

limited to, those specified in the participation agreement with CMS.

**§ 425.212 Changes to program requirements during the agreement term.**

(a)(1) ACOs are subject to all statutory changes that become effective during the term of their participation agreement.

(2) ACOs are subject to all regulatory changes with the exception of the following program areas:

(i) Eligibility requirements concerning the structure and governance of ACOs.

(ii) Calculation of sharing rate.

(iii) Beneficiary assignment.

(b) In those instances where there are changes in law or regulations, the ACO will be required to submit to CMS for review and approval, as a supplement to its original application, an explanation detailing how it will modify its processes to address these changes in law or regulations.

(c) If an ACO does not modify its processes to address a change in law or regulations, it will be placed on a CAP. If the ACO fails to effectuate the necessary modifications while under the CAP, the ACO will be terminated from the Shared Savings Program using the procedures in § 425.218.

(d) An ACO will be permitted to terminate its agreement, in those instances where Shared Savings Program statutory and regulatory standards are established during the agreement period which the ACO believes will impact its ability to continue to participate in the Shared Savings Program.

**§ 425.214 Managing changes to the ACO during the agreement.**

(a)(1) During the term of the participation agreement, an ACO may add or remove ACO participants or ACO providers/suppliers (identified by TINs and NPIs).

(2) An ACO must notify CMS within 30 days of such an addition or removal.

(3) The ACO's benchmark, risk scores, and preliminary prospective assignment may be adjusted for this change at CMS' discretion.

(b) ACOs must notify CMS within 30 days of any significant change. A "significant change" occurs when an ACO

is no longer able to meet the eligibility or program requirements of this Part.

(c) Upon receiving an ACO's notice of a significant change described in paragraph (b) of this section, CMS reevaluates the ACO's eligibility to continue to participate in the Shared Savings Program and may request additional documentation. CMS may make a determination that includes one of the following:

(1) The ACO may continue to operate under the new structure.

(2) The ACO structure is so different from the initially approved ACO that it must terminate its agreement and submit a new application for participation.

(3) The ACO no longer meets the eligibility criteria for the program and its participation agreement must be terminated.

(4) CMS and the ACO may mutually decide to terminate the agreement.

**§ 425.216 Actions prior to termination.**

(a) *Pre-termination actions.* (1) If CMS concludes that termination of an ACO from the Shared Savings Program is warranted, CMS may take one or more of the following actions prior to termination of the ACO from the Shared Savings Program.

(i) Provide a warning notice to the ACO regarding noncompliance with one or more program requirements.

(ii) Request a CAP from the ACO.

(iii) Place the ACO on a special monitoring plan.

(2) Nothing in this part, including the actions set forth in paragraph (a)(1) of this section, negates, diminishes, or otherwise alters the applicability of other laws, rules, or regulations, including, but not limited to, the Sherman Act (15 U.S.C. 1 *et seq.*), the Clayton Act (15 U.S.C. 12), and the Federal Trade Commission Act (15 U.S.C. 45 *et seq.*).

(b) *Corrective action plans.* (1) The ACO must submit a CAP for CMS approval by the deadline indicated on the notice of violation.

(i) The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to the ACO's activities or