STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD
Rule 5.000: OVERSIGHT OF ACCOUNTABLE CARE ORGANIZATIONS

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GREEN MOUNTAIN CARE BOARD
RULE 5.000: OVERSIGHT OF ACCOUNTABLE CARE ORGANIZATIONS

I. GENERAL PROVISIONS

5.100 General Provisions

5.101 Authority

The Board adopts this Rule pursuant to 18 V.S.A. §§ 9375(b), 9380, and 9382, and Act 113 (2015 adj. sess.), §§ 6 and 8(b).

5.102 Purpose

This Rule establishes standards and processes the Green Mountain Care Board (Board) will use to certify Accountable Care Organizations (ACOs) and review, modify, and approve the budgets of ACOs. This Rule also establishes mechanisms that will enable the Board to monitor and oversee the activities and performance of ACOs, including enforcement mechanisms by which the Board may limit, suspend, or revoke the certification of an ACO or require an ACO to take remedial action. The Board adopts this Rule to comply with its duties under 18 V.S.A. §§ 9375 and 9382; to provide sufficient oversight of ACOs operating in Vermont to comply with antitrust laws; and to ensure any all-payer, ACO-based payment reform model in Vermont is implemented in a manner that is consistent with the requirements of 18 V.S.A. § 9551 and the health care reform principles of 18 V.S.A. § 9371.

5.103 Definitions

For purposes of this Rule:

1. "Accountable Care Organization" and "ACO" mean an organization of ACO Participants that has a formal legal structure, is identified by a federal Taxpayer Identification Number, and agrees to be accountable for the quality, cost, and overall care of the patients assigned to it.

2. "ACO Participant" and "Participant" mean a Health Care Provider that has, through a formal, written document, agreed to participate in a Payer program with the ACO and collaborate on one or more ACO programs designed to improve Quality of Care and patient experience, and manage costs.

3. "ACO Provider" means an individual or entity that bills for services under the billing number of an ACO Participant.

4. "Actuary" means an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board.

5. "AHS" means the Agency of Human Services established in Title 3, chapter 53 of the Vermont Statutes Annotated.

6. "Applicant" means an ACO that has submitted an application to the Board for certification pursuant to section 5.301 of this Rule.

7. "At-Risk Enrollee" means an Enrollee identified (e.g., through a validated risk adjustment methodology or an analysis of utilization data) as having a significant burden of illness and being someone for whom considerable future health care expenditures are highly likely.

8. "Benchmark" means a Payer-specific financial target against which expenditures for Contracted Services will be assessed. Payer-specific Shared Savings and Shared Losses for an ACO will be determined based on this assessment.

9. "Board" means the Green Mountain Care Board established in Title 18, chapter 220 of the Vermont Statutes Annotated, and any designee of the Board.

10. "Blueprint for Health" means the State program established in Title 18, chapter 13 of the Vermont Statutes Annotated.

11. "Capitation Payment" and "Capitation Payment Arrangement" mean a contractually based payment or prepayment made to an ACO, or an arrangement for such a payment or prepayment to be made, on a per-member per-month or percentage-of-premium basis, in exchange for one or more Contracted Services to be rendered, referred, or otherwise arranged by the ACO.

12. "CMS" means the Centers for Medicare and Medicaid Services, an agency within the United States Department of Health and Human Services.

13. "Contracted Services" means the services for which an ACO is financially responsible, as defined by the terms of its contract with a Payer.

14. "DVHA" means the Department of Vermont Health Access, a department within AHS.

15. "Enrollee" means an individual covered by a Payer holding a contract with an ACO for whom the ACO has, based on a contractually-defined attribution methodology, assumed responsibility for managing cost and Quality of Care.

16. "Budget Year" means the twelve-month period beginning on January 1 and ending on December 31.

17. "The Office of the Health Care Advocate" means the Office established by Title 18, chapter 229 of the Vermont Statutes Annotated.

18. "Health Care Services" has the same meaning as "health service" in 18 V.S.A. § 9373.

19. "Health Care Provider" and "Provider" mean a person, partnership, or corporation, including a health care facility, that is licensed, certified, or otherwise authorized by law to provide Health Care Services in Vermont to an individual during that individual's medical care, treatment, or confinement.

20. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 and its associated rules and regulations, including the Standards for the Privacy of Individually

Identifiable Health Information ("Privacy Rule") and the Security Standards ("Security Rule") at 42 C.F.R. Parts 160 and 164.

21. "NCQA" means the National Committee for Quality Assurance.

22. "Payer" means a third-party health care payer, including (a) CMS; (b) AHS or a department of AHS (e.g., DVHA); (c) a health insurance company or health maintenance organization licensed or certified under the laws of Vermont or another state; and (d) to the extent permitted under federal law, an employer or employee organization that offers a "group health plan" as defined by the federal Employee Retirement and Income Security Act or any third-party administrator for a group health plan.

23. "Primary Care Provider" means a Provider who, within that Provider's scope of practice, principally provides Primary Care Services.

24. "Primary Care Services" include Health Care Services furnished by Providers specifically trained for and skilled in first-contact and continuing care for persons with signs, symptoms, or health concerns, not limited by problem origin (biological, behavioral or social), organ system, or diagnosis (e.g., health promotion, disease prevention, care planning, and the diagnosis and treatment of acute and chronic illness in a variety of health care settings).

25. "Quality Evaluation and Improvement Program" means a set of policies, procedures, and activities designed to improve the Quality of Care and the quality of the ACO's services to Enrollees and Participants by assessing the Quality of Care or service against a set of establish standards and taking action to improve it.

26. "Quality of Care" means the degree to which Health Care Services for individuals and populations increase the likelihood of desired health outcomes, decrease the probability of undesired health outcomes, and are consistent with current professional knowledge or, where available, clinical best practices.

27. "Risk Cap" means the maximum amount of risk an ACO may assume during a given Budget Year.

28. "Risk Contract" means a contract between a Payer and an ACO under which the ACO is responsible for either the full or partial expense, as defined by the contract, of treating or arranging for the treatment of a group of patients, that exceeds a certain amount (e.g., a Benchmark or Capitation Payment).

29. "Shared Loss" means the monetary amount owed to a Payer by an ACO as determined by comparing the ACO's expenditures for Enrollees against the Benchmark for that Payer and accounting for the ACO's performance against any quality measures.

30. "Shared Savings" means the monetary amount owed to an ACO by a Payer as determined by comparing the ACO's expenditures for Enrollees against the Benchmark for that Payer and accounting for the ACO's performance against any quality measures.

5.104 Applicability

This Rule applies to every ACO operating in Vermont or seeking to be certified by the Board.

5.105 Electronic Filing

Unless otherwise specified in this Rule, all documents submitted to or filed with the Board shall be transmitted electronically, pursuant to Board instructions and processes, except where doing so would cause undue hardship to the person submitting or filing the document or where the document cannot readily be converted to electronic form.

5.106 Confidentiality

(a) The Board will make all materials provided to it under this Rule that are not confidential available to persons upon request, consistent with the Vermont Public Records Act.

(b) If any individual or entity believes that materials it provides to the Board under this Rule are exempt from public inspection and copying under Vermont's Public Records Act, the individual or entity must submit to the Board a written request that the Board treat the materials as confidential. A request for confidential treatment must specifically identify the materials claimed by the requestor to be exempt from public inspection and copying and must include a detailed explanation supporting that claim, including references to the applicable provisions of 1 V.S.A. § 317(c) and other law. A request for confidential treatment must be sent to The Office of the Health Care Advocate at the same time it is filed with the Board.

(c) An individual or entity requesting confidential treatment of materials submitted to the Board under this Rule bears the burden of establishing that the materials are exempt from public inspection and copying.

(d) Within fifteen (15) days of receiving a complete and accurate request for confidential treatment, the Board will issue a written decision on the request, except the Board may shorten or lengthen this period for good cause. The Board's decision to grant or deny a request for confidential treatment will be based on the Board's determination as to whether the information identified in the request meets the statutory requirements pertaining to materials exempt from public inspection and copying under Vermont's Public Records Act. The Board will send a copy of its decision to The Office of the Health Care Advocate. Pending a final decision by the Board, the materials identified in the request will be treated as confidential and will not be made available for public inspection and copying.

(e) If the Board grants in full or in part a request for confidential treatment under this section, the Board will not make the confidential materials available for public inspection and copying and will omit references to the materials in the records of any public deliberations.

(f) Notwithstanding anything to the contrary in this section, the Board may disclose confidential and non-confidential information provided to it under this Rule to The Office of the Health Care Advocate, the State Auditor's Office, and other state or federal agencies, departments, offices, boards, or commissions, subject to any confidentiality order, confidentiality agreement, or other protections deemed appropriate by the Board.

5.107 Severability

If any provision of this Rule or the application thereof to any person or circumstance is for any reason held to be invalid, the remaining provisions of the Rule and the application of such provisions to other persons or circumstances shall not be affected thereby.

5.108 Waiver of Rules

In order to prevent unnecessary hardship or delay, in order to prevent injustice, or for other good cause, the Board may waive the application of any provision of this Rule upon such conditions as it may require, unless precluded by the Rule itself or by statute. Any waiver granted by the Board shall be issued in writing and shall specify the grounds upon which it is based.

5.109 Conflict

In the event this Rule or any section thereof conflicts with a Vermont statute or a federal statute, rule, or regulation, the Vermont statute or federal statute, rule, or regulation shall govern.

5.110 Time

In computing any time period established or allowed by this Rule or by order of the Board or its Chair, the day of the act or event from which the designated time period begins to run shall not be included, nor shall weekends or federal or state holidays be included in the calculation if the last day in the time period falls on such weekend or holiday.

5.111 Effective Date

This Rule shall become effective [insert date].

II. CERTIFICATION OF ACOs

5.200 ACO CERTIFICATION REQUIREMENTS

5.201 Legal Entity

(a) An ACO must be a legal entity that is identified by a unique Taxpayer Identification Number, registered with the Vermont Secretary of State, and authorized to conduct business in Vermont for purposes of complying with this Rule and performing ACO activities.

(b) An ACO formed by two or more ACO Participants, each of which is identified by a unique Taxpayer Identification Number, must be formed as a legal entity separate from any of its ACO Participants.

5.202 Governing Body

(a) An ACO must maintain an identifiable governing body that:

1. is the same as the governing body of the legal entity that is the ACO;

2. is separate and unique to the ACO and not the same as the governing body of any ACO Participant, except where the ACO is formed by a single ACO Participant;

3. has sole and exclusive authority to execute the functions of the ACO and to make final decisions on behalf of the ACO; and

4. has ultimate authority and responsibility for the oversight and strategic direction of the ACO and for holding management accountable for the ACO's activities.

(b) An ACO must have a governance structure that reasonably and equitably represents ACO Participants, including a governing body over which at least seventy-five percent (75%) control

is held by or represents ACO Participants. An ACO's governing body must also include the following Enrollee members, whose positions may not be filled by the same person:

1. at least one Enrollee member who is a Medicare beneficiary if the ACO contracts with CMS;

2. at least one Enrollee member who is a Medicaid beneficiary if the ACO contracts with AHS or a department of AHS;

3. for each commercial insurer the ACO contracts with that has a Vermont market share of greater than five percent (5%), at least one Enrollee member who is a beneficiary of that commercial insurer; and

4. at least two Enrollee members, regardless of the number of Payers the ACO contracts with.

(c) An ACO must consult with local advocacy groups (e.g., The Office of the Health Care Advocate) and Provider organizations when recruiting Enrollee members of its governing body. An ACO must make a good faith attempt to recruit and select Enrollee members who are representative of the diversity of consumers served by the ACO, taking into account demographic and non-demographic factors, including gender, race, ethnicity, socioeconomic status, geographic region, medical diagnoses, and services utilized. Each Enrollee member must have experience or training advocating for consumers on health care issues or be provided training on the subject. No Enrollee member may be an ACO Provider or have an immediate family member who is an ACO Provider.

(d) An ACO must, on an ongoing basis, assist the Enrollee members of its governing body in understanding the processes, purposes, and structures of the ACO, as well as specific issues under consideration by the governing body.

(e) Members of an ACO's governing body must have a fiduciary duty to the ACO, including the duty of loyalty, and must act consistent with that fiduciary duty.

(f) An ACO must have a transparent governing process that includes:

1. posting the names and contact information of each governing body member on the ACO's website;

2. holding public meetings of the ACO's governing body in accordance with 18 V.S.A. § 9572(a), (b), and (e);

3. making the governing body's meeting schedule available to the public in accordance with 18 V.S.A. § 9572(c);

4. making recordings or minutes of governing body meetings available to the public in accordance with 18 V.S.A. § 9572(d);

5. posting summaries of ACO activities provided to the ACO's consumer advisory board on the ACO's website; and

6. providing a publicly accessible mechanism for explaining how the ACO works, including by posting on the ACO's website.

(g) An ACO must have regularly scheduled processes for inviting and considering consumer input regarding ACO policy, including a consumer advisory board that meets at least quarterly. The membership of an ACO's consumer advisory board must be drawn from the communities served by the ACO, including Enrollees of each participating Payer and Enrollees' family members and caregivers. Members of an ACO's management team and governing body must regularly attend consumer advisory board meetings and report back to the ACO's governing body following each such meeting. The results of any other consumer input activities undertaken by an ACO (e.g., hosting public forums or soliciting public comments) must be reported to the ACO's governing body at least annually.

(h) At least once per year, an ACO must arrange for the members of its consumer advisory board to meet with representatives of The Office of the Health Care Advocate to discuss their experiences serving on the consumer advisory board and providing input to the ACO. The Office of the Health Care Advocate may report its findings from this meeting to the ACO.

(i) An ACO must have a conflict of interest policy that applies to members of the ACO's governing body and that:

1. imposes on each member of the governing body a continuing duty to disclose relevant financial interests, including relevant financial interests of immediate family members;

2. provides a procedure to determine whether a conflict of interest exists, including a conflict of interest arising from the financial interests of an immediate family member, and sets forth a process to address any conflicts that arise; and

3. addresses remedial action for members of the governing body that fail to comply with the policy.

5.203 Leadership and Management

(a) An ACO must have a leadership and management structure that aligns with and supports the ACO's mission of improving the Quality of Care for individuals and populations, and reducing the rate of growth in health care expenditures.

(b) An ACO's operations must be managed by an executive officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to facilitate improvements in clinical practice that will lead to greater efficiencies and improved health outcomes.

(c) An ACO's clinical management and oversight activities must be managed by a clinical director who is:

1. part of the ACO's senior management team;

2. a board-certified physician actively licensed to practice medicine in the State of Vermont;

3. an ACO Provider; and

4. physically present on a regular basis at any of the clinics, offices, or other locations participating in the ACO.

(d) An ACO must have a compliance plan that is updated periodically to reflect changes in applicable laws, regulations, and guidance, and that includes at least the following elements:

1. An independent compliance officer who:

   A. is neither legal counsel to the ACO nor subordinate to legal counsel to the ACO;

   B. reports directly to the ACO's governing body; and

   C. is responsible for developing and implementing policies, procedures, and standards of conduct designed to ensure the ACO's compliance with all applicable laws, regulations, and guidance;

2. Mechanisms for identifying, investigating, and addressing compliance problems related to the ACO's operations and performance, including mechanisms for internal monitoring and auditing of compliance risks;

3. A method for anonymously reporting compliance concerns to the compliance officer;

4. Compliance training for the ACO, ACO Participants, and ACO Providers; and

5. A requirement to report probable violations of law to the Medicaid Fraud Unit of the Vermont Attorney General's Office and concurrently to any other appropriate governmental agency or official, and identification of the individual or individuals responsible for making such reports.

5.204 Solvency and Financial Stability

(a) An ACO must conduct ongoing assessments of its legal and financial vulnerabilities and have a process for reporting the results of these assessments to the ACO's governing body.

(b) An ACO must ensure that it maintains at all times an adequate level of financial stability and that its solvency will not be threatened by the losses it may incur under any Risk Contracts it has executed or seeks to execute. To ensure compliance with this requirement, the Board will establish a Risk Cap for each risk-bearing ACO as part of the ACO's annual budget. In addition to any other reporting the Board may require of an ACO and any monitoring activities it may undertake under other sections of this Rule, each risk-bearing ACO must also submit quarterly financial reports or statements to the Board in a form or format to be specified by the Board.

5.205 Provider Network

(a) An ACO must execute written agreements with Participants who agree to adhere to the policies of the ACO. The written agreements between an ACO and its Participants must permit the ACO to take remedial actions to address Participants' noncompliance with the ACO's policies, procedures, and standards of conduct, as well as applicable laws and regulations.

(b) An ACO must have appropriate mechanisms and criteria for accepting Providers, including Primary Care Providers and specialists, to be Participants. The ACO's Participant selection

criteria must relate to the needs of the ACO and the Enrollee population it serves, including access to care and Quality of Care. An ACO's Participant selection mechanisms and criteria may not unreasonably discriminate against Providers by, for example, excluding Providers because they:

1. treat or specialize in treating At-Risk Enrollees;

2. provide a higher-than-average level of uncompensated care; or

3. treat a higher proportion of Medicaid or Medicare beneficiaries than the ACO prefers.

(c) Nothing in this section shall be construed to prohibit an ACO from declining to select a Provider to be a Participant, or from terminating or failing to renew the contract of a Participant, based on the Provider's failure to adhere to other legitimate selection criteria established by the ACO or the Participant's failure to conform to or comply with the ACO's established policies, procedures, or standards of conduct.

(d) An ACO must establish an appeal process through which a Provider who is denied participation in the ACO, and a Participant whose contract has been terminated or not renewed by the ACO, may obtain a review of those decision. The ACO's appeal process must require the ACO to give the Provider or Participant a written statement of the reasons for the ACO's decision. The ACO's appeal process must also include reasonable time limits for taking and resolving appeals and provide a reasonable opportunity for Providers and Participants to respond to the ACO's statement of the reasons supporting its decision. An ACO must communicate the requirements of its appeal process to Providers who have been denied participation in the ACO and Participants whose contracts have been terminated or not renewed by the ACO.

5.206 Population Health Management and Care Coordination

(a) A primary function of an ACO is to improve Enrollees' Quality of Care by enhancing coordination and management of the services Enrollees receive. An ACO must collaborate with Payers, Participants, and non-Participant Providers, including community-based provider organizations (e.g., home health and hospice providers, mental health and substance abuse providers, and disability and long-term care providers) and dental providers, as necessary to enhance coordination of services for Enrollees and reduce duplication of services already being provided effectively and efficiently. In order to support individuals and strengthen community support systems, an ACO's care coordination services must be culturally competent, accessible, and personalized to meet individuals' needs.

(b) An ACO must work closely with the Blueprint for Health to integrate the ACO's population health management and care coordination activities with the following Blueprint for Health functions:

1. Transformation infrastructure (practice facilitators and project managers);

2. Establishment of patient centered medical homes;

3. Performance measurement, analytics, and reporting;

4. Regional community collaboratives;

5. Community Health Teams and team-based care coordination activities; and

6. Support and Services at Home.

(c) An ACO must develop policies and procedures regarding care coordination, including physical and mental health care coordination. An ACO must submit these policies and procedures to the Board and make them available to the public. An ACO must monitor and evaluate the effectiveness of its policies and procedures and develop and implement mechanisms to improve coordination and continuity of care based on such monitoring and evaluation. An ACO must encourage and support Participants in using data for measuring and assessing care coordination activities and their effectiveness, to inform program management and improvement activities.

(d) An ACO must consult with and solicit feedback from its consumer advisory board regarding the ACO's care coordination goals, activities, and policies and procedures.

(e) Enrollees may already be receiving care coordination services from another entity or entities when they are attributed to an ACO. In order to maintain or improve Enrollees' access to care and Quality of Care during their transition to the ACO, an ACO must work with or support Participants in working with the Enrollee and the other entity or entities providing care coordination services to determine how the Enrollee should receive care coordination services across organizations.

(f) An ACO must coordinate or support Participants in coordinating Enrollees' care and care transitions (e.g., through the sharing of electronic summary records across providers and the use of telehealth, remote patient monitoring, care management software, electronic shared care planning, and other enabling technologies) across the continuum of care.

(g) Population Stratification for Care Coordination: An ACO must maintain and utilize or support Participants in maintaining and utilizing a data-driven method for evaluating the needs of the ACO's Enrollee population. As part of its population health strategy, an ACO must have a method of systematically identifying Enrollees who need care coordination services, the types of services they should receive, and the entity or entities that should provide those services. The identification process must include risk stratification and screening, and take into consideration factors such as social determinants of health, mental health and substance abuse conditions (within the limits of current data sharing requirements), high cost or high utilization, poorly controlled or complex conditions, or referrals by outside organizations.

(h) Risk Stratification: An ACO must use or support Participants in using an evidence-based risk adjustment tool to help identify Enrollees who might benefit from care coordination services. An ACO must develop or support Participants in developing descriptions of the various care management levels, and must design or support Participants in designing interventions, methods of communication, frequency of communications, and qualifications of staff for each care management level.

(i) Care Plan Development: An ACO must use or support Participants in using an evidence-based process to develop person-directed shared care plans for those Enrollees participating in complex case management. An ACO must:

1. initiate or support Participants in engaging Enrollees and others chosen by the Enrollee in the development of the care plan, including strategies to engage Enrollees with limited English proficiency;

2. use or support Participants in using data from multiple sources in the development of each Enrollee's care plan;

3. coordinate or support Participants in coordinating the services called for in the care plan, in consultation with any other care managers already assigned to an Enrollee by another entity;

4. develop or support Participants in developing a process for reviewing and updating care plans with Enrollees on an as-needed basis;

5. develop or support Participants in developing a protocol for re-evaluating Enrollees who have moved across care management levels; and

6. ensure that the ACO's clinical director or designee is available to consult with clinicians on an Enrollee's complex case management team as needed and with Payers' medical or clinical directors as appropriate.

(j) Enrollee Engagement and Shared Decision-Making: An ACO must apply or support Participants in applying Enrollee and caregiver engagement and shared decision-making processes that take into account Enrollees' unique needs, preferences, values, and priorities. Such processes must:

1. provide Enrollees access to their own medical records and to information on their diagnoses, treatments, and options for future treatment in ways that are understandable to them, so that they can make informed choices about their care;

2. use decision support tools and other methods that enable Enrollees to assess the merits of various treatment options and their relative risks and benefits in the context of their own values and convictions; and

3. act to foster health literacy in Enrollees and their families.

(k) Enrollee Self-Management: An ACO must assist Participants in supporting Enrollee self-management by:

1. offering Enrollees and their families plain language educational resources to assist them in the self-management of their health and disability, if applicable;

2. adopting procedures to help Enrollees and their caregivers understand and implement any self-management plans;

3. offering Enrollees and their families self-management tools that enable them to record self-care results; and

4. facilitating the connection of Enrollees and their families with self-management support programs and resources.

(l) Reporting Requirements: An ACO must provide the Board with information on its population health management and care coordination processes, capabilities, activities, and results, at times and in the manner specified by the Board under section 5.401 of this Rule.

5.207 Quality Evaluation and Improvement

(a) An ACO must develop and implement a quality evaluation and improvement program that is actively supervised by the ACO's clinical director or designee and that includes organizational arrangements and ongoing procedures for the identification, evaluation, resolution, and follow-up of potential and actual problems in health care administration and delivery, as well as opportunities for improvement.

(b) The ACO's quality evaluation and improvement program must regularly evaluate the care delivered to Enrollees against defined measures and standards regarding access to care, Quality of Care, Enrollee and caregiver/family experience, utilization, and cost, for the overall Enrollee population and for key subpopulations (e.g., medically or socially high-needs individuals or vulnerable populations). The ACO must, to the extent possible, align its quality standards and measures with those established by state and national entities.

(c) An ACO must utilize ACO-, community- and Participant-level performance evaluations to provide feedback to Participants and to maintain or improve access to care and Quality of Care for Enrollees.

(d) An ACO must promote evidence-based medicine, including through the adoption, implementation, and periodic assessment and updating of evidence-based practice guidelines for its Participants covering diagnoses with significant potential for the ACO to achieve quality improvements.

5.208 Patient Protections and Support

(a) An ACO may not interfere with Enrollees' freedom to select their own Health Care Providers, consistent with their health plan benefit, regardless of whether the Providers are ACO Participants.

(b) An ACO may not reduce or limit the services covered by an Enrollee's health plan. An ACO may not offer an inducement to a Provider to forego providing medically necessary Health Care Services to an Enrollee or referring an Enrollee to such services.

(c) An ACO may not increase an Enrollee's cost sharing under the Enrollee's health plan.

(d) An ACO must ensure that no Enrollee or person acting on behalf of an Enrollee is billed, charged, or held liable for Contracted Services provided to the Enrollee which the ACO does not pay the Provider for, or for the ACO's debts or the debts of any subcontractor of the ACO in the event of the entity's insolvency. Nothing in this subsection shall prohibit a Provider from collecting coinsurance, deductibles, or copays, if specifically allowed by the Provider's agreement with a Payer.

(e) An ACO may not prohibit a Participant from, or penalize a Participant for:

1. providing information to Enrollees about their health or decisions regarding their health, including the treatment options available to them;

2. advocating on behalf of an Enrollee, including within any utilization review or grievance processes; or

3. reporting in good faith to state or federal authorities any act or practice of the ACO that jeopardizes patient health or welfare.

(f) An ACO must maintain a consumer telephone line for receiving complaints and grievances from Enrollees and, at a minimum, must post the number for this line on its public website. Enrollees that contact the ACO to appeal a benefit decision must be provided with contact information for The Office of the Health Care Advocate and the appropriate Payer's member services line.

(g) In consultation with The Office of the Health Care Advocate, an ACO must establish and maintain a process that provides Enrollees with a reasonable opportunity for a full and fair review of complaints and grievances, including complaints and grievances regarding the quality of care or services received and, for those ACOs that reimburse Providers, the handling of or reimbursement for such services. An ACO must respond to, and make best efforts to resolve, complaints and grievances in a timely manner, including by providing assistance to Enrollees in identifying appropriate rights under their health plan. An ACO must maintain accurate records of all grievances and complaints it receives, including, at a minimum:

1. the detailed reason for and nature of the grievance or complaint;

2. the date the grievance or complaint was received by the ACO;

3. the date the grievance or complaint was reviewed and the individual or individuals that reviewed the grievance or complaint;

4. the manner in which the grievance or complaint was resolved;

5. the date the grievance or complaint was resolved; and

6. copies of all communications between the ACO and the Enrollee or the Enrollee's representative regarding the grievance or complaint.

(h) An ACO must provide complaint and grievance information to the Board and to The Office of the Health Care Advocate at times and in a manner specified by the Board under section 5.401 of this Rule, but in no event less than twice per year. An ACO must ensure that such information is deidentified in accordance with 45 C.F.R. § 164.514.

5.209 Provider Payment

(a) If an ACO will be responsible for reimbursing Participants for delivering Health Care Services, the ACO, or any contractor performing this function on the ACO's behalf, must maintain the required functionality for, and demonstrated proficiency in, administering payments on behalf of Enrollees.

(b) An ACO must ensure that any Alternative Payment Methodologies implemented by the ACO with respect to Participants (e.g., capitation or fixed revenue budgets for hospitals) include incentives to improve performance or maintain a high level of performance on measures

identified by the ACO and Participants and communicated to the Board, including measures of quality and access.

(c) Any performance incentives incorporated into the payment arrangements between a Payer and the ACO must be appropriately reflected in the performance incentives the ACO utilizes with its Participants. The ACO must report to the Board as part of its application under section 5.301 of this Rule, and thereafter as part of the annual budget review process, the ACO's written plans for:

1. aligning Participant payment and compensation with ACO performance incentives for cost and quality; and

2. distributing any earned shared savings.

5.210 Health Information Technology

(a) Data Collection and Integration.

1. To the best of its ability, with the health information infrastructure available, and with the explicit consent of Enrollees (unless otherwise permitted by law), an ACO must use and support its Participants in using an electronic system that:

   A. records structured (searchable) demographic, claims, clinical, and other data or information required to meet the population health management and performance evaluation and improvement needs of the ACO;

   B. supports appropriate access to and sharing of the data or information required to address the care management needs of Enrollees (e.g., patient portals to enhance Enrollee engagement, awareness and self-management; ability of providers to review medication lists for Enrollees; and alerts and notifications regarding critical incidents and hospital admissions, transfers, and discharges); and

   C. provides patients access to their own health care information and otherwise complies with HIPAA and other applicable laws.

(b) Data Analytics.

1. An ACO must apply health information technology to consolidate, standardize, and analyze the data described in subsection (a) of this section.

2. An ACO must integrate data collected from multiple sources to make it actionable, including for:

   A. detecting practice or physician patterns (e.g., referrals, high costs, and variations from best practices);

   B. predictive modeling and patient risk stratification;

   C. identifying variations in care provided to Enrollees; and

   D. understanding Enrollee population characteristics.

3. An ACO must have in place information systems to measure care process improvements, quality improvements, and costs of care, including the ability to retrieve information about individual Provider performance.

4. The financial data systems of a risk-bearing ACO must be sufficient for assessing and managing financial risk and be integrated with clinical data systems.

5.300 APPLICATION PROCEDURES

5.301 Application for Certification

(a) Each ACO that wishes to be certified must submit a complete application to the Board on forms or in a format prescribed by the Board.

(b) An ACO executive (e.g., chief executive officer or president) with authority to legally bind the ACO must sign the application on behalf of the ACO and verify under oath that the information contained in the application is accurate, complete, and truthful to the best of his or her knowledge, information, and belief.

(c) An ACO must provide as part of its application:

1. the names and addresses of the Applicant's actual or expected ACO Participants and a description of the services provided or expected to be provided by each;

2. evidence that the Applicant satisfies the requirements of 18 V.S.A. § 9382(a) and sections 5.201 – 5.210 of this Rule, examples of which may include:

   A. a certificate of good standing or certificate of status from the Vermont Secretary of State;

   B. a copy of the bylaws, operating agreement, or other authoritative documents that regulate the internal affairs of the Applicant;

   C. a list of the Applicant's governing body members that identifies which members are Enrollee members, which members represent Participants, and, for those members that represent Participants, which Participants they represent;

   D. a copy of the conflict of interest policy that applies to members of the Applicant's governing body;

   E. a description of the Applicant's consumer advisory board and its composition and relationship to the Applicant's governing body, as well as a description of any other methods utilized or to be utilized by the Applicant to obtain input from consumers;

   F. materials documenting the Applicant's organization and leadership and management structure (e.g., organizational charts and descriptions of the purpose and makeup of each committee, advisory board, council, or similar group);

   G. a description of, or documents sufficient to describe, the qualifications and experience of the Applicant's management team, including the Applicant's clinical director;

H. a description of, or documents sufficient to describe, the mechanisms the Applicant utilizes or will utilize to assess its legal and financial vulnerabilities and report the results of these assessments to the Applicant's governing body;

I. the Applicant's Participant selection criteria and a description of how these criteria relate to the needs of the Applicant's patient population;

J. a description of, or documents sufficient to describe, the provider appeals process required by section 5.205(d) of this Rule;

K. illustrative copies of the Applicant's agreements with Participants;

L. written descriptions of, or documents sufficient to describe, the Applicant's:

i. population health management and care coordination program;

ii. quality evaluation and improvement program, including the measures and standards the Applicant will utilize to measure the Quality of Care delivered to Enrollees;

iii. grievance and compliant process;

iv. compliance plan;

v. plans for aligning Participant payment and compensation with the ACO's performance incentives and for distributing shared savings; and

vi. health information technology systems and how these systems are used by the Applicant, for example, to coordinate Enrollees' care and measure Participants' performance;

M. a certification that the ACO will comply with the patient protections set forth in section 5.208(a) – (f) of this Rule;

N. any request for deeming under section 5.302 of this Rule;

O. any request for confidential treatment of application materials under section 5.106 of this Rule; and

P. any other documents or materials requested by the Board for the purpose of reviewing the application.

(d) An application must conform to any guidance or bulletins issued by the Board regarding the certification requirements in sections 5.201 through 5.210 of this Rule.

(e) Within thirty (30) days of receiving an application, the Board will review the application and notify the Applicant in writing whether the application is complete or additional information is needed. If the Board notifies an Applicant that it must submit additional information in connection with its application, the Board will specify the deadline for submitting the additional information. The Board's decision to request additional information or allow an Applicant to

amend a deficient or incomplete application is discretionary. It is the Applicant's burden to establish that it is eligible for certification.

5.302 Deeming

(a) The Board may, in its discretion, deem any requirement of 18 V.S.A. § 9382 or this Rule satisfied based on the determination of an accrediting entity (e.g., NCQA) or a state or federal agency (e.g., CMS) that the Applicant satisfies substantially equivalent standards (e.g., NCQA accreditation standards or CMS requirements for participation in the Medicare Next Generation ACO program).

(b) An Applicant must make a written request for deeming to the Board as part of its application. The ACO's request must:

1. specifically identify each of the requirements the Applicant wishes to be deemed;

2. specifically identify the standards of the accrediting entity or state or federal agency that the Applicant considers to be substantially equivalent to each requirement specified in paragraph 1 of this subsection;

3. identify the entity that determined the Applicant met the standards specified in paragraph 2 of this subsection and provide documentation of the determination; and

4. identify the date the entity made the determination specified in paragraph 3 of this subsection and describe any relevant changes that have occurred since the determination was made.

(c) An Applicant that makes a request under subsection (b) of this section must cooperate with the Board in obtaining any other information the Board may require in its consideration of the request. The Board may deny the request of an Applicant that fails to completely and timely supply any materials required by the Board in its consideration of the request.

5.303 Review of Applications; Decisions

(a) An Applicant bears the burden of establishing that its application should be granted.

(b) Failure by an Applicant to provide the Board with complete, accurate, and timely information during the Board's review process may result in rejection of an application.

(c) The Board must evaluate an application and, no later than sixty (60) days after notifying the ACO that the application is complete, either approve, provisionally approve with conditions, or deny the application based on the Board's determination of whether the Applicant satisfies the requirements of 18 V.S.A. § 9382 and this Rule. The review period may be extended with the consent of the Applicant or for good cause.

(d) If the Board approves or provisionally approves an application with conditions, the legal entity described in section 5.201 of this Rule will be eligible to receive payments from Medicaid or a commercial insurer as specified in 18 V.S.A. § 9382(a).

(e) An ACO may seek relief from any condition imposed as part of a provisional certification by filing a written request to the Board. Within sixty (60) days of receiving a request for relief from a condition, the Board will issue a written decision on the request. Failure of an ACO to conform

to a condition within any timeframe established by the Board will result in a denial of the ACO's application.

(f) The following will be considered final actions or orders of the Board, which may be appealed under 18 V.S.A. § 9381:

1. the denial of an application for certification;

2. the provisional approval of an application for certification with conditions; and

3. the denial of a request for relief from a condition imposed by the Board as part of a provisional certification.

5.304 Application Record

(a) The Board must consider each application based on the materials included in the record, as designated and maintained by the Board. The record includes:

1. all materials submitted by the Applicant in connection with the application, including the application and any attachments thereto, as well as any other materials submitted by the Applicant at the Board's request;

2. all written communications between the Board and the Applicant relating to the application;

3. any other materials relied upon by the Board in rendering its decision on the application;

4. the Board's final, written decision on the application; and

5. all materials submitted subsequent to the Board's decision that relate to the application, including any implementation reports required in connection with a provisional certification.

(b) Materials included in the record are public records, pursuant to 1 V.S.A. § 317, unless specifically exempted.

5.305 Annual Eligibility Verifications

(a) An ACO must annually submit to the Board an eligibility verification which:

1. verifies that the ACO continues to meet the requirements of the 18 V.S.A. § 9382 and this Rule; and

2. describes in detail any material changes to the ACO's policies, procedures, programs, organizational structures, provider network, health information infrastructure, or other matters addressed in sections 5.201 through 5.210 of this Rule that the ACO has not already reported to the Board.

(b) The eligibility verification must be signed by an ACO executive with authority to legally bind the ACO, who must verify under oath that the information contained therein is accurate, complete, and truthful to the best of his or her knowledge, information, and belief.

(c) Within thirty (30) days of receiving an eligibility verification, the Board will notify the ACO in writing if additional information is needed to review the ACO's continued eligibility for certification. An ACO's certification remains valid while the Board's review process is pending.

5.400 MONITORING AND ENFORCEMENT

5.401 Reporting to the Board

(a) An ACO must completely, timely, and accurately report to the Board all data and analyses specified by the Board regarding the activities of the ACO, ACO Participants, ACO Providers, and any other individuals or entities performing functions or services related to ACO activities. Subjects on which the Board may require an ACO to report include Quality of Care, access to care, cost, attribution, utilization, complaints and grievances, Provider payments and incentives, solvency, and financial performance. An ACO must, if necessary, require ACO Participants to cooperate in preparing and submitting any required reports to the Board.

(b) An ACO must, upon request, assist the Board in defining data elements, reporting formats, and other reporting requirements.

(c) In addition to the reports an ACO may be required to submit to the Board under subsection (a) of this section, an ACO must report the following changes to the Board within thirty (30) days of their occurrence:

1. changes to the ACO's bylaws, operating agreement, or similar documents;
2. changes to the ACO's senior management team;
3. changes to the ACO's provider selection criteria; and
4. changes to the ACO's grievance and complaint process.

5.402 Public Reporting and Transparency

(a) An ACO must report on a publicly accessible website maintained by the ACO the following:

1. Organizational information, including:
    A. the name and location of the ACO;
    B. the primary contact information for the ACO;
    C. the identity of each ACO Participant;
    D. each joint venture between or among the ACO and any of its Participants; and
    E. the identity of the ACO's key clinical and administrative leaders.
2. Information on Shared Savings and Shared Losses, broken down by line of business (i.e., commercial, Medicaid, and Medicare), including:
    A. the amount of Shared Savings or Shared Losses for any performance year;

B. the proportion of Shared Savings invested in infrastructure, redesigned care processes, and other resources necessary to improve outcomes and reduce costs for Enrollees; and

C. the proportion of savings distributed to ACO Participants and the bases for determining how the savings were distributed;

3. The ACO's performance on quality measures specified by the Board.

5.403 Monitoring

(a) The Board may conduct an evaluation of an ACO's performance in specific areas of operation at any time. Such reviews may be performed in response to:

1. a complaint or grievance from a patient or health care provider or a pattern of such complaints or grievances, including information provided by The Office of the Health Care Advocate;

2. reports submitted by the ACO under section 5.401 of this Rule;

3. analyses of information in the Vermont Health Care Uniform Reporting and Evaluation System; or

4. any other information that has come to the attention of the Board, including information from a Payer.

(b) The Board shall advise an ACO of the specific areas of operation that will be reviewed and the statutory or regulatory provisions under examination.

(c) The Board's monitoring activities may include:

1. interviews with any individual or entity participating in ACO activities, including members of the ACO's leadership and management team, ACO Participants, and ACO Providers;

2. interviews with Enrollees and their families and caregivers;

3. site visits to the offices of the ACO, ACO Participants, or ACO Providers;

4. audits of charts, medical records, financial statements, and other data from the ACO, ACO Participants, and ACO Providers; and

5. documentation requests sent to the ACO, ACO Participants, or ACO Providers, including surveys and questionnaires.

(d) In monitoring an ACO's activities under this Rule, the Board may, in its discretion, rely on any assessment conducted by or on behalf of CMS, DVHA, NCQA, or another entity. An ACO shall provide all such assessments to the Board within ten (10) days of receipt.

5.404 Remedial Actions; Corrective Action Plans

(a) If the Board determines that an ACO, its Participants, or its Providers are failing to meet any requirements of this Rule, 18 V.S.A. § 9382, or any other legal requirements that apply to the operations of the ACO, the Board may, in its discretion, take remedial action against the ACO, including placing the ACO on a monitoring or auditing plan or requiring the ACO to implement a corrective action plan.

(b) Before requiring an ACO to take remedial action, the Board will provide the ACO with a written explanation of the deficiency or deficiencies it has identified and any supporting data. Within thirty (30) days of receiving the Board's explanation and proposal, the ACO must submit a written response to the Board. If the Board's proposal for remedial action is that the ACO implement a corrective action plan, the ACO's written response must include a detailed description of the ACO's plan to correct the identified deficiencies, including the time in which the deficiencies will be corrected.

(c) Within five (5) days of receiving an ACO's written response, the Board will post the response on its website. Within thirty (30) days of receiving an ACO's written response, the Board may, in its discretion, hold a public hearing. The Board will accept public comments for ten (10) days after the ACO's written response has been posted or, if a hearing is held, the hearing has concluded.

(d) A decision of the Board requiring an ACO to take remedial action shall be considered a final action or order, which may be appealed under 18 V.S.A. § 9381.

5.405 Limitation, Suspension, and Revocation of Certification

(a) The Board may limit, suspend, or revoke the certification of an ACO after written notice and an opportunity for review or hearing. Bases for limiting, suspending, or revoking the certification of an ACO include:

1. imminent harm to patients;
2. financial fraud or abuse;
3. fiscal insolvency or significant threat of fiscal insolvency of the ACO;
4. the imposition of sanctions or other actions against the ACO by an accrediting organization or a state, federal, or local government agency leading to an inability of the ACO to comply with the requirements of this Rule or other applicable law;
5. violations of the physician self-referral prohibition, civil monetary penalties law, anti-kickback laws, antitrust laws, or any other applicable federal or state laws, rules, or regulations relevant to the ACO's operations, taking into account any waivers that may apply to the ACO's operations;
6. failure to comply with the requirements a corrective action plan or other remedial actions required by the Board under section 5.404 of this Rule; and
7. failure to adhere to established quality measures.

(b) Hearings under this section shall be conducted by the Board in accordance with 3 V.S.A. §§ 809, 809a, 809b, and 810. Decisions of the Board under this section shall comply with the requirements of 3 V.S.A. § 812 and may be appealed pursuant to 18 V.S.A. § 9381.

III. REVIEW OF ACO BUDGETS AND PAYER PROGRAMS

5.500 Benchmarks and Required Reporting

5.501 Uniform Formats for Data Filings

An ACO must use the methods, formats, charts, and forms set forth in the annual reporting and budget review manual to report its budget and program-related data and information to the Board. The Board shall provide the manual to ACOs by March 1 of each year.

5.502 Establishing Benchmarks

The Board may establish benchmarks for any indicators to be used by ACOs in developing and preparing their proposed budgets. The Board will meet with ACOs and other interested persons to obtain input prior to establishing benchmarks. The established benchmarks will be included in the annual reporting and budget review manual and will assist the Board in determining whether to approve or modify an ACO's proposed budget.

5.503 ACO Duties and Obligations

(a) On or before June 1 of each year, an ACO must file the following information with the Board in a manner specified in the annual reporting and budget review manual:

1. information on the ACO's structure, composition, ownership, governance, and management;

2. the ACO's proposed budget for the next Budget Year, including:

    A. detailed information on the ACO's expected expenditures, costs of operation, and revenues;

    B. a description of how the ACO proposes to distribute Medicare funding for the Blueprint for Health and Support and Services at Home programs; and

    C. if the ACO will bear risk during the next Budget Year, a proposed Risk Cap that the ACO can absorb given the ACO's financial resources, insurance coverage, and other arrangements, which the ACO must support with:

        i. a full risk mitigation plan describing how the ACO would cover the losses it could incur under the Risk Cap (e.g., through reserves, collateral, or other liquid security; risk transfers to ACO Participants; or reinsurance, withholds, or other risk management mechanisms);

        ii. a certification from an actuary that the ACO is financially solvent within the limits of its proposed Risk Cap; and

iii. any other information requested by the Board, which may include information on the ACO's plans to monitor the utilization of Contracted Services under its Risk Contracts;

3. other financial information, such as information on the ACO's reserves, assets, liabilities, fund balances, other income, short- and long-term investments, rates, charges, units of service, and administrative costs, including wage and salary data;

4. information on the ACO's consumer input activities, including its consumer advisory board, and any feedback provided by The Office of the Health Care Advocate as a result of its annual meeting with members of the ACO's consumer advisory board;

5. information on actions, investigations, or findings involving the ACO or its agents or employees;

6. information on the ACO's anticipated network for the next Budget Year, including the identity of ACO Participants and ACO Providers and the Payer programs they will be participating in;

7. information regarding the ACO's Provider payment strategies and methodologies;

8. information regarding each contract the ACO plans execute with a Payer covering any portion of the next Budget Year (e.g., information on attribution, the scope of Contracted Services, payment rates and mechanisms, quality measures, and risk arrangements);

9. information regarding the ACO's models of care, including its population health initiatives and the benefit enhancements it offers;

10. information regarding Enrollees' utilization of Health Care Services and the effects of care models on appropriate utilization, including the provision of innovative services;

11. a projected three-year capital expenditure budget;

12. any reports from professional review organizations or Payers;

13. information on the efforts and incentives described in 18 V.S.A. § 9382(b)(1)(F) – (J) that the ACO plans to make in the next Budget Year (e.g., the ACO's strategies for strengthening primary care and for integrating community-based providers into its care model or expanding community-based provider capacity);

14. information on the ACO's efforts or plans to make its costs transparent and easy to understand for the public; and

15. such other information as the Board may require.

5.600 Annual ACO Budget Review Procedures

5.601 Public Hearing

(a) After an ACO has provided the Board all the information required by section 5.503 of this Rule, the Board shall meet with the ACO to review and discuss the ACO's proposed budget and

the elements of its Payer-programs. The Board shall hold a public hearing concerning a proposed budget submitted by an ACO, except that the Board may decline to hold a hearing concerning a proposed budget submitted by an ACO that is expected to have fewer than 10,000 attributed lives in Vermont during the next Budget Year or that will not be assuming risk during the next Budget Year. At a public hearing convened by the Board concerning an ACO's proposed budget, the Board may require ACO representatives to provide testimony and respond to questions raised by the Board or the public.

(b) The Office of the Health Care Advocate has the right to receive copies of all materials submitted by an ACO under section 5.503 and shall protect such information in conformity with any confidentiality orders or other protections that the Board may require. The Office of the Health Care Advocate may:

1. ask questions of Board employees related to the Board's review of an ACO's proposed budget;
2. submit written questions to the Board that the Board will ask of the ACO in advance of any hearing held under subsection (a) of this section;
3. submit written comments for the Board's consideration; and
4. ask questions and provide testimony in any hearing held under subsection (a) of this section.

5.602 Review Process

(a) The ACO shall have the burden of justifying its proposed budget to the Board.

(b) In deciding whether to approve or modify the proposed budget of an ACO projected to have 10,000 or more attributed lives in Vermont during the next Budget Year, the Board will take into consideration:

1. any benchmarks established under section 5.502 of this Rule;
2. the criteria listed in 18 V.S.A. § 9382(b)(1);
3. the elements of the ACO's Payer-specific programs and any applicable requirements of 18 V.S.A. § 9551 or the Vermont All-Payer Accountable Care Organization Model Agreement between the State of Vermont and CMS; and
4. any other issues at the discretion of the Board.

(c) In deciding whether to approve or modify the proposed budget of an ACO projected to have fewer than 10,000 attributed lives in Vermont during the next Budget Year, the Board will take into consideration:

1. any benchmarks established under section 5.502 of this Rule;
2. those criteria listed in 18 V.S.A. § 9382(b)(1) that the Board deems appropriate to the ACO's size and scope;

3. the elements of the ACO's Payer-specific programs and any applicable requirements of 18 V.S.A. § 9551 or the Vermont All-Payer Accountable Care Organization Model Agreement between the State of Vermont and CMS; and

4. any other issues at the discretion of the Board.

5.603 Establishment of ACO Budgets; Decisions

On or before November 1, the Board will issue a written decision establishing each ACO's budget for the next Budget Year. The decision of the Board is a final action or order, which may be appealed pursuant to 18 V.S.A. § 9381.

5.700 Enforcement

5.701 Budget Performance Review and Adjustment

(a) The Board may conduct an independent review of an ACO's performance under the budget established for it by the Board at any time. If, after conducting such a review, the Board determines that an ACO's performance has varied substantially from its budget, the Board shall provide written notice to the ACO. The notice shall set forth the results of the Board's review, as well as a description of the factors the Board considered.

(b) Upon application of an ACO, the Board may adjust an ACO's budget. In considering an adjustment of an ACO's budget, the Board will consider the financial condition of the ACO and any other factors it deems appropriate.

(c) An ACO must request and receive an adjustment to its budget under subsection (b) of this section prior to executing a Risk Contract that would cause the ACO to exceed a Risk Cap established by the Board as part of the ACO's budget.