as discussed earlier in this section.

We recognize that rewards for both quality attainment, as well as quality improvement are not always built in to pay-for-performance initiatives. For example, in HVBP (Hospital Value-Based Purchasing) hospitals are scored based on the higher of their achievement or improvement on specified quality measures, with some hospitals receiving incentive payments if their overall performance is high enough relative to their peers. In the November 2011 final rule establishing the Shared Savings Program (76 FR 67897), we indicated in response to comments that we believe the approach of offering more points for better quality performance also offers an implicit incentive for continuous quality improvements, since it incorporates a sliding scale in which higher levels of quality performance translate to higher sharing rates. We believed that high performing ACOs should do well under this approach since it recognizes and provides incentives for ACOs to maintain high quality performance in order to maximize their share of savings and minimize their share of losses.

b. Additional Rewards for Quality Improvement

ACOs and other stakeholders have suggested that the current quality points scale described above does not adequately reward ACOs for both quality attainment and improvement. They request that we further strengthen the incentives for quality improvement by including an additional explicit reward for those ACOs that improve from one year to the next.

As discussed previously, the existing quality performance standard includes a sliding point scale that rewards ACOs for certain levels of attainment. In addition, we note that under the final policy discussed above in which we will establish a stable quality performance benchmark for a period of 2 years, there should be an even greater opportunity for every ACO to demonstrate improvement and be rewarded for that improvement from year to year. However, we were persuaded by suggestions from stakeholders that an additional, more explicit reward should be included for ACOs that improve their quality scores from year to year. Therefore, we proposed to revise our existing quality scoring strategy to explicitly recognize and reward ACOs that make year-to-year improvements in their quality performance scores on individual measures.

To develop such an approach, we looked to the MA program, which has already successfully developed and implemented a formula for measuring quality improvement. The MA five star rating program computes an improvement change score which is defined as the score for a measure in a performance year minus the score in the previous performance year. The MA five star rating program then measures each plan's net quality improvement by calculating the total number of significantly improved quality measures and subtracting the total number of significantly improved quality measures and subtracting the total number of significantly improvement for ACOs. (For more details on the formula for calculating the MA quality improvement measure, see the discussion in "Medicare 2014 Part C & D Star Rating Technical Notes", Attachment I, page 80, which can be downloaded from the

CMS website at http://www.cms.gov/Medicare/Prescription-Drug-

Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.)

We continue to believe it is important to recognize that the Shared Savings Program is not a managed care program. Unlike MA, this program's design retains FFS flexibility and the freedom of choice available to beneficiaries under Medicare Parts A and B which generally necessitates different program requirements. However, in this case we believe there would be significant advantages for the Shared Savings Program to adopt the formula for a quality improvement measure that MA has already developed and implemented rather than attempt to develop a new formula for a quality improvement measure. In particular, the MA measure formula has already been fully developed and vetted with stakeholders, in the context of the MA program, with detailed operational specifications and previously shared with the public.

In addition, we believe it is important to add a quality improvement measure to the Shared Savings Program in a manner that would minimize disruption for ACOs. We believe it would be undesirable for both ACOs and the program if the quality improvement measure were added in a way that required extensive revisions to the current quality measurement methodology, for example, reweighting of the four quality measure domains. Therefore, we proposed to add a quality improvement measure to award bonus points for quality improvement to each of the existing four quality measure domains. For each quality measure domain, we proposed to award an ACO up to two additional bonus points for quality performance improvement on the quality measures within the domain. These bonus points would be added to the total points that the ACO achieved within each of the four domains. Under this proposal, the total possible points that could be achieved in a domain, including up to 2 bonus points, could not exceed the current maximum total points achievable within the domain. ACOs would achieve bonus points for this quality improvement measure in a domain if they achieve statistically significant levels of quality improvement for measures within the domain, as discussed below. Otherwise, the current methodology for calculating the ACO's overall quality performance score would continue to apply (see §425.502(e) and 76 FR 67895 through 67900). Additional details about the proposal to incorporate bonus points into the quality performance scoring methodology are discussed in the CY 2015 Physician Fee Schedule proposed rule (79 FR 40490 through 40492). Highlights of the methodology we proposed are as follows.:

The quality improvement measure scoring for a domain would be based on the ACO's net improvement in quality for the other measures in the domain. The calculation of the quality improvement measure for each domain would generally be based on the formula used for the MA five star rating program, as follows:

<u>Improvement Change Score</u> = score for a measure in performance year minus score in previous performance year.

In general, for a measure to be eligible to be included for purposes of determining quality improvement and awarding bonus points in a domain for a performance year, the measure must be a measure for which an ACO was scored in both the performance year and the immediately preceding performance year. Measures that were not scored in both the performance year and the immediately preceding performance year, for example, new measures, would not be included in the assessment of improvement. Otherwise, for purposes of determining quality improvement and awarding bonus points, we would include all of the individual measures within the domain, including both pay-for-reporting measures and pay-for-performance measures. In determining improvement, the actual performance score achieved by the ACO on the measure would be used, not the score used to determine shared savings. In other words, we would calculate a

performance score for each measure, regardless of whether it is pay for reporting or pay for performance, and include the score in the report we provide to the ACO. For example, all measures are pay for reporting in the first year of an ACO's first agreement period, but even though the ACO will receive full credit for all reported measures, its actual performance on those measures will also be scored and provided to the ACO for informational purposes. We believe it is appropriate to use these actual performance scores to assess improvement on a measure from year to year, regardless of whether the measure is designated as a pay for reporting or a pay for performance measure in that performance year because the performance scores achieved by the ACO provide the best indication of the actual change in quality performance by the ACO.

If the ACO is in its first performance year of its first agreement period, then it would not be possible, of course, to measure quality improvement. Therefore, for these ACOs the existing scoring methodology would continue to apply and no bonus points would be awarded. If an ACO in its second or subsequent performance year does not experience an improvement nor a decline in quality performance for any of the selected measures compared to its previous reporting period, or it experiences an improvement for some measures but has an equal or greater number of measures where quality performance has declined, then the ACO would likewise not be awarded any bonus points. If an ACO renews a participation agreement, then the measurement of quality improvement would be based on a comparison between performance in the first year of the new agreement period and performance in the 3rd year of the previous agreement period.

For each qualifying measure, we would determine whether there was a significant improvement or decline between the two performance years by applying a common standard statistical test. (See the discussion of the t-test for calculating the MA quality improvement measure in "Medicare 2014 Part C & D Star Rating Technical Notes", Attachment I, page 80,

which can be downloaded from the CMS website at <u>http://www.cms.gov/Medicare/Prescription-DrugCovGenIn/PerformanceData.html</u>). Statistical significance testing in this case assesses how unlikely it is that differences as big as those observed would be due to chance when the performance is actually the same. The test recognizes and appropriately adjusts measures at both high and low levels of performance for statistically significant levels of change. Under this methodology, we can be reasonably certain, at a 95 percent level of confidence, that statistically significant differences in an ACO's quality measure performance for a year compared to the previous year are real and not simply due to random variation in measure sampling.

The awarding of bonus points would be based on an ACO's net improvement within a domain, and would be calculated by determining the total number of significantly improved measures and subtracting the total number of significantly declined measures. Up to 2 bonus points would be awarded on a sliding scale based on the ACO's net improvement for the domain compared to the total number of individual measures in the domain.

Consistent with our current quality methodology, the total points earned for measures in each domain, including any quality improvement points, would be summed and divided by the total points available for that domain to produce an overall domain score of the percentage of points earned versus points available. The percentage score for each domain will be averaged together to generate a final overall quality performance score and sharing rate for each ACO that will be used to determine the amount of shared savings or, if applicable the amount of losses it owes, consistent with the requirements under §425.502(e).

In developing this proposal to award bonus points for quality improvement, we considered several alternative options. Specifically, we considered whether it would be more appropriate not to award bonus points but instead to include a computed quality improvement

measure that would be incorporated into the current scoring methodology just as any other measure would be added. Under this alternative approach, we would increase the total possible points that could be awarded in a domain. However, we did not propose that approach because we believe that awarding bonus points would provide the desired incentive, would be more understandable and less disruptive, and would not require extensive changes to the quality performance standard. By awarding bonus points we also avoid the need to develop ways to avoid unfairly penalizing new ACOs. Similarly, ACOs that have already achieved a very high level of quality for an individual measure may not be able to achieve further statistically significant improvement for the measure. Such ACOs could otherwise be disadvantaged if they were not able to earn performance points for a new quality improvement measure added to the total measures in the domain. We believe our quality improvement proposal mitigates these concerns because the measure recognizes incremental improvement at higher levels of performance and does not impose any penalty on ACOs that have already achieved a high level of performance.

We also considered whether we should provide an even greater additional incentive by increasing the total possible bonus points, perhaps up to 4 points to provide a higher incentive for greater levels of quality improvement. However, we did not propose that option because we were concerned that awarding 4 points for the quality improvement measure could overweight the additional incentive for quality improvement given that the program already rewards higher performance with a greater share of any savings.

In addition, we had some concerns about whether it would be appropriate to use the "pay for reporting" data reported to us, given that this information does not affect an ACO's quality performance score in the first performance year. Therefore, we considered whether the quality improvement score should apply only to those ACOs that have completed at least two performance years. Under this alternative approach, ACOs would have an opportunity to be assessed based on their actual quality measure performance before being assessed on their quality improvement scores. We did not select this approach because we wanted to provide an incentive that would apply as soon as possible in the agreement period. Furthermore, as noted earlier, we believe it would be appropriate to include pay-for-reporting measures for purposes of awarding bonus points since under §425.500(f) ACOs are required to report pay-for-reporting measures completely, accurately, and timely.

We proposed to add a new paragraph (e)(4) to §425.502 to incorporate this process for calculating bonus points for quality improvement into the quality performance scoring methodology. We solicited comments on this proposal and welcomed comments on the alternative approaches discussed in the proposed rule. We also solicited comments on whether there are other alternative approaches to explicitly rewarding quality improvement for ACOs, and whether the implicit reward for quality improvement provided under the current regulations is sufficient.

We also welcomed any suggestions on how the Shared Savings Program might integrate elements of other quality improvement methodologies such as those employed by HVBP or MA. Such comments would be considered in developing possible future proposals to further align with other Medicare quality improvement programs.

<u>Comment</u>: Commenters were supportive of explicitly recognizing and rewarding ACOs that make year to year improvements in the manner proposed. Many commenters, however, felt that our proposal did not go far enough and recommended instead that CMS award up to four bonus points (rather than two) for quality improvement in each of the existing four quality measure domains, or permit bonus points in one domain to influence the weighting of the domain. These commenters pointed out that the proposal to award up to two bonus points would

increase the overall quality performance score for an ACO by at most 14 percent. Some commenters suggested additional approaches, such as awarding an additional 10 percent of shared savings for those ACOs that score in the top 10 percent on quality measures. Another example is a suggestion that ACOs be allowed to retain 50% of their share of savings regardless of the MSR if their overall quality score improves year-over-year.

Response: We appreciate the overall support from commenters who generally agreed with the proposal to offer an additional and explicit reward for improving quality performance in the Shared Savings Program. This additional reward would complement and reinforce our current quality performance scoring system that implicitly takes into account improvements over prior performance and rewards ACOs with a greater share in savings for greater quality performance. We believe that adding an explicit incentive places even greater emphasis on quality improvement, encouraging all ACOs to continue to improve quality for their patient populations over time, in addition to maintaining existing high quality levels. The success of the Shared Savings Program is dependent in large part on ACOs further improving the quality of the care they provide, not merely maintaining current levels of quality. Further, we believe that the suggestions from some commenters to increase the additional quality improvement award to up to four bonus points have merit. Although we proposed the improvement measure to increase the domain score by up to 2 points, similar to other measures in the domain, we agree with commenters that increasing this to four bonus points would not appear to overweight the additional incentive since the additional bonus points can only increase a quality score by at most 25 percent overall. (That is, 4 bonus points per domain times 4 domains equals 16, which when divided by the 66 total points possible equals approximately 25 percent). Additionally, we have at least one measure (ACO #11, Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment) that is doubly weighted at 4 points in order to emphasize the importance of

adoption of EHR meaningful use. Permitting the quality improvement measure to be double weighted would similarly emphasize the importance of quality improvement, further encouraging ACOs to improve overall quality for their patient populations over time.

Final Decision: We are finalizing our proposal to provide an additional quality improvement reward for Shared Savings Program ACOs who demonstrate quality improvement on measures in a domain. We believe that this additional and explicit reward for quality improvement would complement and reinforce our current quality performance approach. Specifically, for each quality measure domain, we will award an ACO up to four additional bonus points for quality performance improvement on the quality measures within the domain. These bonus points would be added to the total points that the ACO achieves within each of the four domains. The total possible points that can be achieved in a domain, including up to 4 bonus points, could not exceed the maximum total points achievable within the domain. For example, as shown in Table 82, the total possible points for the patient/caregiver experience domain, which has eight individual measures, is 16 total possible points. Under this new policy that we are finalizing to provide for quality improvement bonus points, the maximum possible points within this domain will remain 16. If an ACO scores 12 points and is awarded four additional bonus points for quality improvement then the ACO's total points for this domain would be 16. However, if instead this same ACO had scored 13 points, then this ACO's total points after adding the bonus points would still not exceed 16. Table 82, which shows the number of points available per domain under the revised quality performance standard, reflects the current quality measure scoring methodology which will continue. Consistent with our current quality scoring methodology, the total points earned for measures in each domain, including any quality improvement bonus points up to the total possible points for the domain, would be summed and divided by the total points available for that domain to produce an overall domain score of the percentage of points earned versus points available. The percentage score for each domain will be averaged together to generate a final overall quality performance score and sharing rate for each ACO that will be used to determine the percentage of savings it shares or, if applicable, the percentage of losses it owes, consistent with the methodology established under §425.502(e).

The calculation of the quality improvement measure for each domain would generally be based on the formula used for the MA five star rating program, as follows:

Improvement Change Score = score for a measure in performance year minus score in previous performance year.

For each qualifying measure, we will determine whether there was a significant improvement or decline between the two performance years by applying a "t-test" which is a common standard statistical test, at a 95 percent level of confidence. (See the discussion of the ttest for calculating the MA quality improvement measure in "Medicare 2014 Part C & D Star Rating Technical Notes", Attachment I, page 80, which can be downloaded from the CMS website at http://www.cms.gov/Medicare/Prescription-Drug-

<u>Coverage/PrescriptionDrugCovGenIn/PerformanceData.html</u>). This test assesses how unlikely it is that differences as big as those observed would be due to chance when the performance is actually the same.

The bonus points, up to a maximum of 4 points, will be awarded in direct proportion to the ACO's net improvement for the domain to the total number of individual measures in the domain. For example, there are eight individual measures for the patient/caregiver experience of care domain. If an ACO achieves a significant quality increase in all eight measures then the ACO would be awarded the maximum of four bonus points for this domain. However, if the ACO achieved a significant quality increase in only one of the eight measures in this domain and no significant quality decline on any of the measures then the ACO would be awarded bonus points for quality improvement in the domain that is 1/8 times 4 = 0.50. The total points that the ACO could achieve in this domain could still not exceed the current maximum of 16 points shown in Table 82. We are also finalizing our proposal to add a new paragraph (4) to \$425.502(e) to incorporate the new bonus points scoring methodology, but are revising the proposed language in order to reflect our decision to award up to 4 bonus points per domain. 7. Technical Corrections

Currently §425.502(d)(2)(ii) states that ACOs must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If an ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take the actions described in §425.216(c). We note that §425.216, which addresses the actions we may take prior to termination of an ACO from the Shared Savings Program does not include a paragraph (c). To encompass all of the actions we may take prior to termination, we believe the correct reference should be to §425.216 generally, and therefore, proposed to make a technical correction to §425.502(d)(2)(ii) to eliminate the specific reference to paragraph (c) of §425.216. We also proposed to correct a typographical error in this provision by revising "actions describe" to read "actions described."

In addition, we also proposed to make a technical correction to §425.502(a)(2). This provision currently states that ACOs will be assessed on performance based on the minimum attainment level for certain measures. However, as explained above and in the November 2011 Shared Savings Program final rule (76 FR 67895 through 67896), ACO performance on a measure is assessed not only based on the minimum attainment level for the measure but also based upon the quality performance benchmark that has been established for that measure. This methodology for calculating the performance score for a measure is codified in the regulations at

§425.502(c). Accordingly, we proposed to amend §425.502(a)(2) to state that ACO performance will be assessed based on the quality performance benchmark and minimum attainment level for certain measures.

We requested comments on these proposed technical corrections.

We received no objections to correcting the typographical errors and making these other minor technical corrections and are finalizing them as proposed.