

which the forum was held, as well as in its annual report to CMS.

(3) The public forum to solicit feedback on the progress of a demonstration project must occur using one of the following:

(i) A Medical Care Advisory Committee that operates in accordance with § 431.412 of this subpart.

(ii) A commission or other similar process, where meetings are open to members of the public, and would afford an interested party the opportunity to learn about the demonstration's progress.

(iii) The State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

(4) [Reserved]

(d) *Terminations and suspensions.* (1) The Secretary may suspend or terminate a demonstration in whole or in part, any time before the date of expiration, whenever it determines that the State has materially failed to comply with the terms of the demonstration project.

(2) The Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes.

(3) The terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.

(e) *Closeout costs.* When a demonstration is terminated, suspended, or if waivers or expenditure authority are withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination of the demonstration or expenditure authority, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) The State must fully cooperate with CMS or an independent evaluator selected by CMS to undertake an independent evaluation of any component of the demonstration.

(2) The State must submit all requested data and information to CMS or the independent evaluator.

#### § 431.424 Evaluation requirements.

(a) *General.* States are permitted and encouraged to use a range of appropriate evaluation strategies (including experimental and other quantitative and qualitative designs) in the application of evaluation techniques with the approval of CMS.

(b) *Demonstration evaluations.* Demonstration evaluations will include the following:

(1) *Quantitative research methods.* (i) These methods involve the empirical investigation of the impact of key programmatic features of the demonstration.

(ii) CMS will consider alternative evaluation designs when quantitative designs are technically infeasible or not well suited to the change made by the demonstration.

(2) *Approaches that minimize beneficiary impact.* The evaluation process must minimize burden on beneficiaries and protect their privacy in terms of implementing and operating the policy approach to be demonstrated while ensuring the impact of the demonstration is measured.

(c) *Evaluation design plan.* (1) The State will submit and receive CMS approval of a design for an evaluation of the demonstration project and publish this document to the State's public Web site within 30 days of CMS approval.

(2) The draft demonstration evaluation design must include all of the following:

(i) A discussion of the demonstration hypotheses that are being tested including monitoring and reporting on the progress towards the expected outcomes.

(ii) The data that will be utilized and the baseline value for each measure.

(iii) The methods of data collection.

(iv) A description of how the effects of the demonstration will be isolated from those other changes occurring in the State at the same time through the use of comparison or control groups to identify the impact of significant aspects of the demonstration.

**§ 431.428**

(v) A proposed date by which a final report on findings from evaluation activities conducted under the evaluation plan must be submitted to CMS.

(vi) Any other information pertinent to the State's research on the policy operations of the demonstration operations.

(d) *Evaluations for demonstration extensions.* (1) In the event that the State requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the State must submit an interim evaluation report as part of the State's request for a subsequent renewal of the demonstration.

(2) State evaluations must be published on the State's public Web site within 30 days of submission to CMS.

(e) *Approved evaluation designs.* The State must publish the CMS-approved demonstration evaluation design on the State's public Web site within 30 days of CMS approval.

(f) *Federal evaluations.* The State must comply with all requirements set forth in this subpart.

(g) *Federal public notice.* CMS will post, or provide a link to the State's public Web site, all evaluation materials, including research and data collection, on its Web site for purposes of sharing findings with the public within 30 days of receipt of materials.

**§ 431.428 Reporting requirements.**

(a) *Annual reports.* The State must submit an annual report to CMS documenting all of the following:

(1) Any policy or administrative difficulties in the operation of the demonstration.

(2) The status of the health care delivery system under the demonstration with respect to issues and/or complaints identified by beneficiaries.

(3) The impact of the demonstration in providing insurance coverage to beneficiaries and uninsured populations.

(4) Outcomes of care, quality of care, cost of care and access to care for demonstration populations.

(5) The results of beneficiary satisfaction surveys, if conducted during the reporting year, grievances and appeals.

**42 CFR Ch. IV (10–1–13 Edition)**

(6) The existence or results of any audits, investigations or lawsuits that impact the demonstration.

(7) The financial performance of the demonstration.

(8) The status of the evaluation and information regarding progress in achieving demonstration evaluation criteria.

(9) Any State legislative developments that may impact the demonstration.

(10) The results/impact of any demonstration programmatic area defined by CMS that is unique to the demonstration design or evaluation hypothesis.

(11) A summary of the annual post-award public forum, including all public comments received regarding the progress of the demonstration project.

(b) *Submitting and publishing annual reports.* States must submit a draft annual report to CMS no later than 90 days after the end of each demonstration year, or as specified in the demonstration's STCs. The State must publish its draft annual report on its public Web site within 30 days of submission to CMS.

(1) Within 60 days of receipt of comments from CMS, the State must submit to CMS the final annual report for the demonstration year.

(2) The final annual report is to be published on the State's public Web site within 30 days of approval by CMS.

**Subparts H–L [Reserved]**

**Subpart M—Relations With Other Agencies**

**§ 431.610 Relations with standard-setting and survey agencies.**

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(9) of the Act, concerning the designation of State authorities to be responsible for establishing and maintaining health and other standards for institutions participating in Medicaid; and

(2) Section 1902(a)(33) of the Act, concerning the designation of the State licensing agency to be responsible for determining whether institutions and