



MEMO

Subject: *Review of FQHC provisions in the final rule on the Medicare Shared Savings Program: Accountable Care Organizations*

Date: November 4, 2011

This memo briefly addresses the FQHC specific provisions of the Accountable Care Organizations (ACOs) final regulation, highlighting the differences between the proposed rule and final rule.

ACOs “are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to the Medicare patients they serve.”¹ The purpose of ACOs is to succeed in both delivering high-quality care and spending health care dollars more wisely.² ACOs will coordinate and integrate Medicare services, with success being gauged by roughly 30 quality measures organized in four domains: patient experience, care coordination and patient safety, preventive health and at-risk populations.³ ACOs which elect to become accountable for shared losses will share in savings they achieve for the Medicare program based on the quality of care providers deliver—the higher the quality, the more shared savings their ACO may earn.⁴ In turn, fee-for-service Medicare patients who see providers who are participating in a Medicare ACO will maintain all their Medicare rights, including the right to choose any doctors and providers that accept Medicare.⁵

The memo includes the following:

- An overview of the major changes related to FQHCs in the Final Rule.
- An outline of the ACO Final Rule text, highlighting the sections pertaining to FQHCs. (*begins on page 3*)
- The relevant text of the Preamble to the Final Rule, highlighting the FQHC specific comments and decisions. The yellow highlights indicate background information, whereas the gray highlights technical information reflected in the final regulation. (*begins on page 6*)

¹ “What is an ACO?” *available at* <http://www.cms.gov/ACO/>.

² *Id.*

³ “The Affordable Care Act: Helping Providers Help Patients” *available at* <http://www.cms.gov/ACO/Downloads/ACO-Menu-Of-Options.pdf>.

⁴ Provided they also lower growth in health care expenditures. *Id.*

⁵ Also, whether a provider chooses to participate in an ACO or not, their patients with Medicare may continue to see them.

“What is an ACO?” *available at* <http://www.cms.gov/ACO/>.

PROPOSED RULE V. FINAL RULE FOR ACOs IN THE MEDICARE SHARED SAVINGS PROGRAM⁶

- **Eligible Entities**
 - Federally Qualified Health Centers and Rural Health Clinics are now also eligible to both form and participate in an ACO.
 - *In the proposed rule*, CMS proposed to use discretion afforded by the statute under section 1899(b)(1)(E) to allow participation of any Medicare-enrolled provider/supplier as an ACO participant. Thus, FQHCs and RHCs were eligible to participate in the program but not independently.
 - *In the final rule*, CMS modified “the proposed assignment process to recognize the different payment methodologies and claims data” that are used by FQHCs and RHCs so that FQHCs and RHCs are now eligible to participate in and independently form ACOs. Additionally, “Medicare enrolled entities may join independent FQHCs, RHCs, and method II billing CAH ACOs.”
- **Assignment of Medicare Fee-for-Services Beneficiaries**
 - CMS is establishing a cross-walk for HCPCS codes to certain revenue center codes used by FQHCs (prior to January 1, 2011) and RHCs so that their services can be included in the ACO assignment process.
 - *In the proposed rule*, the methodology was to assign beneficiaries to an ACO if they receive a plurality of their primary care services from a primary care physician (defined as a physician with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine) affiliated with the ACO.
 - *In the final rule*, in order to identify primary care services rendered in FQHCs and RHCs that are primary care services, and that are not required to be reported by HCPCS codes, CMS adopted the commenter’s suggestions to use the revenue center codes and was able to cross walk the "primary care" HCPCS codes to comparable revenue center codes based on their code definitions. CMS will establish and update this crosswalk through contractor instructions. For FQHCs, CMS will use the HCPCS codes which are included on FQHCs claims starting on January 1, 2011.
- **Shared Savings Program**
 - CMS agrees in the final rule that it can develop a process to allow FQHCs and RHCs to fully participate in the Shared Savings Program. This can be done by using the limited provider NPI information on the FQHC/RHC claims in combination with a supplementary attestation requirement. More specifically, from the FQHC/RHC claims, CMS will use the Attending Provider NPI field data which is defined as being: "the individual who has overall responsibility for the patient's medical care and treatment reported in this claim/ encounter." CMS will then use the combination of the ACO's TINs (or other unique identifiers, where appropriate) and these NPIs provided to them through the attestation process to identify and assign beneficiaries to ACOs that include FQHCs/RHCs using the step-wise assignment methodology as previously explained.
 - The final rule will not contain a sliding scale-based increase in the shared savings rate, up to 2.5 additional percentage points under the one-sided model and up to 5 additional percentage points under the two-sided model, for ACOs that include an FQHC or RHC as an ACO participant.

⁶ CMS Table of modifications available at <http://www.cms.gov/ACO/Downloads/Appendix-ACO-Table.pdf>.

FINAL RULE TEXT: 42 CFR PART 425

PART 425--MEDICARE SHARED SAVINGS PROGRAM

Subpart A--General Provisions

425.10 Basis and scope.

425.20 Definitions.

- Federally qualified health center (FQHC) has the same meaning given to this term under §405.2401(b) of this chapter.
- Primary care physician means a physician who has a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine, or, for services furnished in an FQHC or RHC, a physician included in an attestation by the ACO as provided under §425.404.
 - Primary care services mean the set of services identified by the following HCPCS codes:
 - (1) 99201 through 99215.
 - (2) 99304 through 99340, and 99341 through 99350, G0402 (the code for the Welcome to Medicare visit), G0438 and G0439 (codes for the annual wellness visits);
 - (3) Revenue center codes 0521, 0522, 0524, 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.
 - Primary care services mean the set of services identified by the following HCPCS codes:
 - (1) 99201 through 99215.
 - (2) 99304 through 99340, and 99341 through 99350, G0402 (the code for the Welcome to Medicare visit), G0438 and G0439 (codes for the annual wellness visits);
 - (3) Revenue center codes 0521, 0522, 0524, 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

Subpart B--Shared Savings Program Eligibility Requirements

425.100 General.

425.102 Eligible providers and suppliers.

(a) The following ACO participants or combinations of ACO participants are eligible to form an ACO that may apply to participate in the Shared Savings Program:

- (1) ACO professionals in group practice arrangements.
- (2) Networks of individual practices of ACO professionals.
- (3) Partnerships or joint venture arrangements between hospitals and ACO professionals.
- (4) Hospitals employing ACO professionals.
- (5) CAHs that bill under Method II (as described in §413.70(b)(3) of this chapter).
- (6) RHCs.
- (7) FQHCs.

(b) Other ACO participants that are not identified in paragraph (a) of this section are eligible to participate through an ACO formed by one or more of the ACO participants identified in paragraph (a) of this section.

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- 425.200 Agreement with CMS.
- 425.202 Application procedures.
- 425.204 Content of the application.

(c) Eligibility

- (1) ACO must submit to CMS enumerating supporting materials to demonstrate that the ACO satisfies the eligibility requirements.
- (2) Upon request the ACO must provide to CMS copies of enumerated documents effectuating the ACOs
- (3) Instruction for ACO if requests an exception to (i) Governing body requirements or (ii) Leadership and management requirements
- (4) ACO must certify that it is a legal entity, authorized to conduct business 425.206 Evaluation procedures for applications.

(5) ACO must provide CMS with information about its ACO participants and suppliers/providers:

- (i) ACO must submit a list of all ACO participants and Medicare-enrolled TINs
- (ii) ACOs must also submit any other information by CMS.

(iii) If the ACO includes an FQHC or RHC as an ACO participant, it must also do the following:

- (A) Indicate the TINs, organizational NPIs, and other identifying information for its participant FQHCs or RHCs or both, as well as NPIs and other identifying information for the physicians that directly provide primary care services in the participant FQHCs or RHCs or both.
- (B) Submit any other specific identifying information for its participant FQHCs or RHCs or both as required by CMS in the application process.

(iv) ACO must certify the accuracy of this information

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Subpart E – Assignment of Beneficiaries

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425.404 Special assignment conditions for ACOs including for FQHCs and RHCs.

CMS assigns beneficiaries to ACOs based on services furnished in FQHCs or RHCs or both consistent with the general assignment methodology in §425.402, with two special conditions:

- (a) Such ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO.
- (b) Under the assignment methodology in §425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service if the—
 - (1) NPI of a physician included in the attestation is reported on the claim as the attending provider; and
 - (2) Claim includes a HCPCS or revenue center code that meets the definition of primary care services under §425.20.

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Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

PREAMBLE to FINAL RULE: 42 CFR Ch.4 Part 425

PART 425--MEDICARE SHARED SAVINGS PROGRAM
Outline of the Regulation as provided by the CMS.

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 - (2) multiple start dates in 2012;
 - (3) establishment of a longer agreement period for those starting in 2012;
 - (4) greater flexibility in the governance and legal structure of an ACO;
 - (5) simpler and more streamlined quality performance standards;
 - (6) adjustments to the financial model to increase financial incentives to participate;
 - (7) increased sharing caps;
 - (8) no down-side risk and first-dollar sharing in Track 1;
 - (9) removal of the 25percent withhold of shared savings;
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 - 1. pg.7—
 - a. “We also proposed that ACO participants on whom beneficiary assignment is based, would be exclusive to one ACO agreement in the Shared Savings Program. Under our proposal, this exclusivity would only apply to ACO participants who bill Medicare for the services rendered by primary care physicians

(defined as physicians with a designation of internal medicine, geriatric medicine, family practice and general practice, as discussed later in this final rule). However, we acknowledged the importance of competition in the marketplace to improving quality of care, protecting access to care for Medicare beneficiaries, and preventing fraud and abuse. **Therefore, under our proposal, ACO participants upon which beneficiary assignment was not dependent (for example, acute care hospitals, surgical and medical specialties, RHCs, and FQHCs) would be required to agree to participate in the Medicare ACO for the term of the agreement, but would not be restricted to participation in a single ACO."**

2. Pg. 10—

a. Comment:

- i. Many commenters objected to our proposal that FQHCs and RHCs could not form independent ACOs, but only participate in ACOs that included other eligible entities (for example, hospitals, and physician group practices). However, one commenter welcomed the opportunity for FQHCs to participate in multiple ACOs.

b. Response:

- i. As we discuss in section II.E. of this final rule, we are revising our proposed policy to allow FQHCs and RHCs to form independent ACOs. We have also revised our proposed assignment methodology in order to permit claims for primary care services submitted by FQHCs and RHCs to be considered in the assignment process for any ACO that includes an FQHC or RHC (whether as an independent ACO or in conjunction with other eligible entities). As a consequence of this revised policy, the exclusivity of the ACO participants upon which beneficiary assignment is dependent also extends to the TINs of FQHCs and RHCs upon which beneficiary assignment will be dependent under the new policies discussed in section II.E. of this final rule.

c. Final Decision:

- i. **We are finalizing our proposals regarding operational definition of an ACO as a collection of Medicare-enrolled TINs, the obligation of the ACO to identify their ACO participant TINs and NPIs on the application, the obligation of the ACO to update the list, and the required exclusivity of ACO participants upon whom assignment is based without change under sections 425.20, 425.204(5), 425.302(d), 425.306, respectively. We clarify that ACO participants upon which beneficiary assignment is not dependent are not required to be exclusive to a single Medicare Shared Savings Program ACO. **This final exclusivity policy extends to the ACO participant TINs of FQHCs, RHCs and ACO participants****

that include NP, PAs, and specialists upon which beneficiary assignment will be dependent under the revised assignment methodology discussed in section II.E. of this final rule.

(b) Eligible Participants

i. Pg. 11—

1....Other providers of services and suppliers that play a critical role in the nation's health care delivery system, such as Federally qualified health centers (FQHCs), rural health centers (RHCs), skilled nursing facilities (SNFs), nursing homes, long-term care hospitals (LTCHs), critical access hospitals (CAHs), nurse midwives, chiropractors, and pharmacists, among others, are not specifically designated as eligible participants in the Shared Savings Program under section 1899(b)(1) of the Act. Furthermore, while the statute enumerates certain kinds of provider and supplier groups that are eligible to participate in this program, it also provides the Secretary with discretion to tailor eligibility in a way that narrows or expands the statutory list of eligible ACO participants. Therefore, we explored several options: (1) permit participation in the program by only those ACO participants that are specifically identified in the statute; (2) restrict eligibility to those ACO participants that would most effectively advance the goals of the program; or (3) employ the discretion provided to the Secretary under section 1899(b)(1)(E) of the Act to expand the list of eligible groups to include other types of Medicare-enrolled providers and suppliers identified in the Act. After evaluating the three alternatives, we decided to propose the third option.

Since the statute requires that beneficiary assignment be determined on the basis of utilization of primary care services provided by ACO professionals that are physicians, we considered whether it would be feasible for CAHs, FQHCs, and RHCs to form an ACO or whether it would be necessary for these entities to join with one of the four groups specified in section 1899(b)(1)(A)-(D) of the Act in order to meet statutory criteria. We especially considered the circumstances of CAHs, FQHCs, and RHCs because these entities play a critical role in the nation's health care delivery system, serving as safety net providers of primary care and other health care and social services. At the same time, we noted that the specific payment methodologies, claims billing systems, and data reporting requirements that apply to these entities posed some challenges in relation to their independent participation in the Shared Savings Program. In order for an entity to be able to form an ACO, it is necessary that we obtain sufficient data in order to carry out the necessary functions of the program, including assignment of beneficiaries, establishment and updating of benchmarks, and determination of shared savings, if any. As we discuss in section II.E. of this final rule, section 1899(c) of the Act requires the assignment of beneficiaries to an ACO based on their utilization of primary care services furnished by a physician. Thus, as required by the statute, the assignment methodology requires data that identify the precise services rendered (that is, primary care HCPCS codes), type of practitioner providing the service (that is, a MD/DO as opposed to NP, PA, or clinical nurse specialist), and the physician specialty in order to be able to assign beneficiaries to ACOs.

We proposed that because of the absence of certain data elements required for assignment of beneficiaries, it would not be possible for FQHCs and RHCs to participate in the Shared Savings Program by forming their own ACOs. We stated that as the Shared Savings Program developed, we would continue to assess the possibilities for collecting the requisite data from FQHCs and RHCs, and in light of any such developments, we would consider whether it would be possible at some future date for Medicare beneficiaries to be assigned to an ACO on the basis of services furnished by an FQHC or RHC, thereby allowing these entities to have their Medicare beneficiaries included in the ACO's assigned population.

In the proposed rule, we further considered whether CAHs could participate in the Shared Savings Program by forming an independent ACO. We noted the situation is somewhat more complicated with regard to CAHs because section 1834(g) of the Act provides for two payment methods for outpatient CAH services. We described the payment methods in detail and determined that current Medicare payment and billing policies could generally support the formation of an ACO by a CAH billing under section 1834(g)(2) (referred to as method II).

In summary, we proposed that the four groups specifically identified in section 1899(b)(1)(A)-(D) of the Act (various combinations of physicians, nurse practitioners, physician assistants, clinical nurse specialists, and acute care hospitals), and CAHs billing under method II, would have the opportunity, after meeting the other eligibility requirements, to form ACOs independently. In addition, the four statutorily identified groups, as well as CAHs billing under method II, could establish an ACO with broader collaborations by including additional ACO participants that are Medicare enrolled entities such as FQHCs and RHCs and other Medicare enrolled providers and suppliers not originally included in the statutory definition of eligible entities.

We indicated in the proposed rule that we would consider whether it would be appropriate to expand the list of entities eligible to participate in the Shared Savings Program, either in the final rule or in future rulemaking, if we determined that it was feasible and consistent with the requirements of the program for more entities to participate as ACOs independently. In the interim, and until such time as FQHCs and RHCs would be eligible to form ACOs or have their patients assigned to an ACO, we proposed to provide an incentive for ACOs to include RHCs and FQHCs as ACO participants, by allowing ACOs that include such entities to receive a higher percentage of any shared savings under the program. We discuss our final policies regarding the determination of shared savings under the program in section II.G. of this final rule.

ii. Pg. 12—

1. Comment:

- a. A large number of commenters requested an expansion of those entities eligible to participate in the Shared Savings Program. The commenters requested that entities such as, but

not limited to, integrated delivery systems, emergency medical technicians (EMTs), paramedics, health plans, Medicare Advantage (MA) plans, Medicaid Managed Care Organizations, AEMTs, community based hospitals, DME Suppliers, home health agencies (HHAs), long-term care (LTC) facilities, in-patient rehabilitation facilities, hospice facilities, patient-centered medical homes, RHCs, FQHCs, and Method I CAHs be included as eligible entities. We received one comment inquiring whether non-PECOS (Provider Enrollment, Chain, and Ownership System) enrolled providers can participate as ACO providers/suppliers. PECOS is a directory containing the names, addresses, phone numbers, and specialties of physicians enrolled in Medicare. Other comments suggested that we establish ESRD and cancer care specific ACOs. We received a few comments in support of limiting those entities eligible to participate in the program. These comments suggested that implementation of the Shared Savings Program will demand significant changes to health care delivery, data sharing, and data integration among providers and disparate groups. Providing clear guidance on who can participate reduces confusion and uncertainty within the provider and hospital community.

2. Response:

- a. We agree that limiting eligibility could potentially reduce confusion but also agree that the inclusion of some additional entities as eligible to independently participate in the program could significantly increase the opportunity for success. Although the entities referenced in the comment, with the exception of CAHs billing under method II, RHCs and FQHCs, are not able to independently form ACOs, these entities are not prohibited from participating in the Shared Savings Program so long as they join as an ACO participant in an ACO containing one or more of the organizations that are eligible to form an ACO independently and upon which assignment could be made consistent with the statute and the assignment methodology discussed in section II.E. of this final rule. Thus, although we do not see the need to design distinct ESRD or cancer specific ACOs, neither of these providers types are in any manner excluded from participation in an ACO. This allows for the four groups specifically identified in section 1899(b)(1)(A) through (D) of the Act, and CAHs billing under method II, RHCs, and FQHCs to form ACOs independently. In addition, the four statutorily identified groups, as well as CAHs billing under method II, RHCs, and FQHCs could establish an ACO with broader collaborations by including additional Medicare-enrolled entities defined in the Act as ACO participants. This will afford ACOs the flexibility to include all types of providers and suppliers as ACO participants, as long as the ACO can satisfy the required eligibility standards. Finally, enrollment in the PECOS

system, at this time, is not a condition of eligibility to participate in the Shared Savings Program.

iii. Pg. 12—

1. Comment:

- a. Many commenters, including MedPAC and commenters representing rural health advocates and a wide range of beneficiary and provider groups, raised concerns about the proposal which would preclude FQHCs and RHCs from forming independent ACOs. The commenters raised this issue in reference to eligibility, beneficiary assignment, and benchmarking issues. There were also several comments that agreed with the additional sharing rates for ACOs that include FQHCs and RHCs.

Commenters generally supported eligibility approaches that would allow FQHCs/RHCs to join ACOs formed by other entities. Some commenters also generally supported our proposal that FQHCs/RHCs would not be required to be exclusive to a single ACO. Although commenters were generally appreciative of the proposal to provide a higher sharing rate for ACOs that include FQHCs and RHCs, some commenters believed this approach was flawed, too weak to be effective, and could undercut the objectives of the Shared Savings Program. Most commenters expressed general concerns that the CMS interpretation of the statute was incorrect and that the statute allows the agency to promulgate policies that will allow for full participation of FQHCs in the Shared Savings Program. Some commenters focused their detailed comments on FQHCs, but the concerns/issues they raised were generally similar to those commenters that also addressed RHCs.

Several commenters stated that CMS' conclusions are flawed and that the law allows the agency to promulgate policies that will allow for full FQHC participation in the Shared Savings Program. They believe that "a system that does not allow for meaningful FQHC involvement undercuts the Congressional intent in establishing the ACO/Shared Savings Program and the broader goal of assuring quality cost efficient health care services to Medicare beneficiaries." They expressed fear that other payers such as Medicaid, CHIP and private health insurers will follow Medicare's approach and policies in developing their own ACO rules, leading to disparities in care. Another commenter suggested our proposal would prevent or limit dually eligible patients from receiving integrated care at FQHCs in light of State Medicaid efforts to create ACOs and our definition of "at risk" beneficiaries.

Other commenters argued that RHCs represent a particularly compelling case for ACO formation inclusion. They believe that

the promise of better integrated outpatient care for rural Medicare beneficiaries must begin with RHCs. These commenters believe that the exclusion of RHCs from those eligible to form an ACO independently would only serve to exclude rural providers and the populations they serve from forming efficiency enhancing ACOs that might serve to counterbalance the inpatient service-favoring skew that they believe has developed out of many rural preferential payment provisions.

2. Response:

- a. In this final rule we are addressing the specific comments regarding beneficiary assignment and the establishment of benchmarks for ACOs that include FQHCs and/or RHCs in sections II.E. and II.G. (Assignment and Benchmark) of this final rule while general comments regarding the eligibility of FQHCs and RHCs to form ACOs independently are addressed here. *In the proposed rule* (emphasis added), we proposed to use discretion afforded by the statute under section 1899(b)(1)(E) to allow participation of any Medicare-enrolled provider/supplier as an ACO participant. Thus, entities such as FQHCs and RHCs were eligible to participate in the program under our original proposal. However, we agree that it is highly desirable to allow for FQHCs and RHCs to participate independently and to determine a way to include their beneficiaries in assignment. In order for this to be possible, *in this final rule* (emphasis added) we are making modifications to the proposed assignment process to recognize the different payment methodologies and claims data that are used by FQHCs and RHCs as compared to the payment methodologies and claims data that are available for physician offices/clinics that are paid under the physician fee schedule. The discussion about assignment and benchmarking process is in sections II.E. (Assignment) and II.G. (Benchmarking) of this final rule. *As a result*, under the policies established in this final rule, FQHCs and RHCs will be eligible to form ACOs and may also be ACO participants in ACOs formed by other entities. Additionally, Medicare enrolled entities may join independent FQHCs, RHCs, and method II billing CAH ACOs.

iv. Pg. 13—

1. Comment:

- a. Some commenters suggested using CMS's demonstration authority to include FQHCs and RHCs in the Shared Savings Program or another Shared Savings Program. Others recommended that CMS should continue to work with providers and patients practicing and living in rural underserved areas to

develop ACO models specifically designed to meet the unique healthcare delivery challenges facing rural underserved areas.

2. Response:

- a. We appreciate the comments suggesting the development of ACO models to address the special needs of rural areas and have forwarded them to our colleagues in the Innovation Center. We will consider any additional demonstrations focused on ACOs as part of the regular process for establishing CMS demonstrations. We note, however, that as discussed previously, under the policies adopted in this final rule, FQHCs and RHCs will be eligible to form an ACO independently or to participate in an ACO formed by other eligible entities.

3. Comment:

- a. A few commenters suggested that CMS should refine its strategies to facilitate development of practitioner-driven, rather than hospital-driven ACO's. Comments further suggested that at the very least, waiver authority should be established to enable the agency to waive hospital-oriented requirements for ACOs that consist solely of group practices.

v. Pg.13—

1. Final Decision:

- a. We are finalizing our proposals for identifying groups of providers of services and suppliers that may join to form an ACO under §425.102. Specifically, the entities identified in section 1899(b)(1)(A) through (D) of the Act will be able to form ACOs, provided they meet all other eligibility requirements. Additionally, CAHs billing under method II, FQHCs, and RHCs may also form independent ACOs if they meet the eligibility requirements specified in this final rule. In addition, any Medicare enrolled entities not specified in the statutory definition of eligible entities in section 1899(b)(1)(A)-(D) of the Act can participate in the Shared Savings Program as ACO participants by joining an ACO containing one or more of the organizations eligible to form an ACO. Additionally, in response to comments and after further consideration of the available information, we have established a process by which primary care services furnished by FQHCs and RHCs will be included in the assignment process, as discussed in section II.E. of this final rule. As a result, FQHCs and RHCs will also be able to form ACOs independently, provided they meet all other eligibility requirements.

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- iii. **Overlap with the Center for Medicare & Medicaid Innovation (Innovation Center) Shared Savings Models**

1. Pg. 33—

- a. “Many urged CMS to provide upfront capital support to ACOs to defray start-up and operational expenses and to encourage participation, and some suggested that based on PGP data, ACOs may require more than three years to recoup their start up investment. Several commenters concurred with the need for robust health information technology (HIT) in ACOs but stated that acquisition costs create a substantial barrier to physician ACOs. Numerous commenters urged CMS to create additional ways to help finance physicians' acquisition of HIT. Several explained that shared savings alone will not assist practices with upfront costs nor provide assurance that they will recover their initial investments and that, as a result, transitional models are needed. A few commenters noted that providers should not have to divert resources to two similar initiatives (for example, electronic health records incentives and shared savings) with only technical differences. **Groups identified by commenters that may be especially challenged by the upfront costs of ACO formation and operations include:** private primary care practitioners, small to medium sized physician practices, small ACOs, MAPCP demonstration programs, minority physicians and physicians who see minority patients, safety net providers (that is, RHCs, CAHs, **FQHCs**, community-funded safety net clinics (CSNCs)), rural providers (that is, Method II CAHs, rural PPS hospitals designated as rural referral centers, sole community hospitals or Medicare dependent hospitals), and rural primary care providers. A few commenters suggested that CMS offer special funding or access to capital through grants or no interest loans for ACOs formed by rural and safety-net providers, or other providers, such as home health or hospice providers, to enhance participation of these groups in the Shared Savings Program. A commenter suggested that CMS offer a rural primary care provider incentive, such as an enhanced FFS payment or other payment methods (for example, partial capitation), for joining a Medicare ACO to help fund the infrastructure requirements of a Medicare ACO, buffer risk, and stimulate further participation.

Some commenters made specific suggestions for offsetting costs to the ACO, for example, a number of comments

recommended that the final rule provide an additional financial incentive for the collection and reporting of patient satisfaction data or other quality data. On the other hand, some commenters noted that many high quality organizations are likely to have already made the capital investments to achieve high quality and efficient care delivery, and are therefore poised to become ACOs.”

b. Response :

- i. We recognize that a real commitment to improving care processes for Medicare beneficiaries will require financial investment on the part of the ACO, ACO participants, and ACO providers/suppliers. The Shared Savings Program is designed to provide an incentive for ACOs demonstrating high quality and improved efficiencies. We have passed along comments related to Advance Payment to our colleagues in the Innovation Center.

In this final rule, we have made significant changes to reduce burden on participants and improve the opportunity to share in savings. In section II.F. of this final rule, we note our intent to provide funding for the patient experience of care survey for 2012 and 2013, providing early adopters with additional upfront assistance. In section II.G (shared savings/losses) of this final rule, we describe changes to the financial model that benefit Shared Savings Program participants such as removal of the 25 percent withhold, removal of the net 2 percent requirement so that ACOs may share from first dollar savings once the MSR is overcome, and an increase to the shared savings cap. Additionally, in response to comments, we are reducing the claims run out period from 6 to 3 months, allowing for earlier payment of shared savings. Finally, in section II.C. (Agreement) of this final rule, we discuss lengthening the agreement period for early adopters. Moreover, as noted, the Innovation Center is considering an Advance Payment model for certain ACOs, which would test whether pre-paying a portion of future shared savings could increase participation in the Shared Savings Program.

Finally, we note there are also other public and private options to offset start up costs such as financing arrangements, grants from non-profit and existing government sources, as well as savings from non-Medicare patient populations. Other CMS initiatives, such as the HER Incentive Program, provide incentives

for HIT adoption. Potential participants will want to consider all options available.

- c. Comment:
 - i. Several commenters suggested that CMS provide technical assistance to certain ACOs such as those comprised of safety net providers, or physician-only ACOs, or to ACOs in general.
- d. Response:
 - i. In addition to ongoing technical assistance provided for specific program activities, such as quality measures reporting, we will consider ways in which additional assistance can be provided to Shared Savings Program ACOs. We note that the Innovation Center has held several well-received ADLS sessions designed to provide the executive leadership teams from existing or emerging ACO entities the opportunity to learn about essential ACO functions and ways to build capacity needed to achieve better care, better health, and lower costs through improvement. We will also explore other opportunities to assist Shared Savings Program ACOs.
- e. **Final Decision:**
 - i. We are finalizing our proposal to exclude Pioneer ACO Model participants from participation in the Shared Savings Program. Additionally, since the Pioneer ACO Model may begin before the Shared Savings Program and will assign beneficiaries prospectively, we will work with the Innovation Center to ensure no beneficiaries used to determine shared savings are assigned to both (§425.114).

C. Establishing the Agreement with the Secretary

- (a) Options for Start Date of the Performance Year
- (b) Timing and Process for Evaluating Shared Savings
- (c) New Program Standards Established During the Agreement Period
- (d) Managing Significant Changes to the ACO During the Agreement Period
- (e) Coordination with Other Agencies
 - i. Waivers of CMP, Anti-Kickback, and Physician Self-Referral Laws
 - ii. IRS Guidance Relating to Tax-Exempt Organization Participating in ACOs
 - iii. Antitrust Policy Statement
 - iv. Coordinating the Shared Savings Program Application with the Antitrust Agencies

D. Provision of Aggregate and Beneficiary Identifiable Data

- (a) Data Sharing
- (b) Sharing Aggregate Data
- (c) Identification of Historically Assigned Beneficiaries
- (d) Sharing Beneficiary Identifiable Claims Data
- (e) Giving Beneficiaries the Opportunity to Decline Data Sharing

E. Assignment of Medicare Fee-for-Service Beneficiaries

- (a) **Definition of Primary Care Services**

i. **Consideration of Physician Specialties in the Assignment Process**

1. Pg. 52—

a. Final Decision:

i. We are finalizing our proposal to define "primary care services" in §425.20 as the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439) as primary care services for purposes of the Shared Savings Program. *In addition, as we will discuss later in this final rule, in this final rule we will establish a cross-walk for these codes to certain revenue center codes used by FQHCs (prior to January 1, 2011) and RHCs so that their services can be included in the ACO assignment process.* (emphasis added)

ii. Consideration of Services Furnished by Non-physician Practitioners in the Assignment Process

iii. **Assignment of Beneficiaries to ACOs that Include FQHCs and/or RHCs**

• Pg. 57—

a. "In the proposed rule, we also considered the special circumstances of FQHCs and RHCs in relation to their possible participation in the Shared Savings Program. (For purposes of this discussion, all references to FQHCs include both section 330 grantees and so-called "look alike," as defined under §405.2401 of the regulations.) *Our proposed methodology* (emphasis added) was to assign beneficiaries to an ACO if they receive a plurality of their primary care services (which we proposed to identify by a select set of E&M services defined as "primary care services" for other purposes in section 5501 of the Affordable Care Act, and including the G-codes associated with the annual wellness visit and Welcome to Medicare visit) from a primary care physician (defined as a physician with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine) affiliated with the ACO. Thus, under the proposal, we would need data that identify the precise services rendered (that is, primary care HCPCS codes), type of practitioner providing the service (that is, a physician as opposed to NP or PA), and the physician specialty in order to be able to assign beneficiaries to the entities that wish to participate in the Shared Savings Program.

In general, FQHCs and RHCs submit claims for each encounter with a beneficiary and receive payment based on an interim all-inclusive rate. These claims distinguish general classes of services (for example, clinic visit, home visit, mental health services) by revenue code, the beneficiary to whom the service was provided, and other information relevant to determining

whether the all-inclusive rate can be paid for the service. The claims contain very limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, or NP) who provided the service. (Starting in 2011, FQHC claims are required to include HCPCS codes that identify the specific service provided, in order for us to develop a statutorily required prospective payment system for FQHCs.) In the proposed rule, we indicated that we did not believe we had sufficient data in order to assign patients to ACOs on the basis of services furnished by FQHCs or RHCs. Instead, recognizing the important primary care role played by these entities, we proposed to provide an opportunity for an ACO to share in a greater percentage of any savings if FQHCs/RHCs are included as ACO participants."

b. Comment (pg.57):

- i. Many commenters disagreed with our interpretation of the statute's assignment provision (section 1899(c) of the Act) to require a patient to be assigned to an ACO based solely on that beneficiary's use of services furnished by specific categories of primary care physicians. These commenters encouraged CMS to explore other approaches that would allow FQHCs and/or RHCs to independently form ACOs and to take on a more active role in the ACO by allowing assignment of beneficiaries and establishment of benchmarks to be based upon services furnished by these entities.

MedPAC commented that it would be more straightforward to allow assignment of patients to RHCs and FQHCs and encourage their use directly rather than to introduce special provisions for the savings share and thresholds as the proposed rule does. They indicated that "these are primary care provider teams often associated with a physician and usually providing primary care services. Logically they should be allowed to participate in ACOs and patients should be assigned to them. In many rural areas, RHCs function as primary care physicians' offices and, although they are paid differently under Medicare, they are still fulfilling the same function". MedPAC suggested that "CMS posit that all claims in RHCs and FQHCs are for primary care services and use them for assignment as it would any other primary care claim."

Similarly, other commenters requested that CMS simply deem all FQHC services as primary care services. Other commenters believed it is more than reasonable to – and detrimental to the program's goals not to interpret 1899(c) of the Act to find that the "provided under"

language means not only services provided by the physician personally but also services provided by additional members of the health care team of an FQHC, with whom physicians supervise and collaborate. In short, they believed that the Secretary has the discretion to determine for purposes of patient assignment that patients who receive care from FQHCs can be treated as patients whose care is furnished by physicians since physician services are an integral part of the FQHC service definition, FQHC practice, and FQHC reimbursement.

Other commenters suggested that CMS could assign FQHC beneficiaries to ACOs in other ways. Specifically, a commenter indicated that the UB-04 billing form that FQHCs use to submit their claims contains sufficient information (for example, patient information, revenue codes, and "attending physician" information) to establish a reasonable process for assigning FQHC beneficiaries to ACOs. This commenter also noted that these health centers have a limited set of services that are considered "FQHC services" and that virtually all such services would be considered primary care services.

Another commenter indicated that all FQHCs and RHCs should have the capability to provide additional information about their services beyond the information available on their claims. The commenter stated that to be covered for a malpractice claim, a health care center must be able to demonstrate (through appropriate documentation) that the services at issue were within the center's scope of services, provided at a location that was in the scope of services, were delivered to an established patient of the health center, were documented in a permanent medical record and were properly billed. This commenter categorically stated that the necessary information is available, that it is electronic, and that it can be correlated with contemporaneous claims data.

Other commenters suggested that CMS consider other assignment approaches, such as the methodology it is using to attribute Medicare patients to FQHCs in the Adirondack Regional Medical Home Pilot, an all-payer medical home demonstration project in upstate New York.

Yet other commenters suggested that assignment could be made by an FQHC providing a list of patients for whom it considers itself accountable. CMS could then analyze the claims history for the identified patients and exclude those with a plurality of primary care services associated with a provider other than the FQHC.

Regarding RHCs, a number of commenters agreed that when a clinic submits the claim form, it is not required to identify the specific provider who rendered the service. They conceded that the RHC service could have been provided by a physician, a PA or an NP (and in some circumstances, a nurse midwife). These commenters suggested various ways to address this: (1) require RHCs that are part of an ACO to identify the rendering provider on their claim form using the NPI of the rendering provider, and provide any other information needed through various means (similar to how quality data are submitted; and/or (2) use a patient attestation method for attributing/assigning RHC patients to the ACO.

c. Response:

- i. We agree with the many comments that FQHCs and RHCs should be allowed to participate in ACOs and have their patients assigned to such ACOs, provided that patients can be assigned in a manner that is consistent with the statute.

We indicated in the *proposed rule* (emphasis added) that we would continue to assess the possibilities for collecting the requisite data from FQHCs and RHCs, and consider whether it would be possible for Medicare beneficiaries to be assigned to an ACO on the basis of services furnished by an FQHC or RHC, thereby allowing these entities to have their Medicare beneficiaries included in the ACO's assigned population.

As indicated previously, MedPAC and some other commenters suggested that CMS posit or deem that all claims in RHCs and FQHCs are for primary care services and use them for assignment as it would any other primary care claim. We have not accepted these comments because they do not address the specific requirement in section 1899(c) of the Act which requires assignment of beneficiaries to an ACO based "on their utilization of primary care services... by an ACO professional described in subsection (h)(1)(A)." As discussed previously, section 1899(h)(1)(A) of the Act establishes that for the purposes of beneficiary

assignment, an "ACO professional" is defined as a physician as defined in section 1861(r)(1) of the Act.

Likewise, we have not accepted other commenter suggestions that assignment could be made by an FQHC providing a list of patients for whom it considers itself accountable. Such an approach would also not be consistent with the statutory requirement that we develop an assignment process that is based on utilization of primary care services by an ACO professional, defined by the statute as a physician. We have also not adopted commenter suggestions that CMS should adopt the assignment processes that are being used in certain demonstration programs because these demonstration programs are not subject to the same statutory requirements that apply to this Shared Savings Program.

However, as explained later in this final rule, we are accepting suggestions from other commenters that, in combination, will enable us to adopt a policy in this final rule that will allow us to assign beneficiaries to ACOs on the basis of services furnished by FQHCs and/or RHCs. (As we have explained earlier in section II.B. (Eligible Entities) of this final rule, this will also allow FQHCs and RHCs to form an ACO independently, without the participation of other types of eligible entities. It will also allow the beneficiaries who receive primary care services from FQHCs and RHCs to count in the assignment process for any ACO that includes an FQHC and/or RHC as a provider/supplier.) As discussed previously, the assignment methodology we are adopting in this final rule is to assign beneficiaries to an ACO using a step-wise approach for assignment. Under this step-wise method, beneficiaries are first assigned to an ACO if they have received a primary care service from a primary care physician (defined as a physician with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine) who is a provider/supplier in the ACO, and also receive a plurality of their primary care services (which we identify by a select set of E&M services defined as "primary care services" in section 5501 of the Affordable Care Act, and the G-codes associated with the annual wellness visit and the Welcome to Medicare visit) from primary care physicians who are providers/suppliers in the same ACO. Those beneficiaries who have not received any primary care services from a primary care physician can be assigned

to an ACO in the second step if they have received a primary care service from a specialist physician (that is, a physician that does not meet the definition of a primary care physician) who is a provider/supplier in the ACO, and also receive a plurality of their primary care services from physicians and other ACO professionals who are ACO providers/suppliers in the ACO. Thus, under the final rule, in order to be able to align beneficiaries with the entities that wish to participate in the Shared Savings Program, in general we require data that identify all of the following:

- Services rendered (that is, primary care HCPCS codes).
- Type of practitioner providing the service (that is, a physician, NP, PA, or CNS).
- Physician specialty.

For services billed under the physician fee schedule, these data items are available on the claims submitted for payment. In contrast, as discussed in the proposed rule, FQHCs and RHCs submit claims for each encounter with a beneficiary and receive payment based on an interim all inclusive rate. These FQHC/RHC claims distinguish general classes of services (for example, clinic visit, home visit, mental health services) by revenue code, the beneficiary to whom the service was provided, and other information relevant to determining whether the all-inclusive rate can be paid for the service. The claims contain very limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, NP), who provided the service.

1. Identification of Primary Care Services Rendered in FQHCs and RHCs

a. Pg. 59—

- a. Starting in 2011, FQHC claims are required to include HCPCS codes that identify the specific service provided, in order for us to develop a statutorily required prospective payment system for FQHCs. In addition, FQHCs were required to submit a HCPCS code to receive payment for the Welcome to Medicare visit (G0402) beginning in 2009. Therefore, we can identify primary care services for FQHCs that are participating in an ACO by using their HCPCS codes for services furnished on or after January 1, 2011, and by using HCPCS code G0402 furnished on or after January 1, 2009. RHCs are generally not required to report HCPCS codes, except that: (1) for services furnished on or after January 1, 2009, RHCs may submit HCPCS code G0402 to receive payment for the Welcome to Medicare visit, and (2) for

services furnished on or after January 1, 2011, RHCs may submit HCPCS codes to receive payment for the annual wellness visits (G0438 and G0439). However, for purposes of assigning patients and calculating the benchmark, we will also need to identify other primary care services that were furnished by FQHCs and RHCs. In order to identify primary care services rendered in FQHCs and RHCs that are primary care services, and that are not required to be reported by HCPCS codes, we are adopting the commenters' suggestions to use the *revenue center codes* (emphasis added). We have reviewed these revenue center codes and agree that for purposes of the Shared Savings Program, the revenue center codes can be used as a substitute for the primary care HCPCS codes which RHCs do not report, and which FQHCs were not required to report prior to January 1, 2011. Specifically, we believe that it is possible to employ these revenue codes to identify primary care services by constructing an appropriate cross-walk between the revenue center codes and the HCPCS primary care codes based on their definitions.

In order to establish such a cross-walk, we compared the HCPCS codes that are considered as being primary care services for purposes of the Shared Savings Program with the revenue center codes that are reported on FQHC/RHC claims. As discussed previously, the primary care HCPCS codes used for assignment are as follows:

- 99201 through 99215; (office/outpatient visits)
- 99304 through 99340; (nursing facility visits/domiciliary home visits)
- 99341 through 99350; (home visits)
- Welcome to Medicare visit (G0402)
- Annual wellness visits (G0438 and G0439)

FQHCs and RHCs report services on their claims using the following revenue center codes:

- 0521 Clinic visit by member to RHC/FQHC
- 0522 Home visit by RHC/FQHC practitioner
- 0524 Visit by RHC/FQHC practitioner to a member, in a covered Part A stay at the SNF
- 0525 Visit by RHC/FQHC practitioner to a member in an SNF (not in a covered Part A stay) or NF or ICF MR or other residential facility

We are able to cross walk the "primary care" HCPCS codes to comparable revenue center codes based on their code definitions. For example, HCPCS codes 99201 through 99215 (office/outpatient visits) will be cross-walked to revenue center code 0521. Because the focus of FQHCs and RHCs is on primary care, we believe these revenue center codes, when reported by FQHCs/RHCs, would represent primary care services and not more specialized care. This crosswalk will allow us to use the available revenue center codes as part of the beneficiary assignment process for FQHC/RHC services in place of the unavailable HCPCS codes which will be used more generally. We will establish and update this crosswalk through contractor instructions. For FQHCs, we will use the HCPCS codes which are included on their claims starting on January 1, 2011.

2. Identification of the Type of Practitioner Providing the Service in an FQHC/RHC

d. Pg. 59—

- i. Secondly, in order to be able to align beneficiaries with the entities that wish to participate in the Shared Savings Program, we also generally require data that identify the type of practitioner providing the service (that is, a physician, NP, PA, or CNS). This is because, as discussed previously, section 1899(c) of the Act requires that assignment must be based upon services furnished by physicians. As previously noted, FQHC/RHC claims contain limited information as to the type of practitioner providing a service because this information is not necessary to determine payment rates for services in FQHCs and RHCs.

Based upon our review of the many helpful comments we received on these issues, we now agree that we can develop a process that will allow FQHCs and RHCs to fully participate in the Shared Savings Program. We can do this by using the limited provider NPI information on the FQHC/RHC claims in combination with a supplementary attestation requirement. This would be consistent with comments we received encouraging us to identify the provider that furnished services in FQHCs/RHCs by using the NPI of the attending provider, supplemented by additional information that the FQHCs/RHCs could separately submit.

More specifically, from the FQHC/RHC claims, we will use the Attending Provider NPI field data which is defined as being: "the individual who has overall responsibility for the patient's medical care and

treatment reported in this claim/ encounter." Although the attending provider NPI is used to report the provider who is responsible for overall care, it does not identify whether this provider furnished the patient care for the beneficiary. Therefore, to meet the requirement of section 1899(c) of the Act which requires that assignment must be based upon services furnished by physicians, we will supplement these limited claims data with an attestation that would be part of the application process for ACOs that include FQHCs/RHCs. We will require ACOs that include FQHCs/RHCs to provide to us, through an attestation, a list of their physician NPIs that provide direct patient primary care services, that is, the physicians that actually furnish primary care services in the FQHC or RHC. Other physician NPIs for FQHCs/RHCs will be excluded from the assignment process, such as those for physicians whose focus is on a management or administrative role. The attestation must be submitted as part of the application for ACOs that include FQHCs/RHCs. Such ACOs will also be required to notify us of any additions or deletions to the list as part of the update process discussed in section II.C.4. of this final rule. The attestation by the ACO will better enable us to determine which beneficiaries actually received primary care services from an FQHC/RHC physician.

We will then use the combination of the ACO's TINs (or other unique identifiers, where appropriate) and these NPIs provided to us through the attestation process to identify and assign beneficiaries to ACOs that include FQHCs/RHCs using the step-wise assignment methodology as previously explained.

In this way, we would then be able to assign beneficiaries to ACOs on the basis of services furnished in FQHCs and RHCs in a manner consistent with how we will more generally assign primary care services performed by physicians as previously described. We believe this approach meets the statutory requirement in section 1899(c) of the Act that assignment be based on the utilization of primary care services "provided" by an ACO professional described as a physician in section 1899(h)(1)(A) of the Act.

3. Identification of the Physician Specialty for Services in FQHCs and RHCs

a. Pg.60—

- i. "As previously explained, the third type of information we generally need under the stepwise assignment process discussed previously to assign beneficiaries with

the entities that wish to participate in the Shared Savings Program is data that identify physician specialty. However, we agree with commenters who pointed out that the Medicare FQHC health benefit was established in 1991 to enhance the provision of primary care services in underserved urban and rural communities. Commenters pointed out that virtually all services provided under the Medicare FQHC benefit are primary care services. We also agree with commenters that RHCs predominantly provide primary care services to their populations. Therefore, when a physician provides a service in an FQHC or an RHC, we believe the physician is functioning as a primary care physician comparable to those physicians that define themselves with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine. As a result, we do not believe it is necessary to obtain more detailed specialty information (either through the claims NPI reporting or as part of the attestation process) for the physicians that furnish services in FQHCs and RHCs. Longer term, we will consider establishing definitions for data fields on the claims submitted by FQHCs and RHCs, such as for attending NPI or other NPI fields, which could be used to identify the type of practitioner providing the service. This may enable us to eliminate the attestation which will part of the application process for ACOs that include FQHCs/RHCs.”

b. Pg. 60—

i. Final Decision:

1. In §425.404, we are modifying the policy that we proposed in response to comments to establish a beneficiary assignment process that will allow primary care services furnished in FQHCs and RHCs to be considered in the assignment process for any ACO that includes an FQHC and/or RHC. (These changes to the assignment process will also allow FQHCs and RHCs to form ACOs independently, without the participation of other types of eligible entities.) Operationally we will assign beneficiaries to ACOs that include FQHCs/RHCs in a manner consistent with how we will assign beneficiaries to other ACOs based on primary care services performed by physicians as previously described.

We will require that an ACO that include FQHCs and/or RHCs to provide us, through an

attestation, with a list of the physician NPIs that provide direct patient primary care services in an FQHC or RHC. This attestation will be part of the application process for all ACOs that include FQHCs and/or RHCs as ACO participants. We will then use the combination of the ACO's TINs (or other unique identifiers, where appropriate) and these NPIs provided to us through the attestation process to identify beneficiaries who receive a primary care service in an FQHC or RHC from a physician, and to assign those beneficiaries to the ACO if they received the plurality of their primary care services, as determined based on allowed charges for the HCPCS codes and revenue center codes listed in the definition of primary care services, from ACO providers/suppliers.

- (b) Prospective vs. Retrospective Beneficiary Assignment to Calculate Eligibility for Shared Savings
 - (c) Majority vs. Plurality Rule for Beneficiary Assignment
 - i. Pg. 66—
 - 1. “We considered the nursing association's recommendation that we use RVUs rather than charges. Use of RVUs in place of allowed charges would retain many of the benefits of employing charges (for example, reduced need for a tie-breaker) while correcting for the effects of some factors in allowed charges that arguably should not affect assignment (for example, the application of GPCI values to the physician fee schedule payments). However, it is unclear whether it would be possible and how to include FQHC/RHC services in the assignment process if we were to base assignment on RVUs for specific HCPCS codes rather than allowed charges since, as discussed previously, we have not required that RHCs include HCPCS codes on their claims, and FQHCs have been required to report HCPCS codes only since January 1, 2011. Moreover, the use of allowed charges has resulted in satisfactory assignment results under the PGP demonstration. Therefore, we will retain this proven method of using allowed charges. We note that for purposes of the Shared Savings Program, allowed charges for FQHC/RHC services will be based on the interim payments, since any subsequent adjustments following settlement of their cost reports would not be available in time for assignment purposes. We will continue to consider the alternative of using RVUs as we gain experience under the Shared Savings Program.”
- F. Quality and Other Reporting Requirements
- (a) Introduction
 - (b) Measures to Assess the Quality of Care Furnished by an ACO
 - i. General
 - ii. Considerations in Selecting Measures
 - iii. Quality Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings

- (c) Requirements for Quality Measures Data Submission by ACOs
 - i. General
 - ii. GPRO Web Interface
 - iii. Certified EHR Technology
 - (d) Quality Performance Standards
 - i. General
 - ii. Performance Scoring
 - 1. Measure Domains and Measures Included in the Domains
 - 2. Methodology for Calculating a Performance Score for each Measure within a Domain
 - 3. Methodology for Calculating a Performance Score for each Domain
 - 4. The Quality Performance Standard Level
 - (e) Incorporation of Other Reporting Requirements Related to the PQRS and Electronic Health Records Technology Under Section 1848 of the Act
 - (f) Aligning ACO Quality Measures with other Laws and Regulations
- G. Shared Savings and Losses**
- (a) Authority For and Selection of Shared Savings/Losses Model
 - (b) Shared Savings and Losses Determination**
 - i. Overview of Shared Savings and Losses Determination
 - 1. Table 5. Shared Savings Program Overview, pg. 108
 - ii. **Establishing the Benchmark**
 - 1. Pg.111—
 - a. Comment:
 - i. Some commenters expressed concerns that the proposed assignment methodology would exclude some of Medicare FFS beneficiaries' costs from the ACOs' benchmark and thereby disadvantage certain providers and the populations they serve. One commenter expressed concern that assignment of beneficiaries based on primary care services rendered by physicians with primary care specializations could exclude beneficiaries with disabilities and those needing medical rehabilitation services which rely on care by specialists. This commenter favored a step-wise approach to assignment in which beneficiaries are assigned first on the basis of care by primary care physicians followed by a second "sweep" of assignment based on specialists would help ensure that these beneficiaries' costs would be counted.
- Many commenters expressed concern that Medicare FFS beneficiaries treated by FQHCs and RHCs would not be assigned to an ACO or have their costs reflected in an ACO's benchmark under the proposed assignment and benchmarking methodologies. A commenter stated: "the statute does not appear to require the specific methodology that has been proposed by CMS to determine the benchmark, and certainly does not require a single uniform methodology for all primary

care providers. Under the wording of this provision, CMS appears to have the flexibility to apply a methodology to 'estimate a benchmark' specifically for FQHCs." This commenter and some others suggested various ways to compute the benchmark for FQHCs absent 3 years of benchmark data:

- (1) CMS could use the data and claims it will have from FQHCs for 2011 and assume similar and comparable data and claims for the two years prior with some adjustments as appropriate relating to inflation, etc.;
- (2) CMS could assign beneficiaries utilizing the 2011 data and recover billing data from the prior 2 years with use of health center office visit revenue codes to determine the 3 year benchmark;
- (3) CMS could further investigate the methods that are being used to create benchmarks for demonstrations, such as the methods that were considered for the Pioneer ACO Model Request for Applications;
- (4) a number of FQHCs have been recording HCPCS codes for all of their patients and have this information stored in their practice management systems, dating back prior to the requirement to report to CMS starting on January 1, 2011. Those centers that are able to provide CMS with the data it requires to establish the 3-year benchmark should be allowed to do so; and
- (5) CMS could allow each health center to voluntarily choose whether it would provide any specific requested information. Further, commenters suggested that section 1899(i), if not section 1899(d) of the Act, provides CMS flexibility to estimate a benchmark specifically for FQHCs.

One commenter advocated allowing those RHCs and FQHCs who wish to participate in ACOs the opportunity to provide the requisite data so that they may fully participate in the program. However, another commenter appreciated the Department's reluctance to impose reporting requirements in this rule for both FQHCs and RHCs and other entities without either a statutory requirement or clear support for such a regulatory change from the community at large.

b. Response:

- i. In the section II.E. of this final rule, we establish a step-wise approach to beneficiary assignment that simultaneously maintains the primary care-centric approach to assignment and recognizes the necessary and appropriate role of specialists in providing primary care services. Through this assignment methodology we will be able to attribute to ACOs expenditures for beneficiaries who predominantly rely on care from specialists.

Based on the assignment process that we are adopting in this final rule (see section II.E. of this final rule), we are able to compute a benchmark for ACOs that include FQHCs and RHCs, in the same manner as we would for any other ACO. For ACOs that consist of FQHCs and/or RHCs (either independently or in partnership with other eligible entities), we will establish such ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 years prior to the start of an ACO's agreement period.

2. Pg. 115—

a. Final Decision:

- i. We are making final our proposed methodology under §425.602 for establishing an ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 years prior to the start of an ACO's agreement period using the ACO participants' TINs identified at the start of the agreement period. We will calculate benchmark expenditures by categorizing beneficiaries in the following cost categories, in the order in which they appear: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. This benchmarking methodology will apply to all ACOs, including those consisting of FQHCs and/or RHCs (either independently or in partnership with other eligible entities). We are also making final our proposals to truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark and performance year; weight the most recent year of the benchmark, BY3, at 60 percent, BY2 at 30 percent and BY1 at 10 percent; and reset the benchmark at the start of each agreement period. Further, as specified in section II.C. of this final rule, we will use a 3-month run-

out of claims data and a completion factor to calculate benchmark expenditures.

iii. **Adjusting the Benchmark and Actual Expenditures**

1. **Adjusting Benchmark and Performance Year Average Per Capita Expenditures for Beneficiary Characteristics**

a. Pg.115—

i. Comment:

(1) Commenters typically expressed support for adjusting benchmark expenditures based on the CMS-HCC model; although, some commenters raised technical concerns about the accuracy of HCC risk adjustment. For example, one commenter suggested that CMS needs to improve the accuracy of the HCC risk adjustment model. Other commenters expressed concern that the proposed risk adjuster lacks the capacity to account for socioeconomic status. Another commenter suggested the need for physician input into risk adjustment factors, for example, to be able to identify patients with multiple chronic conditions. Commenters also made a number of recommendations about the proposed risk adjustment methodology, including the need to define other "beneficiary characteristics" that might be used to risk adjust, modify the HCC model to exclude zero spend beneficiaries (while these beneficiaries are included in the HCC model as used in MA, it could disadvantage ACOs whose assigned populations would by definition exclude zero spend beneficiaries), and risk adjust for including safety net providers, such as RHCs, FQHCs and Method I CAHs.

While commenters supported use of the CMS-HCC model for adjusting benchmark expenditures, they also expressed concern that benchmark and performance expenditures would not also be annually updated for risk using this same mechanism. Numerous commenters expressed concern that a cap on risk adjustment in cases where care furnished to a patient is documented and appropriate would diminish the level of shared savings, and serve as a disincentive to manage patients with complex health care needs who can most benefit from better care coordination. MedPAC, among other commenters, expressed concern

that this approach would create incentives for ACO providers to encourage existing patients who are costly to seek care elsewhere and to avoid taking on new patients that could be costly. Another commenter suggested that accurate risk adjustment is especially important for providers, such as academic medical centers, that disproportionately treat the sickest and most complex patients.

ii. Response:

- (1) We continue to believe that risk adjusting benchmark expenditures based on the CMS-HCC model accounts for variation in case complexity and severity and therefore more accurately predicts health care expenditures compared to a demographic-only model or other alternatives suggested by commenters.

We did not intend for our proposed risk adjustment methodology to discourage ACOs from accepting responsibility for beneficiaries that might present higher than average risk, but commenters have persuaded us of the need to better account for risk associated with changes in the ACO's beneficiary population, for instance in terms of acuity and beneficiary movement, during the agreement period. However, we remain concerned that liberally adjusting for changes in risk scores for beneficiaries assigned to the ACO for the entire agreement period could create an incentive for ACOs to use coding practices intended to optimize their risk scores to achieve shared savings. Thus, we are modifying our initial proposal so that ACO benchmarks will better reflect the risk associated with their assigned beneficiaries. We will adjust expenditures to account for changes in severity and case mix for beneficiaries newly assigned in the current performance year ("newly assigned"), and those who are continuously assigned to the ACO year-to-year ("continuously assigned"). A newly assigned beneficiary is a beneficiary assigned in the current performance year who was neither assigned nor received a primary care service from any of the ACO's participants during the most recent prior calendar year. A continuously assigned beneficiary is a beneficiary assigned to the ACO in the current

performance year who was either assigned to or received a primary care service from any of the ACO's participant during the most recent prior calendar year.

First, for newly assigned beneficiaries we will annually update an ACO's CMS-HCC prospective risk scores to adjust for changes in severity and case mix in this population.. Second, each year, we will recalculate the ACO's CMS-HCC prospective risk scores for continuously assigned beneficiaries. If the continuously assigned population shows a decline in its CMS-HCC prospective risk scores, we will adjust for health status changes for this population using this lower risk score. If the continuously assigned population shows no decline, this population will be adjusted using demographic factors only. We believe that this approach to risk adjustment strikes a fair balance between accounting for changes in the health status of an ACO's population while not incenting changes in coding practices for care provided to beneficiaries who remain continuously assigned to the ACO, nor encouraging ACOs to avoid high risk beneficiaries. This methodology implicitly adjusts for beneficiaries who are assigned in the prior year but not the current performance year (patients which leave the ACO), as these beneficiaries will be excluded from the continuously assigned population. We will monitor HCC scores for beneficiaries which are assigned in the prior year who are not assigned in the current performance year, to determine if there is trend in changes in health status for this population. Based on our findings, in future rule making, we may make a more explicit adjustment for beneficiaries assigned to the ACO in the prior year who are not assigned in the current performance year. Further, we agree with the commenter's suggestion on the need for benchmark expenditures to be adjusted relative to the risk profile of the performance year assigned beneficiaries. Therefore the ACO's updated benchmark will be restated in the appropriate performance year risk to ensure fairness recognizing changes in the level of risk among the ACO's assigned beneficiaries.

Additionally, we agree with commenters' suggestions about the need to take account of variations in risk scores across categories of beneficiaries to reflect differences in disease severity across subpopulations. Therefore, in adjusting for health status and demographic changes, we will make adjustments for separate categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries as described in section II.G.2.b. of this final rule.

Also, we agree with the comment recommending that we use the audit process to address coding inaccuracies. Therefore, to assure the appropriateness of ACO coding practices and our methodology for risk adjusting, we are finalizing our proposal to retain the option to audit ACOs, especially those ACOs with high levels or risk score growth relative to their peers, and to adjust the risk scores used for purposes of establishing the 3-year benchmark accordingly. In addition, as we stated in the proposed rule, we intend to monitor and evaluate the issue of more complete and accurate coding and, as we gain experience with the program, we may consider making further revisions through future rulemaking.

iii. Pg. 115—

(1) Final Decision:

- (a) We are making final our proposal under §425.602 to risk adjust an ACO's historical benchmark expenditures using the CMS-HCC model. We are modifying our proposal under §425.604 and §425.606 to make additional risk adjustments to performance year assigned beneficiaries instead of capping growth in risk adjustments during the term of the agreement at zero percent. For newly assigned beneficiaries, we will annually update an ACO's CMS-HCC prospective risk scores, to take into

account changes in severity and case mix for this population. We will use demographic factors to adjust for severity and case mix for the continuously assigned population relative to the historical benchmark. However, if the continuously assigned population shows a decline in its CMS-HCC prospective risk scores, we will lower the risk score for this population. An ACO's updated benchmark will be restated in the appropriate performance year risk relative to the risk profile of the performance year assigned beneficiaries. Further, we will make adjustments for each of the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. We are also making final our proposal to monitor and evaluate the issue of more complete and accurate coding for future rule making and to use an audit process to assure the appropriateness of ACO coding practices and to adjust ACO risk scores. We will also monitor HCC scores for beneficiaries assigned in the prior year that are not assigned in the current performance year, and may make a more explicit adjustment for this population in future rule making.

2. Technical Adjustments to the Benchmark and Performance Year Expenditures

i. Pg. 118—

(1) Commenters offered differing opinions on the treatment of Part D costs. One commenter urged us to include Part D costs, suggesting this could maximize ACO's opportunity for success because of the opportunities for cost savings and improved quality associated with drug benefits. Several commenters expressed concern that in some clinical areas (such as

cancer care and cardiac ablation for atrial fibrillation) ACOs may have an incentive to move patients from appropriate treatments or procedures reimbursed through Parts A or B to Part D therapies which are excluded from the shared savings calculation. Commenters suggested safeguards may be needed for certain clinical areas. One commenter outlined a process for CMS to exclude the costs of certain Part A and B drugs/biologics or medical procedures from the shared savings calculation, but to account for use of Part D drugs as an alternative to procedures paid under Parts A and B. One commenter identified a seemingly countervailing effect resulting from the proposed additional incentive for ACOs to include FQHCs and RHCs, which may be entities eligible for the 340B Drug Pricing Program. The commenter explained that the incentive for including FQHCs and RHCs may prompt ACOs to shift treatment protocols and patients from an inpatient setting to an outpatient setting in order to have access to 340B pricing discounts.

ii. Pg.119—

(1) Response:

- (a) We disagree with commenters' suggestions that we adjust ACO benchmark and performance year expenditures to account for various differences in cost and payment among providers and suppliers. We believe that making such extensive adjustments, or allowing for benchmark adjustments on a case-by-case basis, would create an inaccurate and inconsistent picture of ACO spending and may limit innovations in ACOs' redesign of care processes or cost reduction strategies. Similarly, we do not believe it is appropriate to consider Part D spending in our calculation of benchmark and performance year expenditures. The statute is clear in requiring that we take into account only payments made from the Medicare Trust Fund for Parts A and B services, for assigned

Medicare FFS beneficiaries, when computing average per capita Medicare expenditures under the ACO. Although commenters pointed out important concerns about the potential for inappropriate cost shifting to Part D therapies and unintended shifts in the site of care for beneficiaries with high cost therapies, we believe that the program's quality measurement and program monitoring activities will help us to prevent and detect any avoidance of appropriately treating at-risk beneficiaries. Furthermore to the extent that these lower cost therapies are not the most appropriate and lead to subsequent visits or hospitalizations under Parts A and B, then any costs associated with not choosing the most appropriate treatment for the patient would be reflected in the ACO's per capita expenditures.

As we indicated in the discussion of establishing and updating the benchmark and risk adjusting ACO expenditures, we agree with commenters' suggestions for taking a categorical approach to calculating ACO expenditures. Consistent with our policies stated elsewhere in section II.G. of this final rule, we are adopting a policy whereby performance year expenditures will be calculated for cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries, as described in section II.G.2.b. of this final rule.

(a) We are finalizing our proposal under §425.602, §425.604, and §425.606 to take into account payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, including individual beneficiary identifiable payments made under a demonstration, pilot, or time limited program, when computing average per capita Medicare expenditures under the ACO. Further, we will calculate ACO expenditures for each of the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. Lastly, as specified in section II.C. of this final rule, we will use a 3-month run-out of claims data and a completion factor to calculate performance year expenditures.

a. Impact of IME and DSH

i. Pg. 119—

(1) Several commenters suggested alternatives to excluding IME and DSH payments. One commenter recommended that CMS exclude teaching and DSH payments from the benchmark and savings calculations except for ACOs that include at least one major teaching hospital and one hospital that receives high DSH payments, or a single hospital that satisfies both criteria. This commenter further recommended that we account for other reforms under the Affordable Care Act that relate to hospitals that receive high DSH payments. Other commenters suggested that, in the longer term, CMS use risk adjustment methodologies or additional metrics to assess savings and quality improvements specific to hospitals receiving IME and DSH payments. In the event that CMS decides to favor including IME and DSH costs in the calculation of the benchmark and performance year expenditures, one commenter suggested that ACOs that include hospitals receiving IME and DSH adjustments should have an

opportunity to receive additional shared savings payments, as we proposed for ACOs including FQHCs and RHCs as participants.

ii. Response:

(2) We are modifying our proposal in order to adopt an alternate payment methodology that excludes IME and DSH payments from ACO benchmark and performance year expenditures, as authorized by section 1899(i) of the Act. We believe that care should be provided in the most appropriate setting whether it be a physician office, outpatient clinic, community hospital or teaching hospital. We further recognize the role of teaching hospitals in providing high quality, medically necessary care to Medicare beneficiaries. Commenters have persuaded us that including IME and DSH payments in determining ACO cost performance could create incentives for ACOs to avoid appropriate referrals to teaching hospitals in an effort to demonstrate savings. We remain committed to the societal benefits supported through IME and DSH payments, such as educating the nation's medical workforce, advancing the state of medical science, and ensuring access to care by vulnerable populations.

To exercise our authority under section 1899(i) of the Act, we must demonstrate that this policy (1) "...does not result in spending more for such ACO for such beneficiaries than would otherwise be expended ... if the model were not implemented" and (2) "...will improve the quality and efficiency of items and services furnished under this title." First, we believe that the intent of the program is to reward the prevention of unnecessary services and redundancies in care. By removing IME and DSH payments from benchmark and performance year expenditures we can reward more accurately actual decreases in unnecessary utilization of health care services. Second, excluding IME and DSH payments from determinations of ACO financial performance could help ensure participation of hospitals receiving IME and DSH payments in ACOs, and their engagement in the accountable care model. We believe that removing the

disincentive for ACOs to refer patients to teaching hospitals will help ensure beneficiaries continue to be referred to the most appropriate place of service for their care. In combination, these factors could result in Medicare beneficiaries receiving higher quality, better coordinated and more cost-efficient care in these settings. For these reasons, we do not expect that excluding IME and DSH payments from the determinations of ACO financial performance will result in greater payments to ACOs than would otherwise have been made if these payments were included. However, we intend to monitor this issue and will revisit it if we determine that excluding these payments has resulted in additional program expenditures.

Compared to other alternatives suggested by commenters, we believe that excluding IME and DSH payments from the determination of an ACO's eligibility for shared savings is presently the most effective approach to ensure participation by hospitals that receive IME and DSH payments. We plan to monitor this issue to help us determine whether these adjustments should be maintained and may revisit it in future rulemaking as we gain more experience with the Shared Savings Program.

DGME payments are made outside of the payments of Parts A and B claims. By virtue of this fact, under the methodology in either our proposed or final rules, DGME payments would not be included in an ACO's benchmark and performance year expenditures. Therefore, we do not need to make adjustments to individual claims for these payments.

- iii. Final Decision (Pg. 121):
 - (1) We are modifying our proposal under §425.602, §425.604, and §425.606 so as to exclude IME and DSH payments from ACO benchmark and performance year expenditures.
 - b. Geographic and Other Payment Adjustments
- 3. Trending Forward Prior Year's Experience to Obtain an Initial Benchmark
 - a. Growth Rate as a Benchmark Trending Factor
 - b. National Growth Rate as a Benchmark Trending Factor
- iv. Updating the Benchmark During the Agreement Period
- v. Determining Shared Savings

1. Minimum Savings Rate
 - a. One-Sided Model
 - b. Two-Sided Model
2. Quality Performance Sharing Rate
 - a. Pg. 128—
 - i. As discussed in section II.F. of the proposed rule (76 FR 19620 and 19621), we proposed that ACOs choosing to participate in the one-sided model could share in savings if they exceed a MSR. For those ACOs whose savings exceed the MSR in the one-sided model, we proposed a savings sharing rate of up to 50 percent of total savings, above a 2 percent savings threshold, with a payment cap of 7.5 percent of an ACO's benchmark. We also proposed an additional increase of up to 2.5 percentage points for including FQHCs and/or RHCs as ACO participants, as discussed in section II.F of the proposed rule. Thus, under our proposal, an ACO participating in the one-sided model could realize a maximum shared savings rate of 52.5 percent. Under the two-sided model, we proposed that an ACO that realized savings against its benchmark could qualify for a final sharing rate of up to 65 percent if it was eligible for the maximum adjustments. The 65 percent final sharing rate was comprised of a savings rate of up to 60 percent for quality performance, plus 5 percentage points for including FQHCs and/or RHCs as ACO participants.
 - ii. Final Decision:
 - (1) We are finalizing our proposal under §425.604 and §425.606 that ACOs under the one-sided model can earn up to 50 percent of total savings based on quality performance and ACOs under the two-sided model can earn up to 60 percent of total savings based on quality performance.
3. Additional Shared Savings Payments
 - a. Pg. 129—
 - i. In the *proposed rule* (emphasis added), we recognized the important role that FQHCs and RHCs play as safety net providers and in improving access to primary care for Medicare and Medicaid beneficiaries. Under the proposed rule, FQHCs and RHCs were unable to participate independently in this program by forming their own ACOs. As a result, we believed that providing incentives to ACOs that include FQHCs and/or RHCs as ACO participants was in the interest of the Shared Savings Program as including these types of entities could promote care coordination and the delivery of efficient, high-quality health care. We proposed that

ACOs could be eligible to receive higher sharing rates, based on a sliding scale, for including FQHCs and RHCs as ACO participants. Under the one-sided model we proposed up to a 2.5 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. Under the two-sided model we proposed up to a 5.0 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. We proposed establishing a sliding scale payment, outlined in the Table 7, based on the number of Medicare FFS beneficiaries with one or more visit at an ACO participant FQHC or RHC during the performance year. We also proposed that ACOs specifically identify their FQHC/RHC participant TINs in their initial and annual reporting of ACO participant TINs, and disclose other provider identifiers as requested to assure proper identification of these organizations for the purpose of awarding the payment preference. Further, we proposed to define FQHCs and RHCs, for the purpose of awarding this payment preference, as these terms are defined in 42 CFR 405.2401(b) of our regulations. We sought comment on alternate options for establishing a payment preference with a sliding scale for ACOs that include FQHCs or RHCs as ACO participants, including suggestions for the appropriate method to measure FQHC/RHC involvement and the appropriate level of incentives.

b. Pg. 130—

i. Comment:

(1) While many commenters supported the concept of the proposed incentive, others found the incentive inadequate to encourage meaningful FQHC and RHC participation in ACOs. One commenter envisioned that FQHCs and RHCs would be "latched on" to the ACO in an attempt to achieve a greater share of savings. Commenters were also critical of the incentive's focus on care provided to ACO beneficiaries at FQHCs and RHCs when we proposed to assign beneficiaries to ACOs based on their use of other primary care providers. As one commenter explained, the incentive assumes an unlikely scenario where non-FQHC providers will refer a patient to an FQHC for care. Others considered the incentive, based on a one visit rule, ripe for gaming: ACOs might

schedule their beneficiaries to have one visit at an FQHC or RHC to obtain the incentive, which could result in "primary care discontinuities." One commenter questioned whether the incentive was in line with the letter and spirit of the Affordable Care Act.

Commenters provided various suggestions for how to revise the structure of the incentive, such as the following:

- Increasing the amount of the incentive, for instance to a 10 percent bonus under both models.
- Including Method I CAHs in the incentive payment structure.
- Providing additional payments for including multiple FQHCs.

Commenters also offered alternatives. For instance, one commenter recommended that CMS create incentives for FQHCs and RHCs to participate in ACOs, rather than to reward ACOs for including these organizations.

ii. Response:

(1) In this *final rule* (emphasis added), we are eliminating our proposal to provide an incentive for ACOs to include FQHCs and/or RHCs as participants. We proposed this incentive to address our inability to determine a statutorily satisfactory way of assigning beneficiaries to an ACO on the basis of services furnished by these entities. However, given that we have determined an appropriate methodology for assigning beneficiaries to ACOs on the basis of services furnished by FQHCs and RHCs, therefore allowing FQHCs and RHCs to more fully participate in the program, we believe the incentive is unnecessary and has the potential to cause unintended consequences as articulated by commenters.

iii. Final Decision:

(1) The final rule will not contain a sliding scale-based increase in the shared savings rate, up to 2.5 additional percentage points under the one-sided model and up to 5 additional percentage points under the two-sided model,

for ACOs that include an FQHC or RHC as an ACO participant.

In the proposed rule we also discussed our interest in encouraging providers who serve a large portion of dual eligible beneficiaries to participate in the Medicare Shared Savings Program. We explained that Medicare beneficiaries who are also eligible for Medicaid—that is, are "dually eligible" for these programs—are among the most vulnerable of Medicare beneficiaries. Dual eligible beneficiaries tend to have higher medical costs than other FFS beneficiaries, and, as a result, are expected to benefit even more than other beneficiaries from improvements in the quality and efficiency of their care resulting from the greater care coordination offered by an ACO.

We also stated in the proposed rule that section 1899(j) of the Act provides that "[t]he Secretary may give preference to ACOs who are participating in similar arrangements with other payers." The statute prescribes neither the kind of preference that the Secretary should provide to such ACOs nor what other types of arrangements should be considered "similar" for purposes of such a preference. We stated our belief that the more patients an ACO sees for which it is eligible to receive performance-based incentives, such as shared savings, the more likely it is that the ACO will adopt substantial behavior changes conducive to improved quality and cost savings.

We sought comment on methods to provide preference to ACOs that serve a large **dual-eligible** population or that enter into and maintain similar arrangements with other payers. Specifically, we sought suggestions to encourage accountability for dual-eligible beneficiaries and participation in similar arrangements with other types of payers.

iv. Comment:

1. Comments described the health needs of dual eligible beneficiaries and the potential challenges of managing this population. Some commenters saw the need for CMS to ensure participation by providers that care for dual

eligible beneficiaries as part of the larger issue of the need for CMS to support safety net providers and ACOs more generally. Many commenters favored policies that financially reward ACOs whose assigned populations include a larger proportion of dual eligible beneficiaries. Commenters offered a variety of suggestions on how to structure this payment preference, including the following:

- Higher shared savings rates for ACOs that serve a high percentage of dual eligible beneficiaries, similar to the increased sharing rate proposed for ACOs which included FQHCs and RHCs. Commenters' suggestions for higher sharing rates typically ranged from 2.5 percentage points to 20 percent under the one-sided model and 5 percentage points to 25 percent under the two-sided model.
- Additional incentives coupled with alternative payment models for an ACO whose patient mix is comprised mostly of Medicaid patients, and which care for large percentages for dual eligible beneficiaries.
- Exempt ACOs that treat a larger proportion of dual eligible beneficiaries from the 2 percent net sharing rate.
- Revised benchmarking methodology (for example, a "separate savings target") for ACOs that serve a large population of dual eligible beneficiaries.

Several commenters raised concerns about creating incentives for ACOs to care for dual eligible beneficiaries. One commenter noted that the proposed assignment methodology, under which FQHCs would not be the basis for assignment, would exclude many dual eligible beneficiaries from ACOs. By virtue of this policy, the commenter perceived proposed monitoring for avoidance of at-risk beneficiaries and the proposed rule's emphasis on providing incentives for ACOs to include dual eligible beneficiaries to be flawed. Another commenter, pointing to the unique health care needs of dual eligible beneficiaries, cautioned that ACOs should have the capacity and ability to serve

these individuals; suggesting that CMS condition any dual eligible incentive payment on an ACO not only serving a large proportion of dual eligible beneficiaries, but also having the appropriate infrastructure to coordinate care and benefits for this population. One commenter opposed the use of financial incentives to encourage ACOs to serve dual eligible beneficiaries or to encourage providers serving duals to become ACOs, based on the belief that such financial incentives in the early days of the program may distort provider behavior in ways that are detrimental to beneficiaries and costly to the program. To effectively serve this population, this commenter indicated, for example, that we should ensure that ACO providers are Medicaid participating providers, and that an ACO serving many dual eligible beneficiaries has a relationship with the State Medicaid agency in the State in which it operates. This commenter further pointed out an effort by the Innovation Center in Connecticut to develop an Integrated Care Organization to serve dual eligibles in the State.

We received few comments on our statutory authority to give preference to ACOs who are participating in similar arrangements with other payers. One commenter recommended that CMS give preference to ACOs that have contracts with private payers that include financial accountability and quality performance incentives, and avoid requirements that could have a chilling effect on the willingness of private payers to invest in and partner with ACOs. This commenter further recommended that the definition of "similar arrangement" be consistent across the Shared Savings Program and the Pioneer ACO Model. On a related issue, many commenters expressed their support, generally, for the Innovation Center's Pioneer ACO Model. As a condition of participation in the Pioneer Model, ACOs must commit to entering outcomes based contracts with other purchasers (private health plans, State Medicaid agencies, and/or self insured employers) such that the majority of the ACO's total revenues (including from Medicare) will be derived from

such arrangements, by the end of the second performance period in December 2013. One commenter requested clarification on the extent to which private payers could participate in ACOs.

In addition to the payment incentives and preferences discussed in the proposed rule, commenters recommended that CMS include a variety of other incentives based on an ACO's other quality improvement activities, and the composition of the ACO's participants or the particular populations they serve. For example, commenters suggested we include the following:

- Incentives for early adopters of the accountable care model.
- Incentives for caring for particular populations, such as rewarding ACOs that serve the uninsured, care for beneficiaries in rural areas, or that have diverse patient populations.
- Incentives for including the following providers and suppliers:
 - ++ Patient centered medical homes.
 - ++ Teaching hospitals.
 - ++ Ambulatory Surgery Centers.
 - ++ Community health organizations including Community Mental Health Centers.
 - ++ Home health and hospice agencies.
 - ++ Physicians practicing in rural areas.
- Incentives for including health programs operated by the Indian Health Service, tribes or tribal organizations, and urban Indian organizations.
- Incentives to encourage participation by small, rural, and physician-led ACOs.
- Incentives to ensure some primary care services are delivered by NPs and PAs.
- Incentives to move patients from the acute care setting to appropriate post-acute or outpatient providers.
- Incentives to reward participation in other quality improvement initiatives, such as physician-led quality improvement programs.
- Incentives to use telehealth and remote patient monitoring technologies in innovative modalities extending beyond

what is currently reimbursed under FFS Medicare.

- Incentives for the development of primary care training in new models of care.
- Incentives for ACOs participating in clinical trials, to encourage innovation in health care.

v. Response:

1. We are finalizing our proposal, which does not give preference to ACOs engaged in similar arrangements with other payers, or provide additional incentives for ACOs which care for dual eligible beneficiaries. Similarly, we do not intend to recognize other factors, such as the ACO's other quality improvement activities, the composition of the ACO's participants or the particular populations they serve. CMS' goal is to promote complete integration of care and align incentives whether care is provided under Medicare, Medicaid, or both. ACOs are one valuable new option to assure greater coordination of care for Medicare Parts A and B services for dual eligible beneficiaries. Additionally, there are existing demonstrations and emerging care models underway in the Innovation Center in partnership with the Medicare-Medicaid Coordination Office which will provide further opportunities for the integration of care and financing across both Medicare and Medicaid, including long term services and supports. For dually eligible individuals CMS intends to study the effect of assignment of these individuals to ACOs in the Shared Savings Program on Medicaid expenditures, and may use this information in the development of future models for testing by the Innovation Center. We believe that these demonstrations and models targeting the dual eligible population will further address and create incentives for providers to focus on serving their special needs.

Through the flexibility allowed in the governance requirements, discussed in the Section II.B. of this final rule, we have left room for ACOs to engage with private payers. In

addition, we may revisit our authority to award a preference to ACOs that participate in similar arrangements with other payers as we gain more experience with such arrangements through the Pioneer ACO Model.

We decline to incorporate incentives into this national program to account for the variety of approaches that ACOs may choose for their quality improvement activities outside the Shared Savings Program, as well as their provider and supplier composition and patient mix. We believe that the flexibility allowed in the distribution of shared savings provides the opportunity for ACOs to reward ACO participants' for engaging in other quality improvement initiatives.

We may revisit the issue of incentives related to ACO activities, composition, and patient mix as we gain experience with the ACO model through the Shared Savings Program and the Pioneer ACO Model.

ii. Final Decision:

1. The final rule will not contain additional financial incentives, beyond those established for quality performance, for the care of dual eligible beneficiaries or other factors related to the composition of the ACO or its activities, nor will the final rule include a preference for ACOs participating in similar arrangements with other payers.

4. Net Sharing Rate

a. Pg. 132—

i. Comment:

(1) Commenters were generally supportive of the proposed exemption from the 2 percent net sharing threshold for small ACOs, particularly those in underserved and rural areas. A number of commenters suggested expanding the exemption to other types of ACOs. One, for example, recommended that the exemption include ACOs that treat a large proportion of dual eligible beneficiaries.

However, several commenters expressed concerns about the proposed exemption. One commenter explained that based on the

proposed assignment methodology, ACOs that include FQHCs and RHCs would have difficulty meeting the threshold level to qualify for the exemption. Another commenter suggested the exemption may not be sufficient to encourage participation by ACOs in rural areas.

ii. Response:

- (1) Our elimination of the 2 percent net sharing rate negates the need for an exemption from this requirement. Accordingly, we are eliminating the proposed exemption from the 2 percent net sharing rate as all ACOs that achieve savings in excess of their MSR will share in savings on a first dollar basis.

iii. Final Decision:

- (1) We are revising our proposal under §425.604 to allow for sharing on first dollar savings for ACOs under the one-sided model once savings meet or exceed the MSR. We are finalizing our proposal under §425.606 similarly allowing sharing on a first dollar savings for ACOs under the two-sided model once savings meet or exceed the MSR.

5. Performance Payment Limits

vi. Calculating Sharing in Losses

1. Minimum Loss Rate
2. Shared Loss Rate

a. Pg. 136—

- i. We proposed that ACOs with expenditures exceeding the MLR would be responsible for paying excess expenditures calculated by multiplying the amount of excess above the benchmark by one minus the final sharing rate. In the *proposed rule* (emphasis added) we defined the final sharing rate as the quality performance sharing rate plus any percentage points for including FQHCs and/or RHCs as ACO participants.

ii. Comment:

- (1) We received a few comments on the proposed shared loss rate. One commenter suggested we allow ACOs the choice of a percentage shared loss rate (as proposed) or a fixed dollar amount of risk. Several commenters pointed out that under the proposed methodology for calculating shared savings and losses, an ACO could be accountable for a 100 percent share of losses (for example, if the ACO's quality sharing rate is zero) which is asymmetrical with the shared savings methodology. One commenter suggested that CMS ensure that

the ACO's financial risk equals its potential gains in shared savings.

iii. Response:

(1) We are maintaining our proposal to calculate the shared loss rate as one minus the final sharing rate. Given our elimination of the incentive for an ACO to include FQHCs or RHCs as ACO participants, the final sharing rate is based solely on quality performance. Therefore, under the two-sided model an ACO could achieve a maximum sharing rate of 60 percent based on quality performance. We believe that commenters identified an important concern about the shared loss rate, that an ACO could achieve a 100 percent shared loss rate, while the maximum shared savings rate is set at 60 percent. We are concerned that the prospect of a shared loss rate bounded at 100 percent could significantly deter participation by ACOs in the two-sided model, particularly ACOs that are new to the accountable care model and to riskbearing. On the other hand, we do not want to limit the shared loss rate so much as to dampen the benefit of the program for Medicare or to remove the incentive for ACOs to strive for high quality scores. To balance these issues, we are modifying our proposal to cap the shared loss rate at 60 percent, to align with the maximum shared savings rate based on quality performance under the two-sided model.

iv. Final Decision:

(1) As proposed, under §425.606, the shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark will be determined based on the inverse of its final sharing rate based on quality performance (that is, 1 minus the shared savings rate). However, we are modifying our original proposal to provide that an ACO's shared loss rate will be subject to a cap of 60 percent consistent with the maximum rate for sharing savings.

- vii. Limits on Shared Losses
- viii. Ensuring ACO Repayment of Shared Losses
- ix. Timing of Repayment
- x. Withholding Performance Payments
- xi. Determining First Year Performance for ACOs Beginning April 1 or July 1, 2012

1. Interim Payment Calculation
 2. First Year Reconciliation
 3. Repayment Mechanism for ACOs Electing Interim Payment Calculations
 - (c) Impact on States
 - H. Additional Program Requirements and Beneficiary Protections
 - (a) Background
 - (b) Beneficiary Protections
 - i. Beneficiary Notification
 - ii. ACO Marketing Guidelines
 - (c) Program Monitoring
 - ii. General Methods Used to Monitor ACOs
 - iii. Monitoring Avoidance of At-Risk Beneficiaries
 1. Definition of At-Risk Beneficiaries
 2. Penalty for Avoidance of At-Risk Beneficiaries
 - ii. Compliance with Quality Performance Standards
 - (d) Program Integrity Requirements
 - i. Compliance Plans
 - ii. Compliance with Program Requirements
 - iii. Conflicts of Interest
 - iv. Screening of ACO Applicants
 - v. Prohibition on Certain Required Referrals and Cost Shifting
 - vi. Record Retention
 - vii. Beneficiary Inducements
 - (e) Terminating an ACO Agreement
 - i. Reasons for Termination of an ACO's Agreement
 - ii. Corrective Action Plans
 - (f) Reconsideration Review Process
- III. Collection of Information Requirements
- IV. Regulatory Impact Analysis
 - A. Introduction
 - B. Statement of Need
 - C. Overall Impact
 - D. Anticipated Effects
 - i. Effects on the Medicare Program
 1. Assumptions and Uncertainties
 2. Detailed Stochastic Modeling Results
 3. Further Considerations
 - ii. Impact on Beneficiaries
 - iii. Impact on Providers and Suppliers
 - iv. Impact on Small Entities
 - E. Alternatives Considered
 - F. Accounting Statement and Table
 - G. Conclusion