appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate.'' 40 CFR 300.425(e)(1)(ii). EPA, with the concurrence of the State of New York, through NYSDEC, believes that this criterion for deletion has been met. Consequently, EPA is deleting this Site from the NPL. Documents supporting this action are available in the Site files.

V. Deletion Action

EPA, with the concurrence of the State of New York, has determined that all appropriate responses under CERCLA have been completed and that no further response actions under CERCLA, other than M&M and five-year reviews, are necessary. Therefore, EPA is deleting the Site from the NPL. Because EPA considers this action to be noncontroversial and routine, EPA is taking this action without prior publication. This action will be effective February 13, 2012 unless EPA receives adverse comments by January 12, 2012. If adverse comments are received within the 30-day public comment period of this action, EPA will publish a timely withdrawal of this direct final Notice of Deletion before the effective date of the deletion and the deletion will not take effect. EPA will, if appropriate, prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments received. In such a case, there will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: November 22, 2011.

Judith A. Enck,

Regional Administrator, EPA, Region 2.

For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by removing ''Hiteman Leather,'' ''West Winfield'', ''NY.''

[FR Doc. 2011–31912 Filed 12–12–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 156

[CMS–9983–F]

RIN 0938–AQ98

Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO–OP) Program

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule implements the Consumer Operated and Oriented Plan (CO–OP) program, which provides loans to foster the creation of consumer-governed, private, nonprofit health insurance issuers to offer qualified health plans in the Affordable Insurance Exchanges (Exchanges). The goal of this program is to create a new CO–OP in every State in order to expand the number of health plans available in the Exchanges with a focus on integrated care and greater plan accountability.

DATES: These regulations are effective February 13, 2012.

FOR FURTHER INFORMATION CONTACT:
Meghan Elrington, (301) 492–4388 for general issues and issues related to loan terms and governance standards.
Anne Bollinger, (301) 492–4395 for issues related to definitions and eligibility.
Ilana Cohen, (301) 492–4371 for issues related to CO–OP standards.

SUPPLEMENTARY INFORMATION: The Patient Protection and Affordable Care Act, (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are collectively referred to in this final rule as the ''Affordable Care Act.'' The Department of Defense and Full-Year Continuing Appropriations Act, 2011 (Pub. L. 112–10), which amended Section 1322 of the Affordable Care Act, was enacted on April 15, 2011. Section 1322 of the Affordable Care Act created the Consumer Operated and Oriented Plan program (CO–OP) to foster the creation of new consumer-governed, private, nonprofit health insurance issuers. In addition to improving consumer choice and plan accountability, the CO–OP program also seeks to promote integrated models of care and enhance competition in the Affordable Insurance Exchanges (Exchanges) established under the Affordable Care Act.

The statute authorizes the Secretary to make loans to capitalize eligible prospective CO–OPs with a goal of having at least one CO–OP in each State. It also permits the funding of multiple CO–OPs in any State, provided that there is sufficient funding to capitalize at least one CO–OP in each State. There is $3.8 billion in appropriations for the program.

All CO–OP loans must be repaid with interest, and loans will only be made to private, nonprofit entities that demonstrate a high probability of becoming financially viable. The CO–OP program contains extensive provisions to protect against fraud, waste, and abuse. Loan recipients are subject to strict monitoring, audits, and reporting requirements for the length of the loan repayment period plus 10 years and CO–OPs must meet a series of milestones before drawing down disbursements, as described in their loan agreements.

This final rule—(1) Sets forth the eligibility standards for the CO–OP program; (2) establishes terms for loans; and (3) provides basic standards that organizations must meet to participate in this program and become a CO–OP. This rule is intended to provide flexibility for eligible organizations to encourage diversity in the organizational design and approach while ensuring that the statutory goals are met.

Starting in 2014, individuals and small businesses will be able to purchase private health insurance through State-based competitive marketplaces called Affordable Insurance Exchanges (Exchanges). Insurance companies will compete for new business on the basis of price and value and consumers will have a choice of health plans to fit their needs. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are seeking public input, providing guidance, and issuing regulations implementing Exchanges in several phases. A Request for Comment relating to Exchanges was published in the **Federal Register** on August 3, 2010. Initial Guidance to States on Exchanges was published on November 18, 2010. A proposed rule for the application, review, and reporting process for waivers for State innovation was published in the **Federal Register** on March 14, 2011 (76 FR 13553). On July 15, 2011, two proposed regulations were

published in the **Federal Register** to implement components of the Exchange: ''Establishment of Exchanges and Qualified Health Plans'' and ''Standards Related to Reinsurance, Risk Corridors and Risk Adjustment.'' On August 17, 2011, three proposed regulations were published in the **Federal Register**: ''Eligibility Changes Under the Affordable Care Act of 2010,'' ''Exchange Functions in the Individual Market: Eligibility Determinations; Exchange Standards for Employers,'' and ''Health Insurance Premium Tax Credit.'' Additional regulations will be published in the **Federal Register** to implement Exchange related components of the Affordable Care Act.

Table of Contents

Acronym List

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

CCIIO Center for Consumer Information & Insurance Oversight
CMS Centers for Medicare & Medicaid Services
CO–OP Consumer Operated and Oriented Plan
ERISA Employee Retirement Income Security Act
FACA Federal Advisory Committee Act
FOA Funding Opportunity Announcement
FQHC Federally Qualified Health Center
HHS U.S. Department of Health and Human Services
MLR Medical Loss Ratio
OIG Office of Inspector General
OMB Office of Management and Budget
PHS Act Public Health Service Act
QHP Qualified Health Plan
RFC Request for Comment
SHOP Small Business Health Options Program

I. Background

A. Overview of the Consumer Operated and Oriented Plan (CO–OP) Program

Section 1322 of the Affordable Care Act directs the Secretary to establish the CO–OP program to provide loans to foster the creation of new consumer-governed nonprofit health insurance issuers, referred to as CO–OPs, in every State. These new consumer-run, private, nonprofit insurers will be one vehicle for providing higher quality care that is affordable and uses innovative care models in the Exchanges starting in 2014.

The statute divides the CO–OP loans into two types: loans for start-up costs, to be repaid in 5 years (''Start-up Loans''), and loans to enable CO–OPs to meet State insurance solvency and reserve requirements, to be repaid in 15 years (''Solvency Loans''). Section 1322(b)(2)(A) of the Affordable Care Act directs CMS to ensure that there is sufficient funding to establish at least one CO–OP in each State and to give priority to organizations that can offer these CO–OP qualified health plans on a Statewide basis, provide integrated care, and have significant private support. Section 1301(a)(2) of the statute deems CO–OP qualified health plans offered by a qualified nonprofit health insurance issuer eligible to participate in the Exchanges. By creating more health plan choices, the CO–OP program can benefit all consumers.

The CO–OP program also seeks to promote improved models of care. Existing health insurance cooperatives and other business cooperatives provide possible models for the successful development of CO–OPs around the country. One major barrier to continued development of this model in the health insurance market has been the difficulty of obtaining adequate capitalization for start-up costs and State insurance reserve requirements. The CO–OP program is designed to help overcome this barrier to new issuer formation by providing loans specifically for these critical activities.

Pursuant to section 1322(b)(4) of the Affordable Care Act, the Comptroller General announced the appointment of a 15 member CO–OP Program Advisory Board on June 23, 2010 to make recommendations to CMS on awarding loans. Section 1322(b)(2)(A) directs the Secretary to consider the recommendations of this Advisory Board when awarding loans under the CO–OP program. After taking testimony from experts and comments in 3 day-long public hearings from January through March 2011 and examining written comments, the Advisory Board approved its final recommendations and submitted its public report on April 15, 2011. This final report is available at: *http://cciio.hhs.gov/resources/files/coop_faca_finalreport_04152011.pdf*. The Advisory Board generally advised the Department to develop flexible criteria that recognize the diversity of market conditions around the country to enable the development of various CO–OP models and allow different types of sponsorship. It also encouraged the Department to provide technical assistance at all stages of the process in order to enhance the viability of individual CO–OPs and the success of the program.

The Advisory Board recommended four major principles for awarding loans. CMS concurs with these principles:

(1) Consumer operation, control, and focus must be the salient features of the CO–OP and must be sustained over time;

(2) Solvency and the financial stability of coverage should be maintained and promoted;

(3) CO–OPs should encourage care coordination, quality and efficiency to the extent feasible in local provider and health plan markets; and

(4) Initial loans should be rolled out as expeditiously as possible so that CO–OPs can compete in the Exchanges in the critical first open enrollment period.

This final rule and the Funding Opportunity Announcement (FOA) for the CO–OP program incorporate these four principles endorsed by the Advisory Board.

On February 2, 2011, CMS published a Request for Comment (RFC) in the **Federal Register** (76 FR 5774) seeking public comment on the rules that will govern the CO–OP program. The public comments received in response to the RFC were considered in the development of the proposed rule published in the **Federal Register** on July 20, 2011 with a comment period that ended on September 16, 2011 (76

FR 43237). In addition, a Funding Opportunity Announcement (FOA) for the CO–OP program, available at *www.grants.gov* (CFDA Number 93.545), was published on July 28, 2011 (and amended on September 16, 2011) and provides detailed information regarding the application and award administration process for the CO–OP program.

B. Statutory Basis for the Consumer Operated and Oriented Plan (CO–OP) Program

Section 1322(a) of the Affordable Care Act directs CMS to establish the CO–OP program to foster the creation of member-governed qualified nonprofit health insurance issuers to offer CO–OP qualified health plans in the individual and small group markets in the States in which they are licensed.

Section 1322(b)(1) of the Affordable Care Act directs CMS to make two types of loans available to organizations applying to become qualified nonprofit health insurance issuers: Start-up Loans and repayable grants (Solvency Loans). Start-up Loans will provide assistance with start-up costs and Solvency Loans will provide assistance in meeting solvency requirements of State regulators in the States in which the organization is licensed to issue CO–OP qualified health plans. Although the statute refers to Solvency Loans as ''grants,'' they are loans because they must be repaid.

Section 1322(b)(2) provides that in making awards, CMS must take into account the recommendations of the Advisory Board further described in section 1322(b)(4) and give priority to applicants that offer CO–OP qualified health plans on a Statewide basis, use integrated care models, and have significant private support.

Section 1322(b)(2) also directs CMS to ensure that there is sufficient funding to establish at least one qualified nonprofit health insurance issuer in each State and the District of Columbia. It permits CMS to fund additional qualified nonprofit health insurance issuers in any State if the funding is sufficient to do so. If no entities in a State apply, CMS may use funds to encourage the establishment of a qualified nonprofit health insurance issuer in the State or the expansion of another qualified nonprofit health insurance issuer from another State to that State.

Section 1322(b)(2) also directs any organization receiving a loan to enter into an agreement to meet the standards to become a qualified nonprofit health insurance issuer and any other terms and conditions of the loan awards. Under section 1322(b)(2)(C)(ii), the agreement must provide that no portion of the loans be used for propaganda purposes, attempts to influence legislation, or marketing.

Section 1322(b)(2)(C)(iii) provides that, if CMS determines that an organization has failed to meet any provisions of the loan agreement or failed to correct such failure within a reasonable period of time, the organization must repay an amount equal to the sum of:

- 110 percent of the aggregate amount of loans received; plus
- Interest on the aggregate amount of loans for the period the loans were outstanding starting from the date of drawdown.

CMS must notify the Department of the Treasury of any determination of a failure to comply with the CO–OP program standards (including the provisions of a loan agreement) that may affect an issuer's tax-exempt status under section 501(c)(29) of the Internal Revenue Code of 1986 (the Code).

Under section 1322(b)(3), Start-up Loans must be repaid within 5 years, and Solvency Loans must be repaid within 15 years. Repayment terms in the award of loans must take into consideration any appropriate State reserve requirements, solvency regulations, and requisite surplus note arrangements that must be constructed by a qualified health insurance issuer in a State to receive and maintain licensure. Section 1322(b)(3) provides that, not later than July 1, 2013 and prior to awarding loans, CMS must promulgate these regulations, ''with respect to the repayment'' of the loans. Legal obligations regarding repayment as well as other obligations required for program compliance will be included in loan agreements.

Section 1322(c)(1) defines ''qualified nonprofit health insurance issuer'' as an organization that:

- Is organized under State law as a private, nonprofit, member corporation;
- Conducts activities of which substantially all consist of the issuance of CO–OP qualified health plans in the individual and small group markets in each State in which it is licensed to issue such plans; and
- Meets the other requirements in subsection 1322(c).

Section 1322(c)(2) states that an organization is not eligible to become a qualified nonprofit health insurance issuer if the organization or a related entity (or any predecessor of either) was a health insurance issuer on July 16, 2009. In addition, an organization cannot be treated as eligible to apply for a loan under the CO–OP program if a State or local government, any political subdivision thereof, or any instrumentality of such government or political subdivision sponsors it.

Section 1322(c)(3) establishes governance requirements for a qualified nonprofit health insurance issuer. To ensure consumer control, the governance of the organization must be subject to a majority vote of its members. The organization's governing documents must incorporate ethics and conflict of interest standards to protect CO–OP members against insurance industry involvement and interference. To ensure consumer orientation, the organization is required to operate with a strong consumer focus, including timeliness, responsiveness, and accountability to members.

Section 1322(c)(4) directs the organization to use any profits to lower premiums, improve benefits, or for other programs intended to improve the quality of health care delivered to its members.

Section 1322(c)(5) states that the organization must meet all the State standards for licensure that other issuers of qualified health plans must meet in any State where the issuer offers a CO–OP qualified health plan, including solvency and licensure requirements and any other State law described in section 1324(b).

Section 1322(c)(6) prohibits a qualified nonprofit health insurance issuer from offering a health plan in a State until that State has in effect (or CMS has implemented for the State) the market reforms outlined in part A of title XXVII of the Public Health Service Act (as amended by subtitles A and C of title I of the Affordable Care Act).

Section 1322(d) enables qualified nonprofit health insurance issuers to establish a private purchasing council to enter into collective purchasing arrangements for items and services that increase administrative and other cost efficiencies including claims administration, administrative services, health information technology, and actuarial services. The private purchasing council is prohibited from setting payment rates for health care facilities or providers that contract with qualified nonprofit health insurance issuers.

Section 1322(e) prohibits representatives of any Federal, State, or local government (or of any political subdivision or instrumentality thereof), and representatives of an organization that was an existing issuer or a related entity (or predecessor of either) on July 16, 2009, from serving on the board of directors of the qualified nonprofit health insurance issuer or a private

purchasing council established under section 1322(d).

Together, these provisions form the statutory basis for the CO–OP program established under this rule.

C. Structure of the Final Rule

The regulations outlined in this final rule will be codified in 45 CFR part 156 subpart F. The major subjects covered in this final rule are described below.

- Section 156.500 describes the statutory basis of the CO–OP program and the scope of this proposed rule;
- Section 156.505 sets forth definitions for the terms applied in subpart F;
- Section 156.510 specifies the criteria to be eligible for a loan under the CO–OP program;
- Section 156.515 sets forth the standards for a CO–OP; and
- Section 156.520 sets forth the terms for loans awarded under the CO–OP program including repayment terms and interest rates.

II. Summary of the Proposed Provisions and Responses to Comments on the CO–OP Proposed Regulation

The proposed rule was published in the **Federal Register** on July 20, 2011 with a comment period that ended on September 16, 2011 (76 FR 43237). In addition, a Funding Opportunity Announcement for the CO–OP program, available at *http://www.grants.gov* (CFDA Number 93.545), was published on July 28, 2011 (and amended on September 16, 2011) and provides detailed information regarding the application and award administration process for the CO–OP program. We received approximately 45 public comments that addressed many topics in the proposed rule. Interested parties that submitted comments included private citizens, organizations interested in applying to the CO–OP program, State Departments of Insurance, health insurance issuer trade associations, medical associations, provider and hospital associations, and advocacy groups. In this preamble we provide a summary of each proposed provision, a summary of the public comments received, our responses to them, and any changes to the CO–OP program that we are implementing in the final regulation as a result of comments received. At the end of the comment and response sections of this preamble, we also reference comments we received that were outside the scope of the provisions set forth in the proposed rule. Several of these comments pertain to the provisions of the Funding Opportunity Announcement and will be addressed in program guidance or in loan agreements. Loan recipients will be subject to legal obligations outlined in the loan agreements. Those obligations are not reiterated here.

A. Basis and Scope (§ 156.500)

Section 156.500 specifies the general statutory authority for and scope of standards proposed in subpart F. The CO–OP program awards loans to foster the creation of qualified nonprofit health insurance issuers to offer CO–OP qualified health plans in the individual and small group markets. Subpart F establishes certain eligibility, governance, and health plan issuance standards for CO–OPs as well as certain terms for loans awarded under the CO–OP program. Applicants may apply for loans to help fund start-up costs and meet the solvency requirements of States in which the applicant seeks to be licensed to issue a CO–OP qualified health plan.

Comment: One commenter opposed implementation of the CO–OP program and indicated that no government loan program can bring meaningful resolution to the lack of consumer choice in the health insurance market. The commenter stated that the likelihood of failure will be higher for these start-up organizations than it otherwise would be in the market because the organizations with the best prospects of being able to repay loans, pre-existing health insurance issuers, are excluded from the CO–OP program. The commenter recommended that CMS delay awarding loans. Another commenter expressed concern that the funding appropriated for the CO–OP program will be reduced by the Congress.

Response: We recognize that loan recipients will face challenges entering highly concentrated health insurance markets. This is true for any new market entrant. However, the CO–OP program is responsive to these barriers. The CO–OP program offers resources, in the form of loans, to responsibly capitalize new, private, consumer-oriented issuers by increasing the availability of adequate reserve funding and boosting the ability of CO–OPs to compete in a brand new, broader insurance marketplace. Insurance markets will change and expand considerably in 2014 with the implementation of Exchanges. In order to obtain a loan and be successful, CO–OPs must demonstrate the ability to gain sufficient enrollment and revenue to sustain their organization. Therefore, it is important that CMS begin awarding loans consistent with current law and the Advisory Board's recommendation to give loan recipients sufficient time to become operational and begin accepting enrollment during the first Exchange open enrollment period in the Fall of 2013.

We have considered the comments received regarding the basis and scope of the CO–OP program and are finalizing the provisions of § 156.500 as proposed.

B. Definitions (§ 156.505)

Section 156.505 sets forth definitions for terms that are used throughout subpart F and are not intended to apply to other subparts of section 156. Many of the definitions presented in § 156.505 of the proposed rule were taken directly from the Affordable Care Act, but new definitions were created when necessary. Some of the definitions presented in § 156.505 of the proposed rule have since been revised based on the comments received, including: ''qualified nonprofit health insurance issuer,'' ''related entity,'' and ''sponsor.'' We originally proposed that a ''qualified nonprofit health insurance issuer'' be defined as a loan recipient that satisfies or can reasonably be expected to satisfy the standards in section 1322(c) of the Affordable Care Act and § 156.515 within the time frames specified in this subpart, until such time as CMS determines the loan recipient does not satisfy or cannot reasonably be expected to satisfy these standards. Generally, an entity that has received a loan and has met program requirements for the loan is reasonably expected to satisfy these standards. This definition was proposed to ensure that loan recipients can receive the benefits of section 1322(h), addressing the Federal income tax exemption for qualified nonprofit health insurance issuers, at the appropriate time as determined by the Internal Revenue Service.

We proposed the definition of ''related entity'' be an organization that shares common ownership or control with a pre-existing issuer or a trade association whose members consist of pre-existing issuers, and satisfies at least one of the following conditions: (1) Retains responsibilities for the services to be provided by the issuer; (2) furnishes services to the issuer's enrollees under an oral or written agreement; or (3) performs some of the issuer's management functions under contract or delegation. Thus, CMS proposed permitting a nonprofit organization that is not an issuer or the representative of an issuer but shares control with an existing issuer to ''sponsor'' or facilitate the creation of a CO–OP if the applicant (and resulting CO–OP) and the existing issuer do not share the same chief executive or any of the board of directors. In the proposed

rule, ''sponsor'' was defined as an organization or individual that is involved in the development, creation, or organization of the CO–OP or provides financial support to a CO–OP. The comments we received on these proposed definitions and our responses are provided below.

Comment: Several commenters requested that the definition of ''qualified nonprofit health insurance issuer'' be revised so that qualified nonprofit health insurance issuers may access multiple forms of investment and philanthropic capital (including debt, equity or equity-equivalent, grants, bonds, etc.) in a manner that does not compromise their primary commitment to mission.

Response: Although other legal requirements, including state nonprofit corporation laws and tax rules applicable to tax-exempt grantors and CO–OPs seeking tax-exempt status, may limit the availability to CO–OPs of certain kinds of investments, section 1322 of the Affordable Care Act and the proposed definition of a ''qualified nonprofit health insurance issuer'' do not impose limitations on the capital that may be invested in a ''qualified nonprofit health insurance issuer.'' However, the organization's surplus funds (that is, revenue in excess of expenses) must be ''used to lower premiums, to improve benefits, or for other programs intended to improve the quality of health care delivered to its members.'' In addition, as stated in the FOA and recommended by the Advisory Board, CO–OPs may also use their surplus funds to conduct marketing, repay loans awarded under the CO–OP program, meet State solvency requirements, and provide for enrollment growth, financial stability, and stable coverage for its members. The proposed rule does not prohibit but encourages private investment that can be demonstrated to meet this standard on the application of profits. Therefore, it is not necessary to revise the definition of ''qualified nonprofit health insurance issuer'' to allow CO–OPs to access investment. Other legal requirements applicable to investments in CO–OPs are outside the scope of this rulemaking.

However, in the definition of ''qualified nonprofit health insurance issuer,'' we have replaced the phrase ''loan recipient'' with the word ''entity.'' Because only a loan recipient can satisfy the standards in section 1322(c) and § 156.515, we do not view this as a substantive change from the proposed rule. It is being made to ensure flexibility in determining when entities qualify for the Federal income tax exemption.

Comment: Several commenters requested that the definition of ''member'' be revised to include only those covered lives who are at least 18 years old.

Response: We agree that voting rights should be limited to covered lives who are at least 18 years old, and we have revised § 156.515 accordingly. However, this change to the proposed rule does not necessitate a revision to the definition of member, and we are finalizing the definition as proposed.

Comment: Several commenters requested clarification on whether the definition of ''member'' includes dependents, and some commenters requested that the definition of ''member'' be limited to one adult covered life within each family plan.

Response: The term ''member'' includes all individuals covered under health insurance policies issued by a loan recipient, including dependents. As discussed above, we have also limited voting rights to members over 18 years old. We understand the commenter's concern that allowing adult dependents in family coverage to vote will create an imbalance in the representation of different member interests on the board. However, the statute provides no basis for discriminating among covered lives on the basis of the source of coverage. The limitation proposed by the commenter would prevent certain adults receiving health care coverage under a CO–OP from participating in the organization's governance. As indicated in the testimony from existing health insurance cooperatives, all adults in existing health insurance cooperatives have voting privileges regardless of family or employment status. Therefore, we have concluded that every adult covered by the CO–OP must be eligible to vote and serve on the board of directors in order to ensure that decisions are made in the best interest of all covered lives consistent with both the statute and the traditional model of a cooperative.

Comment: Several commenters requested clarification as to what the term ''representative'' means.

Response: We understand the need for clarification of this term and have included a definition of ''representative'' in this final rule. ''Representative'' means an individual who stands or acts for an organization or group of organizations through a formal agreement or financial compensation such as a contractor, broker, official, or employee.

Comment: Due to the statutory prohibition on the use of loan funding for ''marketing,'' several commenters requested guidance as to what activities are considered ''marketing.'' Several commenters indicated that the description in the FOA released on July 28, 2011 that described marketing as ''activities that promote the purchase of a specific health care plan or explain a product's benefit structure, whether targeted at new or current members'' is overly broad, prohibiting CO–OPs from using loan funds to educate their members. In the Request for Comment (RFC), several commenters recommended that CMS define ''marketing'' narrowly to allow loan recipients to use loan funds to conduct community outreach and member education.

Response: Marketing was not discussed in the proposed rule and therefore, is outside the scope of this rule. Please see the amended FOA, released on September 16, 2011, for additional guidance regarding the activities included in the term marketing.

Comment: Several commenters supported the proposed definition of ''issuer'' because it prohibits insurance companies that were in existence prior to July 16, 2009, from participating in the CO–OP program. One commenter requested that reinsurers be categorized as a qualified sponsor under the term ''issuer.''

Response: The intent of the proposed definition was to prohibit any insurance companies that were in existence prior to July 16, 2009, from participating in the CO–OP program, consistent with the statutory directive. Reinsurers are typically licensed as issuers under State law, and therefore are generally captured under the definition of ''issuer.''

Comment: One commenter requested that multiple employee welfare arrangements (MEWAs) and their affiliates be included within the class of entities that are excluded from the definition of ''issuer.''

Response: MEWAs and their affiliates are typically not licensed by States as ''issuers'' and, therefore, would appear to be eligible for loans if they meet all other eligibility criteria. The definition of ''issuer'' clearly states that an entity is an ''issuer'' if it is ''licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance.'' Consistent with the statute, if a MEWA is not a pre-existing issuer and otherwise meets the eligibility criteria, it would be eligible to apply for CO–OP loans.

Comment: Several commenters concurred with the proposed definition of ''pre-existing issuer'' but requested clarification on whether it prevents existing consumer run healthcare organizations from providing expertise and assistance to prospective CO–OPs. One commenter requested that a new term be used in place of ''pre-existing issuer'' because it is easily confused with a health insurance issuer that excludes coverage for ''pre-existing conditions.''

Response: Section 156.510(b)(2)(i) of this subpart allows a CO–OP to purchase assets and contract services from a ''pre-existing issuer'' as long as it is an arm's length transaction in which each party acts independently of the other and has no relationship with the other. Although we understand and appreciate the commenter's concern, we do not find it necessary to replace the term ''pre-existing issuer.'' Given differences in context, we do not believe that this term will be confused with the term ''pre-existing conditions.''

Comment: We received comments expressing concern that holding companies (companies that exist primarily to own stock in other companies) that control pre-existing issuers are typically not licensed as issuers and therefore, would be eligible to participate in the CO–OP program.

Response: We agree with this concern and have modified the eligibility criterion in § 156.510(b) to exclude holding companies that control pre-existing issuers, foundations established by pre-existing issuers, and trade associations comprised of pre-existing issuers whose purpose is to represent the interests of the health insurance industry. Through its inclusion in the eligibility criteria, this provision will ensure that entities controlled by or serving the interests of pre-existing issuers are unable to participate in the CO–OP program or sponsor a CO–OP. Therefore, no changes to the definition itself of pre-existing issuer are necessary.

Comment: Several commenters supported the proposed definition of ''related entity.'' Some commenters requested that the definition be expanded in order to ensure that CO–OPs are truly independent of pre-existing health insurance issuers. Specifically, one commenter recommended that the term ''related entity'' be expanded so that neither preexisting issuers nor related entities would be permitted to become or sponsor a CO–OP. Conversely, several commenters recommended that a nonprofit organization that is not an issuer but shares control with a pre-existing issuer should be allowed to sponsor or facilitate the creation of a CO–OP.

Response: The primary goal of the CO–OP program is to foster new consumer-governed, private, nonprofit health insurance issuers. The statute expressly prohibits the participation of issuers, related entities, or the predecessors of either, in the CO–OP program. We believe that the intent of this prohibition is to encourage the participation of sponsors that can create a new competitive presence in the marketplace. We agree with the commenters' concerns that the proposed definition did not foreclose avenues of influence that the statute intended to prohibit. Accordingly, we have revised the definition of ''related entity'' to reflect that organizations that share a common governance structure with a pre-existing issuer (for example, their management team or board of directors) are ineligible for the CO–OP program if they also provide services or management functions to the pre-existing issuer.

In addition, we agree that the statute prohibits pre-existing issuers from sponsoring a CO–OP. However, nonprofit, not-for-profit, public benefit, or similarly organized entities that do not sell insurance as their primary purpose or mission but share control with a pre-existing issuer should be permitted to sponsor a CO–OP. For example, a religious organization that is not a health insurance issuer, but is affiliated with one to help its members obtain health insurance would be able to also sponsor a CO–OP to offer a health plan in the Exchanges. This is permitted because all pre-existing issuers are prohibited from sharing control or having undue influence over the governance of the CO–OP itself. Therefore, we have expanded the exclusions from eligibility in § 156.510(b)(1)(i) to exclude organizations sponsored by a pre-existing issuer. Due to this addition, no further changes to the definition of ''related entity'' are necessary to reflect that pre-existing issuers are not permitted to sponsor a CO–OP. A nonprofit, not-for-profit, public benefit, or similarly organized entity that is not an issuer but shares common control or governance with a pre-existing issuer would not be considered a ''related entity'' and hence, excluded from sponsorship of a CO–OP, unless it—(1) Retains responsibilities for the services to be provided by the pre-existing issuer, (2) furnishes services to the pre-existing issuer's enrollee under contract, or (3) performs some of the pre-existing issuer's management functions under contract or delegation.

Comment: One commenter stated that the term ''related entity'' unnecessarily limits the types of associations allowed to sponsor a CO–OP and requested that all nonprofits regardless of board composition be able to sponsor a CO–OP because to do otherwise would limit the experience and financial support available to a prospective CO–OP to create a working, stable insurance entity.

Response: It is important for a CO–OP to have adequate financial support and an experienced management team and governing board in order to be viable in the market. However, the statute expressly prohibits ''related entities'' from becoming qualified nonprofit health insurance issuers and without this prohibition, a CO–OP becomes vulnerable to undue influence from pre-existing issuers, which would undermine the statutory goals of this program. As set forth in § 156.515(b) of this subpart, CO–OPs may contract for services with experienced entities and include individuals with expertise on their board of directors to gain the benefit of experience.

Based on the comments received, we are finalizing the definitions proposed in § 156.505 of the proposed rule, along with the exception of revisions to the definitions of ''qualified nonprofit health insurance issuer'' and ''related entity,'' described in our responses above and revisions to the definitions of ''sponsor'' and ''Start-up Loan'' discussed in the Eligibility and Loan Terms sections of the preamble, respectively. In addition, we have added a definition for ''representative'' in response to the comments received. We define ''representative'' as an individual who stands or acts for an organization or group of organizations through a formal agreement or financial compensation such as a contractor, broker, official, or employee.

Because the proposed rule ''Establishment of Exchanges and Qualified Health Plans'' (76 FR 41866) has not yet been finalized, we have revised the definitions for the terms ''individual market,'' ''small group market,'' ''SHOP,'' ''Exchange,'' and ''CO–OP qualified health plan'' to remove references to this rule. We also include definitions of ''group health plans,'' ''health insurance coverage,'' ''small employer,'' ''qualified employer,'' and ''qualified health plan'' as they were proposed in ''Establishment of Exchanges and Qualified Health Plans'' (76 FR 41866), because those terms are referred to within other definitions used in this

subpart. Once the ''Establishment of Exchanges and Qualified Health Plans'' rule has been finalized, the definitions in this subpart will be revised in the final ''Establishment of Exchanges and Qualified Health Plans'' rule to incorporate the definitions adopted in the new part 155.

C. Eligibility (§ 156.510)

Section 156.510 of the proposed rule outlined the minimum standards that an organization must meet to be eligible to receive a loan from the CO–OP program in order to create a new private consumer-operated insurer. We proposed codification of the conditions in section 1322(c)(2) of the Affordable Care Act under which an organization will not be eligible to participate in the CO–OP program. If an organization is a pre-existing issuer, a related entity, or any predecessor of either, it is not eligible for loans under the CO–OP program and therefore, cannot become a CO–OP. In addition, an organization is not eligible for the CO–OP program if the organization or a related entity (or any predecessor of either) is a trade association whose members consist of pre-existing issuers. We also proposed codification of the requirement that, if an organization is sponsored by a State or local government, any political subdivision thereof, or any instrumentality of such government or political subdivision, it is not eligible to be a CO–OP and cannot apply for a loan under the CO–OP program.

Under § 156.510(b)(2)(i) of the proposed rule, a nonprofit organization that is not an issuer but that currently sponsors an issuer would remain eligible to sponsor an applicant for a CO–OP loan in certain circumstances. Specifically, we proposed that such an organization could sponsor an applicant for a CO–OP loan provided that the pre-existing issuer does not share any of the board or the same chief executive with the applicant. In § 156.510(b)(2)(ii), we further proposed that an organization that has purchased assets from a pre-existing issuer in an arm's-length transaction where each party acts independently of the other and has no other relationship with the other is eligible to apply for a CO–OP loan. We also proposed that an applicant and a pre-existing issuer could have common control by a non-issuer organization. The applicant and pre-existing issuer would not be related entities unless the pre-existing issuer also provided the CO–OP's services or management functions.

The comments we received on the proposed eligibility criteria and our responses are provided below.

Comment: Several commenters requested that CMS expand the eligibility criteria to allow the participation of for-profit consumer-oriented health insurance issuers. Conversely, a few commenters suggested that CMS bar entities affiliated with pre-existing issuers—such as organizations that sponsor pre-existing issuers, foundations established by pre-existing issuers, holding companies that control pre-existing issuers, or associations that represent pre-existing issuers—from sponsoring a CO–OP. One commenter suggested that CMS evaluate whether applicants have previously competed in insurance markets before awarding any funding.

Response: As stated in section 1322 of the Affordable Care Act, the goal of the CO–OP program is to ''foster the creation of qualified nonprofit health insurance issuers.'' Accordingly, eligibility is limited to nonprofit member organizations as previously defined. In response to concerns about permitting entities that are controlled by or serve the interests of pre-existing issuers from participating in the CO–OP program or sponsoring a CO–OP, we modified the eligibility criteria in § 156.510(b) to exclude (1) Holding companies that control pre-existing issuers, foundations established by pre-existing issuers, and trade associations that are comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry (2) organizations sponsored by a pre-existing issuer, and (3) organizations that receive more than 25% of their total funding (excluding any loans received from the CO–OP program) from pre-existing issuers. This modification would allow applicants to receive limited funding from pre-existing issuers (up to 25% of their total funding excluding any loans received from the CO–OP program) to help with application costs and other expenses while ensuring that pre-existing issuers are not providing a level of funding that would give them meaningful control of each CO–OP. We believe that these exclusions from eligibility are consistent with the intent and direction of the statute as written. These exclusions will help to ensure that CO–OP loans are provided to new organizations and are not used to further develop plans offered by current health insurers.

Comment: Two commenters expressed support for our statement that the prohibition against sponsorship of a CO–OP by a State or local government would not apply to Indian tribes because a tribe is neither a State nor local government.

Response: We agree with the commenters that this prohibition would not apply to Indian tribes.

Comment: Several commenters requested that CMS clarify whether private non-profit hospitals and physician hospital organizations, State-affiliated academic medical centers, three-share and multi-share programs, and other organizations that receive grant funding and other financial support from a State or local government would be eligible to participate in the CO–OP program.

Response: Recognizing that the term ''instrumentality'' does not effectively distinguish among the organizations that could arguably be classified as related to a State or local government, we are revising the eligibility criterion in § 156.510(b)(1)(ii) to provide additional guidance regarding the types of organizations that would be excluded from eligibility as instrumentalities of a State or local government. Specifically, an organization would not be considered an instrumentality of a State or local government and therefore, would be eligible to sponsor a CO–OP if:

- The entity is a not a government organization under State law;
- No employee of a State or local government acting in his or her official capacity serves as a senior executive (for example, President, chief executive officer, or chief financial officer) for the organization; and
- Fewer than half of the organization's directors are employees of a State or local government acting in their official capacities.

Thus, an organization, such as an academic medical center, that has received funding from a State or local government but has a governance structure that satisfies all three of these criteria and otherwise meets the eligibility criteria in § 156.510 and the FOA would be eligible to sponsor a CO–OP. A private organization that receives disproportionate share hospital payments or grants from State-appropriated funds but has a governance structure that satisfies the three criteria listed above and is otherwise qualified could sponsor a CO–OP. In addition, a three-share or multi-share program that accepts funding from State-appropriated funds in the course of a business relationship with a State would not be considered an instrumentality of the State as long as it meets these criteria.

In addition, we are revising the definition of ''sponsor'' in § 156.505 of this subpart and the eligibility criteria in § 156.510(b)(1) to allow organizations that receive funding from pre-existing

issuers or State or local governments to participate in the CO–OP program, provided that the pre-existing issuers or State or local governments are not involved in the applicant's development, creation, or organization, and that pre-existing issuers do not contribute more than 25 percent of the organization's funding (excluding any loans received from the CO–OP program) and no single State or local government contributes more than 40 percent of the organization's funding (excluding any loans received from the CO–OP program). We have established a lower limit on funding from pre-existing issuers than grants and other funding provided by State and local governments to ensure that CO–OPs are free from any undue influence that may result from receiving substantial funding from pre-existing issuers. We believe that applicants may receive greater levels of funding from State and local governments without serving as an actor or instrumentality of the government.

Comment: Many commenters asked CMS to clarify the entities that are eligible to receive loan funding. Two commenters suggested that CMS impose additional prohibitions on the relationship between a CO–OP and a sponsor. One commenter suggested that any entity that shares common leadership with a pre-existing issuer be barred from sponsoring a CO–OP; another suggested that CMS prohibit sponsors and CO–OPs from sharing any financial interest. Finally, two commenters suggested CMS further consider eligibility for specific types of applicants, such as those that have previously participated in the issuance of health insurance.

Response: We appreciate the concern that permitting entities with financial or organizational ties to pre-existing issuers to sponsor CO–OPs could allow de facto conversions of pre-existing issuers and conflict with the statutory intent to foster the creation of new market entrants. However, the statute excludes from eligibility only those organizations that were existing issuers on July 16, 2009, and their related entities and predecessors. An organization that was not licensed to issue health insurance policies on July 16, 2009; is not a foundation established by a pre-existing issuer; is not a holding company that controls a pre-existing issuer; is not a trade association that is comprised of pre-existing issuers and whose purpose is to advocate for the interests of pre-existing issuers; and is not a related entity or predecessor to a pre-existing issuer would be eligible to participate in the CO–OP program provided that it meets all other eligibility criteria. CMS believes that permitting such organizations to sponsor CO–OPs maintains the appropriate balance between preventing the flow of program funds to entities that are not new market entrants and promoting the success of CO–OPs by permitting a variety of sponsorship and partnership arrangements.

Comment: One commenter asked CMS to clarify how antitrust rules may affect providers who wish to develop CO–OPs and expressed concern that antitrust and self-referral laws may limit provider participation in the development and sponsorship of CO–OPs.

Response: We believe that it is possible for providers to create viable CO–OPs within the boundaries of existing anti-trust and self-referral laws. Promoting competition within the health insurance marketplace is a key goal of the CO–OP program, but the statute does not give us authority to waive or exempt CO–OPs from anti-trust or self-referral laws. Therefore, it is the responsibility of each applicant to assess the relevant laws and regulations and ensure compliance.

Comment: While several commenters supported CMS' proposal to permit CO–OPs to purchase assets from or contract with existing issuers, some commenters were concerned about the potential for issuers to exert undue influence on CO–OPs. For example, one commenter suggested that CO–OPs be prohibited from contracting with pre-existing issuers that represent more than five percent of the local market. Similarly, another commenter suggested specific requirements around the purchase of reinsurance; for example that reinsurance be purchased at a fair market price.

Response: Under the rule, loan recipients and CO–OPs may purchase assets and services, such as premium billing services, from pre-existing issuers through arm's length transactions. Based on the comments received, we are further clarifying ''arm's length transaction'' to mean a transaction in which the buyer and seller act independently and have no relationship to one another. We believe that applying the arm's length standard prevents loan recipients from entering into agreements or transactions that could jeopardize member control while maintaining flexibility for recipients to enter into the business agreements that best meet their needs. In addition, pursuant to § 156.515(b)(3), each CO–OP must have procedures in place to protect against insurance industry interference and address any conflict of interests, such as those between the CO–OP and its sponsor(s).

We have considered the many comments received regarding eligibility and are finalizing the provisions in § 156.510 of the proposed rule with the exception of the revisions described above and the revision to § 156.510(b)(2)(i) discussed in the Definitions section of the preamble. Specifically, § 156.510(b) is revised to exclude foundations established by a pre-existing issuer, holding companies that control pre-existing issuers, organizations sponsored by pre-existing issuers, and organizations that receive more than 25% of their total funding (not including loans under the CO–OP program) from pre-existing issuers from eligibility for the CO–OP program. Section 156.510(b)(1)(iii) is revised to clarify that organizations that receive funding from a State or local government but are not government organizations under State law and are not governed or controlled by a State or local government may be eligible for the CO–OP program. Section 156.510(b)(2)(i) is revised to clarify that certain nonprofit, not-for-profit, public benefit, or similarly organized entities that are also a sponsor for a pre-existing issuer are permitted to sponsor a CO–OP provided that the pre-existing issuer does not share any of its board or the same chief executive with the CO–OP. Section 156.510(b)(2)(ii) is revised to clarify that an ''arm's length transaction'' consists of a transaction between two parties in which neither party is in a position to exert undue influence on the other.

D. CO–OP Standards (§ 156.515)

1. General

A CO–OP must satisfy the *standards* set forth in all statutory, regulatory, or other requirements as applicable. CMS proposed additional standards that a CO–OP must meet in § 156.515, many of which are recommendations made by the Advisory Board in the final report dated April 15, 2011. We requested public comments on these proposed standards.

2. Governance Requirements

Section 1322(c)(3)(C) of the Affordable Care Act directs the Secretary to promulgate regulations requiring the organization to operate with a strong consumer focus, including timeliness, responsiveness, and accountability to members. Pursuant to this authority, CMS proposed governance standards in § 156.515(b) of the proposed rule that reflect the

recommendations of the Advisory Board. We proposed that the organization be governed by an operational board with each of its directors elected by a majority vote of its members. We also proposed that the first election of the operational board of directors occur no later than one year after the effective date on which the CO–OP provides coverage to its first member to protect against delaying the introduction of consumer governance beyond a point where it can have an impact on the strategic direction of the CO–OP.

Section 156.515(b)(2)(v) of the proposed rule codified the limitation in section 1322(e) of the Affordable Care Act that no representative of any Federal, State or local government (or of any political subdivision or instrumentality thereof) and no representative of a pre-existing issuer, a trade association whose members consist of pre-existing issuers, a related entity, or a predecessor of either may serve on the board of directors.

The comments we received on these proposed governance standards and our responses are provided below.

Comment: While several commenters expressed support for the proposed governance requirements as written, several commenters suggested that CMS extend the period of transition from the formation board to the operational board to two years after enrollment begins and to permit staggered election of the operational board over the two-year period. Commenters also suggested that CO–OPs be permitted to fill director positions vacated due to resignation, death, or removal except removal by the CO–OP members.

Response: We agree that staggered elections over a longer period will provide additional flexibility for loan recipients and will allow operational boards to retain important expertise and experience gained during formation. Allowing CO–OPs to fill vacant director positions in the specific circumstances outlined above will permit efficient operation and governance of the CO–OP without compromising the consumer role.

Therefore, we have revised § 156.515 of the regulations to provide that a loan recipient may implement a staggered transition from the formation board to the operational board over a period of two years. The transition to a member-elected operational board must begin within one year of a loan recipient first providing coverage to its first enrollee. The operational board must be in place in its entirety two years after the loan recipient begins providing coverage to its first enrollee. Additionally, in the case of resignation, death, or removal, CO–OPs may fill vacant director positions for the remainder of the relevant term without conducting a contested election.

Comment: One commenter requested clarification regarding whether a loan recipient may begin the loan process with an initial management team that will transition to a permanent management team as dictated by the organization's board of directors. The commenter indicated that many potential long-term management candidates are currently employed and cannot quit their jobs to join a CO–OP until they know it will be funded.

Response: Under the proposed rule, loan recipients may establish an initial management team that will transition to a permanent management team. Loan recipients should clearly outline their process for identifying and transitioning to a permanent management team in their applications.

Comment: Several commenters supported CMS' decision to permit designated seats on the board of directors. However, one commenter suggested that CMS strike or modify this provision due to the potential difficulty of classifying directors based on designated seat categories (for example, provider, employer). Commenters also asked CMS to clarify the role of non-members on the board of directors and to clarify whether representatives or officers of certain entities, such as sponsors or employers, may sit on the board.

Response: It is important to balance meaningful member governance with experienced management. Some of the skills and expertise necessary to administer a CO–OP successfully may be unavailable among the membership. Therefore, we are finalizing the proposal to permit a CO–OP to designate certain seats on its operational board for individuals with specified areas of expertise and backgrounds. How each CO–OP identifies the designations—for example, providers, employers, or representatives from the CO–OP's sponsoring organization—to best serve the needs of the members is a business decision for the CO–OP. We note, however, that seats designated for individuals with specialized expertise, experience, or affiliation cannot comprise the majority of the operational board.

Comment: Several commenters asked that CMS clarify the meaning of ''contested'' with respect to elections of the board of directors. One commenter suggested that CMS permit the establishment of member classes, each of which would represent a specified share of votes. Several commenters recommended that CMS permit CO–OPs to elect directors based on a majority of a quorum of the CO–OP's members. Finally, one commenter requested that CMS clarify that each member may vote for each contested seat in an election.

Response: The proposed rule stated that ''there must be more candidates for open positions on the board than there are positions.'' This requirement applies to all positions open during a particular election, and not to individual open positions. We have revised § 156.515(b)(1) of the regulation to clarify this requirement.

The establishment of member classes could jeopardize the role of members in governance by permitting one type of member to exert disproportionate influence on the direction of the organization. Also, the establishment of member classes conflicts directly with the principle of one member, one vote, which we believe is critical to protecting the voice of consumers and the accountability of a CO–OP to its membership. Further, as indicated in testimony before the Advisory Board, existing successful health insurance cooperatives do not classify their members.

We agree that it may be burdensome or logistically impossible for all members of a CO–OP to participate in each election for the board of directors. Therefore, we have revised § 156.515(b)(1) to allow CO–OPs to conduct elections for the board of directors based on a quorum of members and to clarify that members may vote for each seat during an election.

Comment: Several commenters suggested that CMS clarify additional features of board operations. One commenter suggested that CMS expressly allow boards to include members-at-large; another suggested that CMS direct CO–OPs to impose term limits. Another commenter suggested that CMS strengthen its proposed requirement on disclosure of financial relationships and require recusal in certain circumstances.

Response: Beyond the minimum requirements to ensure that members of the CO–OP are a majority of the operational board, CO–OPs have substantial flexibility in the structure and operation of the board of directors. At its option, a CO–OP may choose to have designated seats or non-voting directors, or impose term limits or additional disclosure requirements on board members. Decisions of this type should be made by individual CO–OPs based on their expected business needs. In addition, each CO–OP is responsible for establishing procedures for

identifying and addressing potential conflicts of interest, including conflicts arising from financial relationships.

Comment: One commenter recommended that there be an active structure supported by the CO–OP board to incorporate geographic and ethnic diversity into their policies and decisions based on the State's demographics. Another commenter sought additional guidance on the relationship between sponsors and CO–OP boards and whether issues between these two parties will be addressed in the contracts between sponsors and CO–OPs. The commenter indicated that sponsors investing significant amounts in a prospective CO–OP need assurance that the board of directors has sufficient expertise to fulfill its fiduciary responsibilities and will be held accountable so that the sponsor can meet its own fiduciary responsibilities

Response: CO–OPs must abide by the governance standards set forth under § 156.515 to ensure that they operate with a strong consumer focus, including timeliness, responsiveness, and accountability to members. Decisions on how to ensure that a CO–OP's governing board has sufficient expertise are best made by the individual CO–OP based on its market, enrollment, and business plan. CO–OPs have the flexibility to make additional requirements and/or decisions on their governance structure beyond these rules, including how they define the ability to have designated seats on the board or promote diversity among board members.

Comment: One commenter asked CMS to clarify whether directors may consider interests other than those of the CO–OP—such as the interests of the local community or of the organization's employees—when making decisions.

Response: We agree that considering the interests of a CO–OP's local geographic community and acting in the interest of the CO–OP are not mutually exclusive.

Comment: One commenter stated that the governance requirements in § 156.515 may conflict with State nonprofit governance requirements and recommended that CMS give deference to State laws and regulations regarding governance of nonprofit risk bearing entities.

Response: Loan recipients must comply with all applicable State laws and should apply organizational structures that will minimize the potential for conflicting governance requirements.

We have reviewed and considered the comments received and are finalizing the standards set forth in § 156.515(b) of the proposed rule with the exception of the revisions described above and the revisions to the governance provisions in § 156.515(b)(1) discussed in the Definitions section of the preamble. We have modified the governance provisions in § 156.515(b)(1) to limit voting to members over the age of 18 and provide loan recipients with greater flexibility in electing directors and transitioning from a formation board to an operational board. We have also modified § 156.515(b)(2) and § 156.515(b)(3) to permit a loan recipient's board of directors to consider the interests of the loan recipient's local community.

3. Requirements To Issue Health Plans and Become a CO–OP

Section 156.515(c)(1) of the proposed rule codified section 1322(c)(1)(B) of the Affordable Care Act that provides that substantially all of the activities of the CO–OP consist of the issuance of CO–OP qualified health plans in the individual and small group markets in each State in which it is licensed to issue such plans. CMS proposed that a CO–OP will satisfy this standard if at least two-thirds of the contracts for health insurance coverage issued by a CO–OP are CO–OP qualified health plans offered in the individual and small group markets in the States in which the CO–OP operates. An organization must continually meet this requirement to be considered a CO–OP. Each insurance policy or contract that an issuer sells constitutes a single activity. We requested public comments on whether two-thirds is the appropriate threshold for this standard. This proposed standard would allow providers wishing to sponsor CO–OPs to enroll their own employees in the CO–OP and thereby encourage provider participation and would also permit CO–OPs to participate in Medicaid and the Children's Health Insurance Program (CHIP). CO–OP participation in public programs would enable individuals and families to remain with the same health insurance issuer and providers if family income fluctuates.

In paragraph (c)(2), CMS proposed that a CO–OP applicant receiving a Start-up Loan or Solvency Loan offer at least one CO–OP qualified health plan at both the silver and gold benefit levels, as defined in section 1302(d) of the Affordable Care Act, in every individual market Exchange that serves the geographic market in which it is licensed and intends to provide health care coverage (market area). In addition, if a CO–OP chooses to offer coverage in the small group market outside the Exchange, a CO–OP must commit to offering at least one CO–OP qualified health plan at both the silver and gold benefit levels in the SHOP of any market area where the CO–OP is licensed.

Within the earlier of 36 months following the initial drawdown of a Start-up Loan or 6 months following the initial drawdown of the Solvency Loan, we proposed that a loan recipient must be licensed in a State and offer at least one CO–OP qualified health plan at the silver and gold benefit levels (as defined in section 1302(d) of the Affordable Care Act) in an individual market Exchange and, if offering a health plan in the small group market, in a SHOP. Thus, the loan recipient must satisfy the requirements of title XXVII of the Public Health Service Act applicable to health insurance coverage in the individual market and small group market, if applicable, and comply with all standards generally applicable to qualified health plan issuers. To continue offering CO–OP qualified health plans in the Exchanges, a CO–OP must continue to meet these standards.

Due to concerns regarding the ability of a CO–OP to establish sufficient enrollment to make its health plans viable, CMS proposed that when offering a CO–OP qualified health plan in an Exchange for the first time, loan recipients may only begin to offer health plans and accept enrollment during an open enrollment period for the applicable Exchange when they can attract the largest and most diverse enrollment. This limitation does not affect when a CO–OP may offer plans in the market outside the Exchanges.

We proposed that a loan recipient must also satisfy the requirements of section 1322(c) of the Affordable Care Act and § 156.515 and become a CO–OP within fifty-four months following the first drawdown of a Start-up Loan or eighteen months following the initial drawdown of a Solvency Loan. These provisions were intended to ensure that loan recipients actively work toward becoming a CO–OP that offers CO–OP qualified health plans in the Exchanges.

The comments we received on these proposed standards and our responses are provided below.

Comment: A few commenters asked CMS to clarify that CO–OPs must become licensed before issuing any health insurance policies inside or outside of any Exchange.

Response: As stated in the proposed rule and § 1322(c)(5) of the Affordable Care Act, loan recipients under the CO–OP program must satisfy all requirements and comply with all standards that generally apply to qualified health plan issuers including State insurance laws and regulations. Accordingly, loan recipients must be

licensed by the relevant State agency before issuing any individual or small group health insurance policies regardless of whether they are offered inside or outside of the Exchanges.

Comment: One commenter requested clarification regarding licensure for CO–OPs that operate in multiple States. The commenter recommended that CMS require licensure in one State and allow operation in additional States through a multi-state agreement or licensure provided to a foreign-domiciled issuer.

Response: The statute requires that a CO–OP be licensed in each State in which it operates and licensure is controlled by State law. No carrier may conduct business in a State market without appropriate licensure approved by the applicable State insurance department. CO–OPs have the same options for licensure as other health insurers that operate in multiple States. For example, CO–OPs may establish a State of domicile for licensure and file expansion applications to achieve licensure in other States.

Comment: Two commenters disagreed with the proposed interpretation of ''activity'' when applying the substantially all requirement under section § 156.515(c)(1). These commenters stated that defining ''activities'' in terms of contracts or policies rather than the number of covered lives diminishes the focus on individual and small group coverage. However, most other commenters on this issue and the Advisory Board recommendation supported the interpretation that each insurance policy or contract that an issuer sells constitutes a single activity. Commenters in support of this interpretation felt that it provides flexibility that is essential in the development of successful CO–OP models. They indicated that this flexibility would lead to better health care coverage for patients, particularly low-income working families and individuals in the individual and small group markets.

Response: We considered alternative methods to evaluate the definition of ''activity'' but concluded that the final rule will maintain the proposed policy that each insurance policy or contract that an issuer sells constitutes a single activity, consistent with the proposed rule. Alternatives would unreasonably burden enrollment operations for CO–OPs by requiring ongoing counting of covered lives as family size or number of employees change, could violate guaranteed issue requirements by placing caps on the number of members that could be accepted from different groups that do not apply to other issuers, and may result in disruptions of coverage. Such a requirement may create a competitive disadvantage for CO–OPs that is not required by the statute and a significant ongoing administrative burden. Also, the CMS interpretation of ''activity'' is consistent with the interpretation generally used by State regulators in measuring issuer activity, which typically includes the following: Number of plans in the individual market, number of plans in the small group market, and number of plans in the large group market. Moreover, in using the term ''activities consisting of the issuance of plans,'' the statute makes no reference to enrollment or covered lives. This definition will provide the flexibility needed for CO–OPs to become viable in the health care market and ensure repayment of loans.

Comment: CMS received several comments in response to § 156.515(c)(1) which states that a CO–OP will satisfy the ''substantially all'' standard at section 1322(c)(1) if at least two-thirds of the contracts for health insurance coverage issued by a CO–OP are CO–OP qualified health plans offered in the individual and small group markets in the States in which the CO–OP operates. The Advisory Board recommended that CMS apply the most flexible standard possible in interpreting ''substantially all.'' Most commenters on this issue stated that measuring two-thirds of the contracts for the substantially all standard was an appropriate level, was easy to measure, and would give CO–OPs the needed flexibility to implement successful health plans. Two commenters felt that the two-thirds standard was too low and should be raised to 80–90 percent to ensure that CO–OPs operate primarily in the individual and small group markets. Other commenters felt that measuring two-thirds of the contracts was too high a standard and should be lowered to 50 percent. One commenter recommended that CMS explore ways to allow CO–OPs to participate in other markets, such as providing coverage for large employers or State employees.

Response: In order for these new health insurers to be viable, CO–OPs must achieve a minimum level of enrollment as soon as possible. Therefore, we believe that measuring two-thirds of the contracts when applying the substantially all requirement is an appropriate threshold.

The two-thirds standard for the issuance of health plans applies to all of the activities of the CO–OP, including plans issued outside of the Exchanges. This interpretation allows CO–OPs to have a stable base of enrollment that will enhance a CO–OP's long-term success in the individual and small group market and ensure repayment of loans. It will also encourage providers who may want to offer a CO–OP option to their employees to participate in CO–OP provider networks and permit CO–OPs to participate in the Medicaid and CHIP program.

The two-thirds standard used in this rule is consistent with other regulations in which CMS has interpreted the term ''substantially all.'' An example is the mental health parity regulations for group health plans and group health insurance coverage under section 712 of the Employee Retirement Income Security Act of 1974 (ERISA), section 2726 of the PHS Act, and section 9812 of the Code.

Comment: Several commenters recommended that section § 156.515(c) be modified to permit CO–OPs to market themselves and accept enrollment before an Exchange open-enrollment period or prior to market reform rules having been implemented in a State.

Response: Section 1322(c)(6) of the Affordable Care Act explicitly prohibits a CO–OP from ''offer[ing] a health plan in a State until that State has in effect (or the Secretary has implemented for the State) market reforms required by part A of title XXVII of the Public Health Service Act.'' Therefore, a loan recipient cannot offer health coverage in a State until market reforms under the Affordable Care Act have been put into effect in the State. Once reforms have been put into effect in a State and a CO–OP satisfies State requirements such as licensure, a CO–OP may offer coverage in that State.

Comment: One commenter requested clarification regarding the difference between a loan recipient and a CO–OP.

Response: A loan recipient is any organization that has received a loan under the CO–OP program. As defined in § 156.505, a CO–OP is a loan recipient that has established a member elected operational board, is offering CO–OP qualified health plans at the gold and silver benefit levels in the Exchanges serving the CO–OP's target markets, and meets the other requirements in § 156.515.

Comment: Several comments addressed the timelines for beginning to offer CO–OP qualified health plans and for becoming a CO–OP. One commenter recommended that the deadline for meeting the ''substantially all'' and other standards to become a CO–OP under § 156.515(c) be 48 months from Start-up loan drawdown rather than 54 months. Other commenters recommended that this deadline be extended because it will be difficult for

CO–OPs as new entities to conform to these requirements within 54 months.

Response: Given the process and requirements for achieving licensure in each State, we agree that the deadline to meet the requirements under section § 156.515(c) should be extended. Therefore, we have revised the final rule. A loan recipient must meet the standards set forth under § 156.515(c)(3) within 36 months following the initial drawdown of the Start-up Loan (as indicated in the proposed rule) or one year following the initial drawdown of the Solvency Loan as opposed to the initially proposed timeframe of six months. In addition, since we have extended the timeframe for a loan recipient to transition from a formation board to an operational board from one year to two years, we have extended the timeframe for a loan recipient to become a CO–OP. Specifically, we have changed the timeframe from within the earlier of 54 months following the initial drawdown of the Start-up Loan or 18 months following the initial drawdown of the Solvency Loan to within 5 years and 3 years respectively. This policy generally gives a loan recipient two years after it begins providing health care coverage through the Exchanges to fully implement its member elected operational board and meet all of the CO–OP minimum standards. We do not anticipate that these changes will affect when a loan recipient can offer coverage either through the Exchanges. This change will simply allow loan recipients to receive Solvency loans earlier, which will provide them with more time to ensure licensure before offering coverage.

Comment: Two commenters requested modifications to § 156.515(d) that would exempt health plans sponsored by Indian tribes from State insurance standards and provide Indian tribes flexibility in setting up and operating a CO–OP. Commenters also recommended that CO–OP enrollment eligibility criteria allow for a CO–OP to focus on a defined subset of the population.

Response: Pursuant to section 1322(c)(5) and (c)(6) of the Affordable Care Act, a loan recipient must comply with all standards required under applicable State insurance laws and regulation in the State in which the CO–OP operates as well as the market reforms required by part A of the title XXVII of the Public Health Service Act. These standards include the requirement that qualified health plans abide by guaranteed issue and other State insurance laws in order to maintain a level playing field with health insurance issuers. Therefore, loan recipients cannot offer qualified health plans to only a defined subset of enrollees in their target area. The statute does not provide authority to modify these requirements.

We have reviewed and considered the comments received and are finalizing the standards set forth in § 156.515(c) and § 156.515(d) of the proposed rule with the exception of the revisions described above. We have modified the standards in § 156.515(c)(3) and § 156.515(d) to provide additional time for loan recipients to begin offering CO–OP qualified health plans and become a CO–OP.

E. Loan Terms (§ 156.520)

1. Overview of Loans

Organizations that meet the eligibility standards in § 156.510 and the CO–OP program FOA may apply for two types of loans: Start-up Loans and Solvency Loans. Start-up loans assist with the start-up costs associated with establishing a CO–OP. Solvency Loans are intended to help loan recipients meet the reserve requirements, solvency regulations, and requisite surplus note arrangements in each State in which the applicant seeks to be licensed. We proposed that all loans awarded under the CO–OP program must be used in a manner that is consistent with the FOA, loan agreement, and all other statutory, regulatory, or other requirements established by CMS.

Solvency and the financial health of insurance issuers is historically a State-regulated function. As a condition of licensure as a health insurance issuer, State insurance departments require that an issuer maintain an amount of capital that is consistent with its size and risk profile. This measure of reserve is called risk-based capital (RBC). A loan is considered a liability and typically would not assist an organization in meeting solvency requirements, since the liability would have to be subtracted from the calculation of reserves in order to determine the net protection afforded to enrollees. Since Solvency Loans must be repaid to the Federal government within 15 years, the Advisory Board expressed concern that they will be treated by States as debt rather than capital that satisfies State solvency and reserve requirements.

Per section 1322(b)(3) of the Affordable Care Act, the standards for the repayment of loans awarded under the CO–OP program must take into consideration ''any appropriate State reserve requirements, solvency regulations, and requisite surplus note arrangements that must be constructed in a State.'' Therefore, in § 156.520(a)(3) of the proposed rule, CMS proposed to structure Solvency Loans to each loan recipient in a manner that meets State reserve and solvency requirements so that the loan recipient can fund its required capital reserves. In order to assist CO–OPs in meeting State solvency requirements, the loans will be structured so that premiums would be used to meet cash reserve requirements before repayment to CMS. This ensures that the Solvency Loans are recognized as contributing to State reserve and solvency requirements in the States in which the applicant intends to offer CO–OP qualified health plans. We requested public comment on this provision.

The comments received on the loan terms in § 156.520(a) of the proposed rule and our responses are provided below.

Comment: One commenter requested clarification regarding whether the terms of each CO–OP's Solvency Loan will be tailored to the specific requirements of each State in which the CO–OP intends to offer health care coverage. Several commenters supported our proposal to structure Solvency Loans so that they are recognized as contributing to State reserve and solvency requirements. They acknowledged the concern discussed in the proposed rule that solvency requirements vary across States and that loans are typically considered debt rather than capital for the purposes of State reserve requirements. Generally, commenters agreed that Solvency Loans should be structured so that each CO–OP's premium revenue is applied towards paying claims and meeting cash reserve requirements before loan repayments to CMS. However, some commenters indicated that such a structure would be insufficient. They explained that Solvency Loans must be structured as surplus notes as they are the only types of loans that State insurance regulators will recognize as assets rather than debt. One commenter advised against creating a new Federal requirement that States treat Solvency Loans as ''capital.'' It was also recommended that CMS coordinate with NAIC to establish a means for CO–OPs to meet State solvency and reserve requirements.

Response: We will work with each loan recipient to structure their Solvency Loans in a manner that will contribute towards meeting State reserve and solvency requirements consistent with State insurance regulation. States are not required to take action that would be inconsistent with State insurance regulation. Therefore, loan recipients must work with State insurance regulators to

identify loan structures that will meet State requirements. Significant flexibility is afforded to loan applicants in structuring their Solvency Loans to meet State standards. Applicable loan structures may include but are not limited to structuring a Solvency Loan as a surplus note or responsibly structuring a Solvency Loan so that premium revenue is applied towards paying claims for covered services to enrollees and meeting cash reserve requirements before loan repayments to CMS.

Comment: One commenter asked what actions can be taken if a State is unwilling to recognize a loan recipient's Solvency Loan as meeting State reserve and solvency requirements. The commenter recommended that CMS exercise flexibility in structuring and, if necessary, re-structuring Solvency Loans if a State revises its reserve and solvency requirements.

Response: It is incumbent upon applicants to work with their State insurance regulators to identify appropriate loan structures that will meet the requirements of their State insurance department.

Comment: One commenter requested clarification regarding whether CMS will provide loan recipients with sufficient funding to meet State solvency requirements in the initial distributions of loan funds. In addition, commenters including State Departments of Insurance requested clarification regarding whether additional loan funding will be made available if a loan recipient requires additional Solvency Loans after 2012 and recommended that loan funding remain available after 2012.

Response: The full amount of Solvency Loans anticipated should be requested in the loan application. Loan disbursements will be made available to loan recipients on a timetable based on the business plan and milestones proposed and approved in their applications after we review the loan recipient for compliance. The initial solvency disbursements received by loan recipients should allow a loan recipient to meet their applicable State solvency and reserve requirements. Applicants should consider the potential needs for funding due to unforeseen market changes or changes in State regulatory requirements as well as unforeseen enrollment and benefit cost growth. These will be considered in the size of the initial award. A loan recipient may draw down on the Start-up Loans and Solvency loans to the extent such conditions exist, consistent with the terms of the loan agreement.

Comment: One commenter recommended that CMS prohibit loan recipients from using their loan funding to pay claims or subsidize reimbursements to providers in any way that would give them an advantage over existing health insurance issuers.

Response: Under the Affordable Care Act, loan recipients are permitted to use their loan funds to assist with their start-up costs and State solvency requirements, provided that the funds are not used to conduct propaganda, or otherwise attempt to influence legislation, or for marketing. The purpose of State reserve requirements is to preserve the financial viability of carriers and enable the payment of claims when provider costs exceed premium revenue. A CO–OP that fails to maintain appropriate reserves or surplus may be subject to regulatory action, seizure, or liquidation. Such a prohibition would therefore not only defeat the purpose of the loans but would be contrary to the framework of State regulation. Furthermore, the statute does not prohibit these costs. Given that these loans must be repaid to us in full and that CO–OPs should structure their premiums, claims, and administrative costs to ensure sustainability, we do not believe that the use of loan funds to pay claims would give CO–OPs an advantage over existing health insurance issuers. Existing health insurance issuers may use their reserves to pay claims under equivalent circumstances.

We have considered the comments received and are finalizing the provisions set forth in § 156.520(a) of the proposed rule.

2. Repayment Period

Section § 156.520(b) of the proposed rule codified the standard in section 1322(b)(3) of the Affordable Care Act that Start-up Loans and Solvency Loans awarded must be repaid within 5 years and 15 years respectively, taking into consideration any appropriate State reserve requirements, solvency regulations, and requisite surplus note arrangements that must be constructed in a State. Loan recipients must make loan payments consistent with the repayment schedule approved by CMS and agreed to by the loan recipient in the loan agreement until the loans have been paid in full. CMS proposed to permit individualized repayment schedules to promote the growth of CO–OPs, ensure compliance with the laws of different States, serve the interests of the CO–OP members and the public, and enhance the likelihood of full repayment. Flexibility in the repayment schedule helps address the diversity in each CO–OP's local market conditions, projected member risk profiles, business strategy, and projected enrollment size. The repayment schedule is submitted with the application and may include features such as a grace period, graduated repayments, or balloon payments at the end of the repayment period.

The Advisory Board recommended an enhanced oversight process for cases where a loan recipient is not meeting the terms and conditions of its loan but where CMS has concluded that discontinuing funding is not in the best interest of the CO–OP's members, the public, or the government. Consistent with the Advisory Board's recommendation, a loan modification or workout may be executed when a loan recipient is having difficulty making loan repayments. If a loan recipient is unable to (1) Make repayments or meet other conditions of the loan without adversely affecting coverage stability, member control, quality of care, or the public interest generally or (2) meet State reserve and solvency requirements, CMS would have the discretion to execute a loan modification or workout if appropriate, or terminate the agreement and recoup the loans in accordance with the loan agreement.

The comments received on the repayment periods described in § 156.520(b) of the proposed rule and our responses are provided below.

Comment: Most commenters expressed support for our flexibility in allowing applicants to propose individualized repayment schedules consistent with their business plans. They indicated that loan recipients will likely need time to build enrollment and revenue before beginning their loan repayments. Some commenters recommended that CMS not permit CO–OPs to wait until the end of their repayment period to make a balloon payment. They stated that instead CO–OPs should be required to make payments at regular intervals in order to reduce the cost of the program and ensure that CO–OPs are factoring loan repayments into their premium pricing.

Response: Flexible repayment schedules promote the growth of each CO–OP and improve each CO–OP's ability to fully repay its loans. We agree that CO–OPs must factor loan repayments into their premium pricing; however, we do not believe that it is necessary to require repayment at uniform intervals among all CO–OPs. As described in the FOA, all loan applicants must demonstrate their ability to repay their loans and describe

their process for determining accurate and appropriate premium pricing.

Comment: One commenter requested guidance regarding whether a repayment schedule can be established on a per member per month basis.

Response: Applicants have flexibility in proposing a responsible repayment schedule. A loan may have a repayment schedule on a per member per month basis, provided that each loan is fully paid within the repayment period and the proposed repayment schedule is supported by the CO–OP's business plan. CMS will consider the applicant's proposed schedule and has discretion in determining a responsible repayment schedule that will be approved and established in the loan agreement.

Comment: One commenter recommended that we add ''market competition'' to the list of considerations for modifying loan terms. The commenter stated that terminating a functioning CO–OP due to loan repayment issues could significantly reduce competition and harm the enrollees in areas with few active health plans.

Response: We have added ''market stability'' as a consideration for executing a loan workout or modification.

We have considered the comments received and are finalizing the provisions set forth in § 156.520(b) of the proposed rule with the exception of the revisions described above. Specifically, we have revised § 156.520(b)(3) to reflect that a loan modification or workout may be executed if we determine that a loan recipient is unable to repay its loans under its original loan agreement without destabilizing the loan recipient's target market.

3. Interest Rates

In § 156.520(c), we proposed that loan recipients pay an interest rate benchmarked to the average interest rate on marketable Treasury securities of similar maturity. In the FOA, we specified that the interest rate for Start-up loans is the average interest rate on marketable Treasury securities of similar maturity minus one percentage point and the interest rate cannot be less than zero percent. In addition, we specified that the interest rate for Solvency loans is the average interest rate on marketable Treasury securities of similar maturity minus two percentage points and the interest rate cannot be less than zero percent. These interest rates are tied to prevailing market conditions while providing low cost loans that are consistent with the statute's direction to foster the development of viable CO–OPs.

The comments we received on the interest rates described in § 156.520(c) of the proposed rule and our responses are provided below.

Comment: Commenters supported establishing low interest rates for loan recipients to give CO–OPs the best chance of success, to protect the Federal investment, and to encourage new market entrants to provide coverage to medically underserved communities. Lastly, one commenter stated that the interest rates for Start-up Loans and Solvency Loans could determine, in large measure, the ability of CO–OPs to successfully compete with other health insurers.

Response: We agree with the commenters and therefore, are codifying the interest rates announced in the FOA in § 156.520(c) of this final rule. These interest rates will encourage and promote the success of CO–OPs.

Comment: One commenter requested guidance regarding whether loan recipients may be charged a lower interest rate during their initial years of operation.

Response: The interest rates for Start-up Loans and Solvency Loans will be determined based on the date of award and will be fixed for the life of the loan. If an applicant anticipates difficulty making repayments during the initial years of operation, it may request a repayment schedule where repayments begin later in the loan repayment period.

Comment: Pursuant to section 1322(b)(2)(C)(iii) of the Affordable Care Act, if an organization fails to meet any provisions of the loan agreement or has not corrected such a failure within a reasonable period of time established by CMS, the organization must repay an amount equal to 110 percent of the total loans received plus interest. One commenter recommended that we codify this provision in the final rule in addition to the FOA in order to give this penalty more weight and ensure greater compliance.

Response: We agree with the commenter and therefore, are codifying this provision of the Affordable Care Act as described in the FOA in § 156.520(c) of this final rule.

Comment: One commenter expressed support for the proposed interest rates and asked if CMS could take any additional steps to reduce the financial barriers that CO–OPs face when entering a concentrated health insurance market. Another commenter indicated that CMS should encourage States to offer CO–OPs the lowest possible premium rates or a tax-free status because State taxation requirements may create significant barriers for CO–OPs. Commenters also recommended that CMS develop national purchasing pools or mechanisms to assist CO–OPs in adequately spreading their risk (for example, with a national CO–OP risk pool, Federally-funded stop-loss insurance, or Federally-funded reinsurance), particularly in the first few years of operation.

Response: In addition to providing low-interest loans with tailored repayment schedules to assist with start-up cost and State reserve requirements, the Affordable Care Act reduces the financial barriers for CO–OPs by creating a new Federal income tax exemption under 501(c)(29) of the Internal Revenue Code for qualified nonprofit health insurance issuers that have received loans under the CO–OP program. These measures provide CO–OPs with significant assistance in overcoming financial barriers to entering a health care market while maintaining a level playing field with other issuers. We do not have the authority to require States to offer CO–OPs tax-exempt status or the lowest possible premium tax rates. CO–OPs, like other health insurers that participate in the Exchanges, will benefit from premium and risk stabilization programs, risk adjustment, risk corridors, and reinsurance programs operating under sections 1341, 1342, and 1343 of the Affordable Care Act. In addition, CO–OPs may purchase reinsurance and other administrative services individually or through a private purchasing council.

Comment: One commenter recommended that CMS give deference to State statutory interest rate caps on Solvency Loans.

Response: The interest rates for Solvency Loans are below market rates. We do not anticipate that they will exceed any interest rate caps established by a State regulation. However, loan recipients must comply with all applicable State insurance laws.

We have considered the comments received and are finalizing the provisions set forth in § 156.520(c) of the proposed rule. We have also added provisions (1) To reflect that the interest rate for Start-up Loans equals the greater of the average interest rate on marketable Treasury securities of similar maturity minus 1 percentage point or 0 percent; (2) to reflect that the interest rate for Solvency loans equals the greater of the average interest rate on marketable Treasury securities of similar maturity minus 2 percentage points or 0 percent; and (3) to codify the penalty described in 1322(b)(2)(C)(iii) of

the Affordable Care Act. If a loan recipient fails to meet any provisions of the CO–OP program or their loan agreement and has not corrected such failure within a reasonable period of time established by CMS, the organization must repay an amount equal to 110 percent of the total loans received plus interest.

4. Failure To Pay

In § 156.520(d), CMS proposed to use any and all remedies available to it under law to collect loan payments or penalty payments if a loan recipient fails to make payments consistent with the repayment schedule in its loan agreement or in a loan modification or workout.

The comments we received on the failure to pay provisions described in § 156.520(d) of the proposed rule and our responses are provided below.

Comment: One commenter stated that the terms of a loan recipient's obligations in the event of a loan default or failure to meet loan requirements seems overly punitive.

Response: A loan recipient's obligations in the event of a loan default or failure to meet loan requirements are consistent with the provisions in section 1322(b)(2)(C)(iii) of the Affordable Care Act and are appropriate to protect Federal investment in the CO–OP program. We will work with loan recipients experiencing difficulty making timely repayments and will provide the option to request a loan workout. Furthermore, organizations that fail to meet program requirements, depending on the nature of the failure, may be given sufficient opportunity (as determined by CMS) to take corrective action.

Comment: One commenter recommended that CMS not hold a loan recipient's incorporators and formation board liable for loan repayment unless they engaged in fraud or any other prohibited conduct. The commenter indicated that such an assurance would encourage additional participation in the CO–OP program.

Response: Under the rule, loan applicants are incorporated or organized entities under State law. Therefore, the liability of the loan recipient's incorporators and formation board will, in part, be determined by the organizational vehicles, including corporations or other limited-liability organizations, the applicants use under State law.

We have considered the comments received and are finalizing the provisions set forth in § 156.520(d) of the proposed rule.

5. Deeming of CO–OP Qualified Health Plans

Section 156.520(e) of the proposed rule codified the ''deeming'' provisions of section 1301(a)(2) of the Affordable Care Act. A loan recipient that is deemed certified to participate in the Exchanges would be exempt from the certification procedures for each applicable Exchange. To be deemed certified to participate in an Exchange, we proposed that a loan recipient must be in compliance with the terms of the CO–OP program, the Federal standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, and State standards that are applicable to all insurers. CMS or an entity designated by CMS will make a determination regarding whether or not a loan recipient meets these standards based on evidence provided by the loan recipient. CMS or its designee will notify the Exchange in which the loan recipient proposes to operate that the loan recipient is deemed certified to participate. Similarly, if a loan recipient loses its deemed status for any reason, CMS or its designee will provide notice to the applicable Exchanges.

The comments we received on the ''deeming'' provisions described in § 156.520(e) of the proposed rule and our responses are provided below.

Comment: Several commenters recommended that CMS subject CO–OPs to the same standards, operational requirements, and certification processes as other health insurance issuers participating in the Exchanges including any competitive bidding process or selective contracting process in order to maintain a level playing field. State regulators requested that CMS defer to the relevant Exchange for certification. Commenters indicated that States are in the best position to assess whether a CO–OP meets the standards of an Exchange. Two commenters welcomed a prominent Federal role in the ''deeming'' of health plans offered by CO–OPs and indicated that such a role would remove a potential barrier to the sponsorship of CO–OPs by Indian tribes and ensure that Indian tribes are not subjected to State-specific attempts to regulate their CO–OP plans.

Response: CO–OPs must comply with all of the same requirements as other qualified health plans. CO–OPs will be subject to the same State and Federal standards as other health insurance issuers to ensure a level playing field. However, to ensure CO–OPs are not held to standards that it is not possible for them to meet as CO–OPs, we have revised the final rule to clarify that to be deemed as certified, loan recipients must meet all State-specific standards established by an Exchange except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP. Enforcing such standards would defeat the statutory purpose of the CO–OP program. CMS (or an entity designated by CMS) will work with each CO–OP to ensure that they are meeting the applicable standards, including program standards.

The goal of the CO–OP program is to provide additional options for consumers in the Exchanges that are consumer governed and consumer focused. The ''deeming'' provision of section 1301(a)(2) of the Affordable Care Act is pursuant to this goal and ensures that qualified health plans offered by CO–OPs are made available to consumers in the Exchanges.

Comment: One commenter requested confirmation that CO–OPs will participate in the reinsurance, risk corridors, and risk adjustment programs envisioned by the Affordable Care Act and thus are subject to the same taxes, assessments, and costs as other qualified health plans.

Response: CO–OPs will participate in the reinsurance, risk corridor, and risk adjustment programs implemented under sections 1341, 1342, and 1343 of the Affordable Care Act as issuers in the individual and small group markets. They are responsible for the same costs as other qualified health plans.

Comment: Commenters expressed concern that deeming CO–OPs for up to 10 years following the life of their loans would remove incentives for CO–OPs to perform at the market standard, harm meaningful competition in the Exchanges, and potentially put consumers at risk. Two commenters recommended that CMS clarify when the 10-year period would begin and that CMS exempt CO–OPs sponsored by an Indian tribe, tribal organization, or an Indian-controlled Managed Care Entity from this time limit so that they could be deemed as certified to participate in the Exchanges indefinitely. Commenters also requested additional information regarding the deeming process.

Response: Based on comments received, we are revising the final rule to implement a recertification process for all loan recipients including CO–OPs sponsored by an Indian tribe, tribal organization, or an Indian-controlled Managed Care Entity. Loan recipients will be deemed as certified to participate in the Exchanges for two years and may apply to CMS for ''deeming'' recertification every two

years for up to a total of 10 years following the date their loans have been fully repaid. To be deemed as certified or recertified to participate in the Exchanges, a loan recipient must provide evidence to CMS (or an entity designated by CMS) that it complies with the applicable Federal and State standards for qualified health plans. If a loan recipient fails to provide sufficient evidence that it is in compliance with Federal and State standards, the organization will no longer be deemed as certified to participate in the Exchanges. Additional information regarding the deeming process will be provided in program guidance.

Comment: One commenter requested clarification regarding whether CMS intends to designate an entity to deem qualified health plans offered by CO–OPs as certified to participate in the Exchanges. In addition, the commenter requested the specific criteria for selecting a designated entity.

Response: Additional information regarding the deeming process will be provided in program guidance.

Comment: One commenter requested confirmation that loan recipients must be accredited as required under section 1311(c)(1)(D)(i) of the Affordable Care Act and recommended giving loan recipients a maximum of 18 months to complete accreditation. The commenter also recommended granting provisional accreditation status, for fulfilling some, but not all, accreditation requirements.

Response: Consistent with section 1322(c)(5) of the Affordable Care Act, loan recipients must meet the same requirements as other similarly situated issuers including rules regarding network adequacy, solvency, and guaranteed issue. Therefore, loan recipients will be subject to the same standards as other health insurers in the Exchanges and must meet the same applicable accreditation requirement.

We have considered the comments received and are finalizing the deeming provisions set forth in § 156.520(e) of the proposed rule with the exceptions described above. Specifically, we have revised the provisions in § 156.520(e) to clarify that loan recipients are deemed as certified to participate in the Exchanges for 2 years and may be recertified every 2 years for up to 10 years following the life of their loans. We have also revised the provisions in § 156.520(e) to clarify that loan recipients will be subject to all State-specific standards established by an Exchange except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP.

6. Conversions

Due to concerns that successful CO–OPs may become targets for conversion to for-profit, non-consumer operated entities, we proposed to prohibit such conversions. Conversions would likely reduce consumer control, limit choice, and weaken competition in the insurance marketplace and would be contrary to the goals of the CO–OP program. We also proposed to prohibit any transaction by a CO–OP that would result in a change to a governance structure that does not meet the standards in § 156.515 or any other program standards. These prohibitions would ensure that loans awarded under this program are used to sustain program goals over time.

The comments we received on the conversion prohibitions described in § 156.520(e) of the proposed rule and our responses are provided below.

Comment: Several commenters expressed strong support for the proposed prohibition on conversions to for-profit or non-consumer operated entities. They indicated that such a conversion would be contrary to the legislative intent and that organizations receiving Federal funding to develop a CO–OP should not be permitted to abandon the mission of the CO–OP program. Commenters requested additional guidance regarding this prohibition and any exceptions to the prohibition. Some commenters recommended allowing CO–OPs to convert to a different organizational structure under certain circumstances, such as to preserve plan coverage, avert plan insolvency, or respond to subsequent changes in the Affordable Care Act. One commenter recommended establishing penalties for CO–OPs that convert to a for-profit or non-consumer governed entity.

Response: We believe that successful CO–OPs may be targets for conversions and agree with commenters that such conversions would be inconsistent with the legislative intent. As a result, we are not implementing any exceptions to this policy. CO–OPs are not permitted to convert to a for-profit or non-consumer operated entity at any time or to partake in any activities that have the effect of such a conversion (for example, selling a substantial portion of its enrollment to a for-profit entity), even after they have fully repaid their Start-up Loans and Solvency Loans. In the potential case of insurer financial distress, a CO–OP follows the same process as traditional issuers and must comply with all applicable State laws and regulations.

We have considered the comments received and are finalizing the provisions set forth in § 156.520(f) of the proposed rule.

F. Comments Beyond the Scope of the Final Rule

In response to the proposed rule, many commenters chose to raise issues that are beyond the scope of the proposed rule. Several of these comments pertain to the provisions of the Funding Opportunity Announcement (FOA) and will be addressed in subsequent program guidance. These comments are summarized below.

Comment: One commenter requested that this final rule prohibit discrimination in the operation of the CO–OP program. In addition, the commenter requested that State law prevail over the minimum protections codified in the CO–OP rules if a State provides additional protections to consumers.

Response: Loan recipients must comply with applicable Federal law regarding discrimination. In addition, we intend to include provisions in the loan agreement with each loan recipient that will prohibit discrimination. Under section 1322(c) of the Affordable Care Act, a CO–OP must meet all State standards for licensure under the market reforms outlined in the Affordable Care Act. Per § 156.520(e) of this subpart, CO–OPs must also comply with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange that apply to all qualified health plans, and the standards of the CO–OP program.

Comment: One commenter expressed concern that the Governance and Licensure criteria in the FOA do not sufficiently emphasize the importance of the licensure requirements. The commenter recommended that licensure requirements account for up to five points in the application reviews.

Response: The review criteria for CO–OP loan applications are addressed in the Funding Opportunity Announcement. We recognize that establishing a reasonable strategy for achieving licensure is critical for the success of every prospective CO–OP.

Comment: One commenter suggested that this final rule explicitly require Federally Qualified Health Centers (FQHCs), or at least ''safety net providers,'' to be included in the provider networks of all CO–OPs since FQHCs already demonstrate and will ensure that the CO–OP program succeeds in its purpose of providing care coordination, quality, and efficiency.

Response: Section 1311(c)(1)(C) of the Affordable Care Act governs the inclusion of safety net providers for issuers that participate in the Affordable Insurance Exchanges.

Comment: Commenters requested clarification regarding whether CO–OPs are required to operate statewide. Two commenters recommended that CMS permit CO–OPs to limit their service areas to regions primarily comprised of Indian reservations and other tribally controlled land. One commenter recommended that an applicant's feasibility study dictate how quickly a CO–OP expands its service area. Another commenter requested clarification regarding whether an applicant can receive preference in the application reviews if they plan to offer coverage initially in a local service area and then expand to statewide.

Response: Loan recipients are not required to offer coverage statewide. For CO–OPs that intend to provide coverage across an entire State, we recognize that depending on local market conditions, it may be more prudent for a CO–OP to offer coverage in a locally defined service area first and then expand coverage to the entire State. However, applicants should define a potential service area in conjunction with the State insurance department, as they must comply with all applicable State laws. Accordingly, as indicated in the FOA, applicants will be awarded points toward their application review based on their ability to operate statewide over time. Applicants may also receive points towards their application review by providing evidence of private support or submitting a reasonable plan to provide integrated or coordinated care.

Comment: One commenter recommended that CMS encourage all applicants to build expenses related to networking and information sharing into their financial projections and business plans.

Response: Networking and information sharing between CO–OPs will be beneficial for CO–OPs. Reasonable expenses related to information sharing may be eligible costs funded through Start-up Loans.

Comment: One commenter recommended that CMS re-invest funds that have been paid back by loan recipients to capitalize future CO–OP applicants.

Response: We are not authorized under the statute to award additional loans using repaid loan amounts.

Comment: One commenter recommended that we increase the $100,000 limit on the retroactive reimbursement of costs associated with preparing a feasibility study and business plan for the CO–OP loan application.

Response: See section IV.E. of the FOA for more information regarding the start-up costs eligible for retroactive reimbursement. We recognize that there are other costs that applicants may incur in developing their applications. Therefore, applicants are encouraged to solicit private support (for example, grants and in-kind services) to assist with these costs.

Comment: We received a comment regarding whether we envision CO–OPs competing with one another if their service areas overlap.

Response: The statute permits us to award loans to multiple applicants in a State if there is sufficient funding. Loans will be awarded, in part, based on the feasibility of an applicant developing a viable CO–OP given existing and expected market conditions. We will examine the service areas in evaluating CO–OP applications and implementation to ensure actuarial viability of the CO–OPs.

Comment: One commenter requested additional information regarding the technical assistance that CMS will offer to applicants and loan recipients. Another commenter recommended that CMS identify other organizations to provide technical assistance, if CMS does not intend to perform this function.

Response: As stated in the FOA, technical assistance and support will be provided to applicants and loan recipients as available and when deemed appropriate. Information regarding available technical assistance will be provided in subsequent program guidance.

Comment: One commenter requested that CMS permit CO–OPs to outsource administrative functions to organizations such as private purchasing councils.

Response: Under section 1322(d)(1) of the statute, CO–OPs may establish private purchasing councils to enter into collective purchasing arrangements for administrative services to increase administrative and cost efficiencies. As described in the FOA, the costs associated with establishing a private purchasing council are eligible costs for Start-up Loans.

Comment: One commenter requested guidance regarding whether CO–OPs must provide additional reporting demonstrating compliance with Federal law. Another commenter recommended that CMS establish an autonomous body, with the power to issue sanctions, to monitor CO–OPs and ensure that the goals of the CO–OP program are met.

Response: As described in the FOA, CMS will closely monitor and assess the performance of each loan recipient in complying with Federal law, the requirements of the CO–OP program including its reporting requirements, and the specific terms of its loan agreement.

Comment: One commenter stated that CO–OPs offer a unique opportunity for providers to foster emerging models of integrated delivery systems, improve quality and health outcomes, and reduce costs. When reviewing CO–OP loan applications, the commenter recommended that CMS consider an applicant's plan to collect quantifiable health outcomes data, their willingness to adjust clinical behavior based on the informatics collected, and the likelihood that they will minimize costs and achieve improvements in patient outcomes through reliance on quantifiable data metrics. The commenter provided specific examples of questions that should be asked of CO–OPs in order to ensure the most efficient patient outcomes.

Response: We share the commenter's goals of improved patient care and improved health outcomes. The extent to which an applicant intends to monitor quality of care and use information technology to evaluate and improve care outcomes are components of the operational criteria used in the evaluation of CO–OP loan applications as described in the FOA.

Comment: Several commenters suggested that CMS allow CO–OPs to use or implement new care models, systems, and products over time such as value-based insurance design (VBID) products.

Response: CO–OPs have the flexibility to implement care models, systems, and products that best serve the needs of their members as long as the CO–OP abides by the standards and requirements set forth in this final rule, the FOA, the loan agreement, and other program guidance. In accordance with the statute, care models that improve the integration or coordination and value of care will receive points contributing to the overall score of their application in the award of loans.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection

should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency;
- The accuracy of our estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited comments on the extension of the information collection requests associated with the implementation of the CO–OP program (for example, application, reporting) currently approved under 0938–1139 in a 60-day notice that was published in the **Federal Register** on August 5, 2011 (76 FR 47591). OMB previously reviewed and approved the Information Collection Request under emergency processing according to 5 CFR 1320.13. We did not receive any public comments regarding this extension and therefore, are finalizing the information collection.

IV. Regulatory Impact Analysis (RIA)

A. Introduction

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for rules with economically significant effects ($100 million or more in any 1 year). This final rule is economically significant. Accordingly, the Office of Management and Budget has reviewed this final rule.

B. Summary and Need for Regulatory Action

The Affordable Care Act established the CO–OP program and requires CMS to promulgate regulations to implement this program. The purpose of this program is to create a new CO–OP in every State to expand the number of qualified health plans available in the Exchanges with a focus on integrated care and greater plan accountability.

Only a handful of insurance choices are available that are sponsored and managed by entities primarily focused on meeting the health insurance needs and preferences of consumers, as determined directly by consumers or their elected representatives. There are four issuers in the country that meet this standard, located in the States of Minnesota, Washington, Idaho, and Wisconsin. The combined membership for these four health insurance cooperatives is approximately 2.1 million, meaning that the current CO–OP market share is a little over one percent of the total enrollment in the private insurance market.[1]

There are $3.8 billion in appropriations for loan subsidy and program administration costs to assist sponsoring organizations in creating such plans and to do so with enough capital and reserves to become licensed and ultimately effective competitors in State insurance markets. These funds will enable CO–OPs to use Federal government loans (''Solvency Loans'') to meet the requirements for risk-based capital that State insurance departments require of health plans to ensure that they will be able to meet future obligations they have contractually promised their enrollees.

The Affordable Care Act, as implemented through this regulation, prohibits issuers that existed on July 16, 2009 from participating in the CO–OP program but allows CO–OPs to use experienced managers and health care organizations to manage the functions they have to perform in providing health insurance. Further, as indicated throughout the preamble to this final rule, the CO–OP Advisory Board in its advice to the Secretary and the Department has consistently favored provisions that would give CO–OPs flexibility, within the statutory boundaries, in setting up and operating these plans. At least two-thirds of a CO–OP's activities must consist of the issuance of policies in the individual and small group market.

C. Costs

There will be costs involved in administration of the program, and we currently estimate that these could be approximately $10 million a year on an annualized present value basis, as shown in the Accounting Statement. Actual administrative costs may be higher or lower, and are expected to vary over time.

D. Transfers

As previously explained, the Congress has provided $3.8 billion to assist sponsoring organizations in creating CO–OPs with enough capital and reserves to become licensed and ultimately effective competitors in State insurance markets.[2] The capital requirements for CO–OPs would be financed, in part, by member premiums and in part by the $3.8 billion appropriation.

The net Federal subsidies provided through CO–OP Start-up and Solvency Loans are referred to as ''transfers.'' These transfers result from (1) Assessing below-Treasury interest rates over the relevant 5-year (Start-up Loan) and 15-year (Solvency Loan) periods assuming full and timely repayment and (2) losses due to delayed repayment in accordance with the loan terms designed to comply with State insurance regulations, failure to repay in accordance with the loan contract (losses due to default net of loan recoveries), and other factors that affect the cash flows to and from the Federal government resulting from these loans. Actual subsidy costs for these loans will be determined per the requirements of the Federal Credit Reform Act of 1990, as amended (FCRA). The cost to the Federal government of these subsidies is the net present value of all cash flows to and from the Federal government resulting from the loans, excluding administrative costs, and will be recorded at the time they are incurred. These costs and associated transfers will reflect the terms and conditions of the loans as well as the performance of the loans. The business plan, disbursement schedule, and repayment terms will vary for each loan recipient. As such, these transfers are uncertain, and will vary from loan to loan. In the Accounting Statement in Table 1 below, the analysis reflects annualized estimated transfers associated with below-Treasury interest rates over the anticipated repayment period for a notional borrower with $115 million in CO–OP loans ($15 million for start-up funding and $100 million for solvency funding). This analysis assumes full and timely repayment. Consistent with the final rule, we use one percent below the current yields for 5-year U.S. Treasury bonds as the repayment interest rate on Start-up Loans and two percent below the current yields for U.S. Treasury

[1] The membership counts for Health Partners, Group Health Cooperative, and Group Health Cooperative of Eau Claire are based on their testimony to the CO–OP program Advisory Board available at *http://cciio.cms.gov/resources/co_op/index.html*. The membership count for Group Health Cooperative of South Central Wisconsin is based on its annual report available at *https://ghcscw.com/Media/Annual_Report_2010/annual_report_2010_web.pdf*.

[2] We note that these capital requirements are not ''costs'' for the purpose of calculating the benefits and costs of this Federal program. Costs, in the context of this program, are the resources spent on applying for and complying with the terms of the loans.

Bonds with a similar maturity to the repayment terms for the Solvency Loans. There will be additional transfers due to delayed repayment in accordance with the loan terms designed to comply with State insurance regulations, failure to repay in accordance with the loan contract (losses due to default net of loan recoveries), and other factors that affect the cash flows to and from the Federal government resulting from these loans. These transfers may vary significantly between different loans and borrowers. The actual credit subsidy costs will recognize these costs at the time they are incurred, pursuant to FCRA.

E. Benefits

CO–OPs also offer a unique opportunity to foster and spread emerging models of integrated delivery systems, both to improve health outcomes and to lower health costs (see, for example, testimony of Sara Collins before the Advisory Committee, The Consumer Operated and Oriented Plan (CO–OP) Program Under the Affordable Care Act: Potential and Options for Spreading Mission-Driven Integrated Delivery Systems, at *http://www.commonwealthfund.org/~/media/Files/Publications/Testimony/2011/Jan/Collins_CoOp%20testimony_11311.pdf*). CO–OPs can adopt new models and new arrangements that are more patient-centered than the current fragmented delivery system. Improved delivery systems may provide better health outcomes due to coordinated care, better chronic disease management, and improved quality of care.

In addition, by adding competition to State markets, CO–OPs have the potential to promote efficiency, reduce premiums and/or premium growth, and improve service and benefits to enrollees. By their nature, traditional cooperatives, on which the CO–OP program is modeled, focus on responsiveness to their members and accountability to member needs, which may create flexibility to reduce administrative costs. Direct savings could be substantial after the initial start-up period. Resulting attempts to maintain or regain market share by traditional insurance issuers competing with CO–OPs could lead to system-wide savings across millions of enrollees.

F. Alternatives Considered

Throughout this final rule, we have presented and analyzed alternatives, including not only those originally proposed, but also useful options presented in the public comments. In this final rule, we have sought to choose implementation options that would best enable newly formed CO–OPs to offer CO–OP qualified health plans, as this is the primary goal of the program.

The most important alternatives to our originally proposed standards would be to impose either a higher or lower interest repayment on loans. Among the Federal programs providing financial assistance to this sector, many make grants that are not required to be repaid. The Federal government also provides financial assistance through loan programs. Borrower interest rates, in some cases, are higher than Treasury rates, while in other cases rates are subsidized by the Federal government (see the estimates in the Federal Credit Supplement volume of the Budget of the United States Government for FY 2012, at *http://www.gpoaccess.gov/usbudget/fy12/cr_supp.html*). As discussed elsewhere in the preamble, generally commenters agreed with our proposed interest rates and this final rule codifies the proposed interest rates.

We received no comments directed specifically at the Regulatory Impact Analysis. Several commenters did, however, raise the question of potential insolvencies. Specific issues related to reducing the risk of insolvency or managing insolvency are discussed elsewhere in the preamble, as are many issues related to strengthening the ability of CO–OPs to survive in the market for health insurance. We believe that the changes we have made to the proposed rule improve the potential viability of CO–OPs. Most of those who have expressed interest in the program are provider organizations and small business organizations that are likely to be viable because of their private support, healthcare experience, and business expertise.

G. Accounting Statement

As required by OMB Circular A–4, we have prepared an accounting statement. We have provided a quantitative estimate for one hypothetical CO–OP receiving both a Start-up loan of $15 million and a Solvency loan of $100 million, assuming repayment of both in full. The transfers shown are notional estimated costs resulting from below Treasury interest rates over the relevant 5-year (Start-up Loan) and 15-year (Solvency Loan) periods. As previously explained, the notional estimates in Table 1 are not subsidy cost estimates under FCRA and do not include transfers due to delayed payment, defaults net of recoveries, or other losses. Transfers will vary from borrower to borrower and each type is not included in the notional estimate because of uncertainty. Pursuant to FCRA, the lifetime estimated cost will be recorded up front as they are incurred.

Table 1 also reflects estimates of $200 million total for program administration over the first 20 years of the program. Consistent with the final rule, we use 1 percent below the current yields for 5-year U.S. Treasury bonds as the repayment interest rate on Start-up loans and 2 percent below the current yields for the average of 10-year and 20-year U.S. Treasury Bonds as the repayment rate for the Solvency Loans (see *http://www.treasury.gov/resource-center/data-chart-center/interest-rates/Pages/TextView.aspx?data=yield*). The figures shown are the annualized estimated Federal administrative costs for the entire program and estimated means of financing transactions for one notional loan, as described above.

TABLE 1—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS

[$ in millions]

Category	Primary estimate	Units		
		Year dollars	Discount rate	Period covered*
Benefits				
Qualitative: New CO-OP enrollees served may experience better care. There are also potential cost savings system-wide from competitive effects on other health care plans. Net benefits will depend on the extent to which CO-OP plans augment or substitute for other health care insurance and services.				

TABLE 1—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS—Continued

[$ in millions]

Category	Primary estimate	Units		
		Year dollars	Discount rate	Period covered*
Costs				
Qualitative: Costs include administrative burdens associated with applying for and complying with the terms of the loans and program oversight.				
Quantified, Annualized Program Oversight and Administration for all loans ..	$10 $10	2012 2012	7% 3%	2011–31 2011–31
Transfers				
Qualitative: Amounts below reflect means of financing transfer related only to charging below-Treasury rate interest on CO-OP loans to one notional borrower. There are expected transfers in addition to those quantified below that may result from variations in size of loan, delayed repayment, defaults net of loan recoveries, and other potential losses. These transfers vary between loans and borrowers. The full, estimated effects of all such transfers will be recorded up front as costs are incurred, pursuant to FCRA.				
Quantified, Annualized Federal Government Loan Interest Subsidies for 1 notional joint Start-up Loan and Solvency Loan	$5* $1*	2012 2012	7% 3%	2012–31 2012–31

* Reflects notional estimate of transfers related to interest subsidies for one performing loan. Actual costs to the Government will vary loan by loan.

V. Other Requirements for Analysis of Economic Effects

The Regulatory Flexibility Act (RFA) requires agencies to determine whether final rules would have a ''significant economic impact on a substantial number of small entities'' and, if so, to prepare a Regulatory Flexibility Analysis to identify options that could mitigate the impact of the proposed regulation on small businesses.

All CO-OPs established under the program will be private nonprofit organizations and qualify as small entities under the RFA. CMS interprets the requirement as applying only to regulations with negative impacts but routinely prepares a voluntary Regulatory Flexibility Analysis for regulations with significant positive impacts.

The positive economic impacts of the program on CO-OPs will clearly be ''significant,'' particularly in the effects on thousands of small businesses that are likely to purchase insurance through the Exchanges and would benefit from the lower premium costs that CO-OPs will likely create. Moreover, small businesses will have the opportunity to create consortia to help sponsor CO-OPs and may actively pursue these savings. In light of the benefits to these small entities, the Department has prepared a voluntary Regulatory Flexibility Analysis. The preceding economic analysis, together with the remainder of this preamble, constitutes that analysis.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates on State, local, or tribal governments in the aggregate, or on the private sector, require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. This final rule would impose no such mandates. Accordingly, no analysis under UMRA is required.

Executive Order 13132 on Federalism establishes requirements that an agency must meet when a proposed rule imposes substantial costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule does not trigger these requirements.

List of Subjects in 45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Loan programs—health, Organization and functions (Government agencies), Medicaid, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, and Technical Assistance.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B by adding part 156 to read as follows:

PART 156—HEALTH PLAN REQUIREMENTS UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT, INCLUDING REQUIREMENTS RELATED TO EXCHANGES

Subparts A–E—[Reserved]

Subpart F—Consumer Operated and Oriented Plan Program

Sec.

Authority: Secs. 1301–1304, 1311–1312, 1321, 1322, 1324, 1334, 1342–1343, and 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18042).

Subparts A–E—[Reserved]

Subpart F—Consumer Operated and Oriented Plan Program

§ 156.500 Basis and scope.

This subpart implements section 1322 of the Affordable Care Act by establishing the Consumer Operated and Oriented Plan (CO–OP) program to foster the creation of new consumer-governed, private, nonprofit health insurance issuers, known as ''CO–OPs.'' Under this program, loans are awarded to encourage the development of CO–OPs. Applicants that meet the eligibility standards of the CO–OP program may apply to receive loans to help fund start-up costs and meet the solvency requirements of States in which the applicant seeks to be licensed to issue CO–OP qualified health plans. This

subpart sets forth the eligibility and governance requirements for the CO–OP program, CO–OP standards, and the terms for loans awarded under the CO–OP program.

§ 156.505 Definitions.

The following definitions apply to this subpart:

Applicant means an entity eligible to apply for a loan described in § 156.520 of this subpart.

Consumer operated and oriented plan (CO–OP) means a loan recipient that satisfies the standards in section 1322(c) of the Affordable Care Act and § 156.515 of this subpart within the timeframes specified in this subpart.

CO–OP qualified health plan means a health plan that has in effect a certification that it meets the standards established by CMS pursuant to section 1311(c) of the Affordable Care Act, except that the plan can be deemed certified by CMS or an entity designated by CMS as described in § 156.520(e).

Exchange means a governmental agency or non-profit entity that meets the applicable requirements established by CMS, pursuant to sections 1311 and 1321 of the Affordable Care Act, and makes qualified health plans available to qualified individuals and qualified employers. Unless otherwise identified, this term refers to State Exchanges, regional Exchanges, subsidiary Exchanges, and a Federally-facilitated Exchange.

Formation board means the initial board of directors of the applicant or loan recipient before it has begun accepting enrollment and had an election by the members of the organization to the board of directors.

Group health plan has the meaning given to the term in § 144.103 of this subchapter.

Health insurance coverage has the meaning given to the term in § 144.103 of this subchapter.

Individual market means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

Issuer means an insurance company, insurance service, or insurance organization (including a health maintenance organization) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance.

Member means an individual covered under health insurance policies issued by a loan recipient.

Nonprofit member organization or *nonprofit member corporation* means a nonprofit, not-for-profit, public benefit, or similar membership entity organized as appropriate under State law.

Operational board means the board of directors elected by the members of the loan recipient after it has begun accepting enrollment.

Predecessor, with respect to a new entity, means any entity that participates in a merger, consolidation, purchase or acquisition of property or stock, corporate separation, or other similar business transaction that results in the formation of the new entity.

Pre-existing issuer means a health insurance issuer that was in existence on July 16, 2009.

Qualified employer means a small employer that elects to make, at a minimum, all full-time employees of the employer eligible for one or more qualified health plan (QHPs) in the small group market offered through a small business health options program (SHOP). Beginning in 2017, if a State allows large employers to purchase coverage through the SHOP, the term ''qualified employer'' shall include a large employer that elects to make all full-time employees of such employer eligible for one or more QHPs in the large group market offered through the SHOP.

Qualified health plan or *QHP* means a health plan that has in effect a certification that it meets the standards established by CMS pursuant to section 1311(c) of the Affordable Care Act issued or recognized by each Exchange through which such plan is offered pursuant to the process established by CMS pursuant to sections 1311(d) and 1311(e) of the Affordable Care Act.

Qualified nonprofit health insurance issuer means an entity that satisfies or can reasonably be expected to satisfy the standards in section 1322(c) of the Affordable Care Act and § 156.515 of this subpart within the time frames specified in this subpart, until such time as CMS determines the entity does not satisfy or cannot reasonably be expected to satisfy these standards.

Related entity means an entity that shares common ownership, control, or governance structure (including management team or Board members) with a pre-existing issuer, and satisfies at least one of the following conditions:

(1) Retains responsibilities for the services to be provided by the issuer.

(2) Furnishes services to the issuer's enrollees under an oral or written agreement.

(3) Performs some of the issuer's management functions under contract or delegation.

Representative means an individual who stands or acts for an organization or group of organizations through a formal agreement or financial compensation such as a contractor, broker, official, or employee.

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define small employer by substituting ''50 employees'' for ''100 employees.''

SHOP means a Small Business Health Options Program operated by an Exchange through which a qualified employer can provide its employees and their dependents with access to one or more qualified health plans.

Small group market means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer.

Solvency Loan means a loan provided by CMS to a loan recipient in order to meet State solvency and reserve requirements.

Sponsor means an organization or individual that is involved in the development, creation, or organization of the CO–OP or provides 40 percent or more in total funding to a CO–OP (excluding any loans received from the CO–OP Program).

Start-up Loan means a loan provided by CMS to a loan recipient for costs associated with establishing a CO–OP.

State means each of the 50 States and the District of Columbia.

§ 156.510 Eligibility.

(a) *General.* In addition to the eligibility standards set forth in the CO–OP program Funding Opportunity Announcement (FOA), to be eligible to apply for and receive a loan under the CO–OP program, an organization must intend to become a CO–OP and be a nonprofit member organization.

(b) *Exclusions from eligibility.* (1) Subject to paragraph (b)(2) of this section, an organization is not eligible to apply for a loan if:

(i) The organization or a sponsor of the organization is a pre-existing issuer, a holding company (an organization that exists primarily to hold stock in other companies) that controls a pre-existing issuer, a trade association comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, a foundation

established by a pre-existing issuer, a related entity, or a predecessor of either a pre-existing issuer or related entity;

(ii) The organization receives 25 percent or more of its total funding (excluding any loans received from the CO–OP Program) from pre-existing issuers, holding companies (organizations that exists primarily to hold stock in other companies) that control pre-existing issuers, trade associations comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, foundations established by a pre-existing issuer, a related entity, or a predecessor of either a pre-existing issuer or related entity; or

(iii) A State or local government, any political subdivision thereof, or any instrumentality of such government or political subdivision is a sponsor of the organization. The organization receives 40 percent or more of its total funding (excluding any loans received from the CO–OP Program) from a State or local government, any political subdivision thereof, or any instrumentality of such a government or political subdivision.

(2) The exclusions in paragraphs (b)(1)(i) and (b)(1)(ii) of this section do not exclude from eligibility an applicant that:

(i) Has as a sponsor a nonprofit, not-for-profit, public benefit, or similarly organized entity that is also a sponsor for a pre-existing issuer but is not an issuer, a foundation established by a pre-existing issuer, a holding company that controls a pre-existing issuer, or a trade association comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, provided that the pre-existing issuer sponsored by the nonprofit organization does not share any of its board or the same chief executive with the applicant; or

(ii) Has purchased assets from a preexisting issuer provided that it is an arm's-length transaction where each party acts independently and has no other relationship with the other party.

(3) The exclusion of any instrumentality of a State or local government in paragraph (b)(1)(iii) of this section does not exclude from eligibility or sponsorship an organization that:

(i) Is not a government organization under State law;

(ii) Has no employee of a State or local government serving in his or her official capacity as a senior executive (for example, President, Chief Executive Officer, or Chief Financial Officer) for the organization; and

(iii) Has a board of directors on which fewer than half of its directors are employees of a State or local government serving in their official capacities.

§ 156.515 CO–OP standards.

(a) *General.* A CO–OP must satisfy the standards in this section in addition to all other statutory, regulatory, or other requirements.

(b) *Governance requirements.* A CO–OP must meet the following governance requirements:

(1) *Member control.* A CO–OP must implement policies and procedures to foster and ensure member control of the organization. Accordingly, a CO–OP must meet the following requirements:

(i) The CO–OP must be governed by an operational board with all of its directors elected by a majority vote of a quorum of the CO–OP's members that are age 18 or older;

(ii) All members age 18 or older must be eligible to vote for each director on the organization's operational board;

(iii) Each member age 18 or older of the organization must have one vote in the election of each director of the organization's operational board;

(iv) The first elected directors of the organization's operational board must be elected no later than one year after the effective date on which the organization provides coverage to its first member; the entire operational board must be elected no later than two years after the same date;

(v) Elections of the directors on the organization's operational board must be contested so that the total number of candidates for vacant positions on the operational board exceeds the number of vacant positions, except in cases where a seat is vacated mid-term due to death, resignation, or removal; and

(vi) The majority of the voting directors on the operational board must be members of the organization.

(2) *Standards for board of directors.* The operational board for a CO–OP must meet the following standards:

(i) Each director must meet ethical, conflict-of-interest, and disclosure standards including that each director act in the sole interest of the CO–OP and, as appropriate, the health and wellbeing of its local geographic community;

(ii) Each director has one vote unless he or she is a non-voting director;

(iii) Positions on the board of directors may be designated for individuals with specialized expertise, experience, or affiliation (for example, providers, employers, and unions);

(iv) Positions on the operational board that are designated for individuals with specialized expertise, experience, or affiliation cannot constitute a majority of the operational board even if the individuals in those positions are members of the CO–OP. This provision does not prevent any individual from seeking election to the operational board based on being a member of the CO–OP; and

(v) *Limitation on government and issuer participation.* No representative of any Federal, State or local government (or of any political subdivision or instrumentality thereof) and no representative of any organization described in § 156.510(b)(1)(i) may serve on the CO–OP's formation board or operational board.

(3) *Ethics and conflict of interest protections.* The CO–OP must have governing documents that incorporate ethics, conflict of interest, and disclosure standards. The standards must protect against insurance industry involvement and interference. In addition, the standards must ensure that each director acts in the sole interest of the CO–OP, its members, and its local geographic community as appropriate, avoids self dealing, and acts prudently and consistently with the terms of the CO–OP's governance documents and applicable State and Federal law. At a minimum, these standards must include:

(i) A mechanism to identify potential ethical or other conflicts of interest;

(ii) A duty on the CO–OP's executive officers and directors to disclose all potential conflicts of interest;

(iii) A process to determine the extent to which a conflict exists;

(iv) A process to address any conflict of interest; and

(v) A process to be followed in the event a director or executive officer of the CO–OP violates these standards.

(4) *Consumer focus.* The CO–OP must operate with a strong consumer focus, including timeliness, responsiveness, and accountability to members.

(c) *Standards for health plan issuance.* A CO–OP must meet several standards for the issuance of health plans in the individual and small group market.

(1) At least two-thirds of the policies or contracts for health insurance coverage issued by a CO–OP in each State in which it is licensed must be CO–OP qualified health plans offered in the individual and small group markets.

(2) Loan recipients must offer a CO–OP qualified health plan at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in every individual market Exchange that serves the geographic regions in which the organization is licensed and intends to provide health

care coverage. If offering at least one plan in the small group market, loan recipients must offer a CO–OP qualified health plan at both the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in each SHOP that serves the geographic regions in which the organization offers coverage in the small group market.

(3) Within the earlier of thirty-six months following the initial drawdown of the Start-up Loan or one year following the initial drawdown of the Solvency Loan, loan recipients must be licensed in a State and offer at least one CO–OP qualified health plan at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in the individual market Exchanges and if the loan recipient offers coverage in the small group market, at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in the SHOPs. Loan recipients may only begin offering plans and accepting enrollment in the Exchanges for new CO–OP qualified health plans during the open enrollment period for each applicable Exchange.

(d) *Requirement to become a CO–OP.* Loan recipients must meet the standards of § 156.515 no later than five years following initial drawdown of the Start-up Loan or three years following the initial drawdown of a Solvency Loan.

§ 156.520 Loan terms.

(a) *Overview of Loans.* Applicants may apply for the following loans under this section: Start-up Loans and Solvency Loans.

(1) *Use of loans.* All loans awarded under this subpart must be used in a manner that is consistent with the FOA, the loan agreement, and all other statutory, regulatory, or other requirements.

(2) *Solvency loans.* Solvency Loans awarded under this section will be structured in a manner that ensures that the loan amount is recognized by State insurance regulators as contributing to the State-determined reserve requirements or other solvency requirements (rather than debt) consistent with the insurance regulations for the States in which the loan recipient will offer a CO–OP qualified health plan.

(b) *Repayment period.* The loan recipient must make loan payments consistent with the approved repayment schedule in the loan agreement until the loan is paid in full consistent with State reserve requirements, solvency regulations, and requisite surplus note arrangements. Subject to their ability to meet State reserve requirements, solvency regulations, or requisite surplus note arrangements, the loan recipient must repay its loans and, if applicable, penalties within the repayment periods in paragraphs (b)(1), (b)(2), or (b)(3) of this section.

(1) The contractual repayment period for Start-up Loans and any applicable penalty pursuant to paragraph (c)(3) of this section is 5 years following each drawdown of loan funds consistent with the terms of the loan agreement.

(2) The contractual repayment period for Solvency Loans and any applicable penalty pursuant to paragraph (c)(3) of this section is 15 years following each drawdown of loan funds consistent with the terms of the loan agreement.

(3) Changes to the loan terms, including the repayment periods, may be executed if CMS determines that the loan recipient is unable to repay the loans as a result of State reserve requirements, solvency regulations, or requisite surplus note arrangements or without compromising coverage stability, member control, quality of care, or market stability. In the case of a loan modification or workout, the repayment period for loans awarded under this subpart is the repayment period established in the loan modification or workout. The revised terms must meet all other regulatory, statutory, and other requirements.

(c) *Interest rates.* Loan recipients will be charged interest for the loans awarded under this subpart. Interest will be accrued starting from the date of drawdown on the loan amounts that have been drawn down and not yet repaid by the loan recipient. The interest rate will be determined based on the date of award.

(1) *Start-up Loans.* Consistent with the terms of the loan agreement, the interest rate for Start-up Loans is equal to the greater of the average interest rate on marketable Treasury securities of similar maturity minus one percentage point or zero percent. If the loan recipient's loan agreement is terminated by CMS, the loan recipient will be charged the interest and penalty described in paragraph (c)(3) of this section.

(2) *Solvency Loans.* Consistent with the terms of the loan agreement, the interest rate for Solvency Loans is equal to the greater of the average interest rate on marketable Treasury securities of similar maturity minus two percentage points or zero percent. If a loan recipient's loan agreement is terminated by CMS, the loan recipient will be charged the interest and penalty described in paragraph (c)(3) of this section.

(3) *Penalty payment.* If CMS terminates a loan recipient's loan agreement because the loan recipient is not in compliance with program rules or the terms of its loan agreement, or CMS has reason to believe that the organization engages in, or has engaged in, criminal or fraudulent activities or activities that cause material harm to the organization's members or the government, the loan recipient must repay 110 percent of the aggregate amount of loans received under this subpart. In addition, the loan recipient must pay interest on the aggregate amount of loans received for the period the loans were outstanding equal to the average interest rate on marketable Treasury securities of similar maturity.

(d) *Failure to pay.* Loan recipients that fail to make loan payments consistent with the repayment schedule or loan modification or workout approved by CMS will be subject to any and all remedies available to CMS under law to collect the debt.

(e) *Deeming of CO–OP qualified health plans.* Health plans offered by a loan recipient may be deemed certified as a CO–OP qualified health plan to participate in the Exchanges for two years and may be recertified every two years for up to ten years following the life of any loan awarded to the loan recipient under this subpart, consistent with section 1301(a)(2) of the Affordable Care Act.

(1) An Exchange must recognize a health plan offered by a loan recipient as an eligible participant of the Exchange if it is deemed certified by CMS or an entity designated by CMS.

(2) To be deemed as certified to participate in the Exchanges, the plan must comply with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange for qualified health plans operating in that Exchange, except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP, and the standards of the CO–OP program as set forth in this subpart.

(3) A loan recipient seeking to have a plan deemed as certified to participate in the Exchanges must provide evidence to CMS or an entity designated by CMS that the plan complies with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange for qualified health plans operating in that Exchange, except for those State-specific standards that operate to exclude loan recipients due

to being new issuers or based on other characteristics that are inherent in the design of a CO–OP, and the standards of the CO–OP program as set forth in this subpart.

(4) If a plan offered by a loan recipient is deemed to be certified to participate in the Exchanges or loses its deemed status and is no longer certified to participate in the Exchanges, CMS or an entity designated by CMS will provide notice to the Exchanges in which the loan recipient offers CO–OP qualified health plans.

(f) *Conversions.* The loan recipient shall not convert or sell to a for-profit or non-consumer operated entity at any time after receiving a loan under this subpart. The loan recipient shall not undertake any transaction that would result in the CO–OP implementing a governance structure that does not meet the standards in this subpart.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 25, 2011.

Donald Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 29, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–31864 Filed 12–8–11; 4:15 pm]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[WT Docket No. 07–250; FCC 08–68]

Amendment of the Commission's Rules Governing Hearing Aid-Compatible Mobile Handsets

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (FCC) announces the effectiveness of hearing aid compatibility requirements that have been approved by the Office of Management and Budget (OMB).

DATES: 47 CFR 20.19(h) and (i), published May 7, 2008 at 73 FR 25566, are effective December 13, 2011.

FOR FURTHER INFORMATION CONTACT: Contact Michael C. Smith, Federal Communications Commission, at (202) 418–0584 or via the Internet at *MichaelC.Smith@fcc.gov.*

SUPPLEMENTARY INFORMATION: On July 2, 2008, the Commission received approval from OMB for a revision to public information collection 3060–0999, which relates to new and modified information collection requirements under §§ 20.19(h) and 20.19(i) of the Commission's hearing aid compatibility rules. The revision was necessitated by the adoption of reporting requirements applicable to manufacturers and service providers, as well as requirements that manufacturers and service providers post certain information on their Web sites regarding the hearing aid-compatible handsets they offer. As the Commission previously announced the OMB approval on July 21, 2008, 73 FR 42344, the above-referenced rule sections are effective.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011–31988 Filed 12–12–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 110908575–1687–03]

RIN 0648–BB27

Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; 2012 Specifications and Management Measures and Secretarial Amendment 1

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This final rule establishes the 2012 harvest specifications and management measures for certain groundfish species taken in the U.S. exclusive economic zone (EEZ) off the coasts of Washington, Oregon, and California consistent with the Magnuson-Stevens Fishery Conservation and Management Act and the Pacific Coast Groundfish Fishery Management Plan (PCGFMP). This action includes regulations to implement Secretarial Amendment 1 to the PCGFMP. Secretarial Amendment 1 contains the rebuilding plans for overfished species and new reference points for assessed flatfish species.

DATES: This rule is effective January 1, 2012.

ADDRESSES: Information relevant to this final rule, which includes a final environmental impact statement (FEIS), a regulatory impact review (RIR), and a final regulatory flexibility analysis (FRFA) is available for public review during business hours at the office of the Pacific Fishery Management Council (Council), at 7700 NE Ambassador Place, Portland, OR 97220, phone: (503) 820–2280. Copies of additional reports referred to in this document may also be obtained from the Pacific Fishery Management Council.

FOR FURTHER INFORMATION CONTACT: Sarah Williams, phone: (206) 526–4646, fax: (206) 526–6736, or email: *sarah.williams@noaa.gov*

SUPPLEMENTARY INFORMATION:

Electronic Access

This rule is accessible via the Internet at the Office of the **Federal Register** Web site at *http://www.access.gpo.gov/su_docs/aces/aces140.html.* Background information and documents are available at the NMFS Northwest Region Web site at *http://www.nwr.noaa.gov/Groundfish-Halibut/Groundfish-Fishery-Management/index.cfm* and at the Council's Web site at *http://www.pcouncil.org.*

Summary of Provisions in This Final Rule

NMFS published a proposed rule on September 27, 2011 (76 FR 59634) and a Notice of Availability of Secretarial Amendment 1 to the Pacific Coast Groundfish Fishery Management Plan (PCGFMP) on September 9, 2011 (76 FR 55865). The comment periods on both the proposed rule and FMP amendment closed on November 8, 2011. NMFS has approved Secretarial Amendment 1. This final rule implements the provisions from the September 27, 2011, proposed rule, except for the proposed regulatory change to add a geographical split for lingcod at 42° N. latitude. As a consequence, this final rule makes no changes to area-specific management of lingcod, and lingcod continue to be managed as a coastwide stock in 2012.

A discussion of the comments and NMFS's responses can be found in the Changes from the Proposed Rule and Comments and Responses section of this final rule. See the preamble to the proposed rule for additional background information on the fishery and on this final rule. The specifics associated with the development and decision making processes for the rebuilding plans in