STATE LEGISLATIVE AND REGULATORY APPROACHES TO SHARED DECISION MAKING:
A Companion Document To
SHARED DECISION MAKING: ADVANCING PATIENT-CENTERED CARE THROUGH STATE AND FEDERAL IMPLEMENTATION

MARCH 2012
This document is a companion for *Shared Decision Making: Advancing Patient-Centered Care through State and Federal Implementation*. It includes examples of legislation and regulations that states have enacted or considered that are referred to in that report. The purpose is to provide readers with language states have used to implement shared decision making. In some cases, legislation that was vetoed (e.g. Minnesota Omnibus Bill: Patient-Centered Decision-Making) is included because it provides context for the state’s implementation experience. Legislation and other documents that were not discussed in the referenced report are not included in this document. To access that report, please go to follow this [link](#).
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Shared decision making segment
NEW SECTION. Sec. 2. A new section is added to chapter 41.05 RCW to read as follows:

(1) The legislature finds that there is growing evidence that, for preference-sensitive care involving elective surgery, patient-practitioner communication is improved through the use of high-quality decision aids that detail the benefits, harms, and uncertainty of available treatment options. Improved communication leads to more fully informed patient decisions. The legislature intends to increase the extent to which patients make genuinely informed, preference-based treatment decisions, by promoting public/private collaborative efforts to broaden the development, certification, use, and evaluation of effective decision aids and by recognition of shared decision making and patient decision aids in the state's laws on informed consent.

(2) The health care authority shall implement a shared decision-making demonstration project. The demonstration project shall be conducted at one or more multispecialty group practice sites providing state purchased health care in the state of Washington, and may include other practice sites providing state purchased health care. The demonstration project shall include the following elements:

(a) Incorporation into clinical practice of one or more decision aids for one or more identified preference-sensitive care areas combined with ongoing training and support of involved practitioners and practice teams, preferably at sites with necessary supportive health information technology;

(b) An evaluation of the impact of the use of shared decision making with decision aids, including the use of preference-sensitive health care services selected for the demonstration project and expenditures for those services, the impact on patients, including patient understanding of the treatment options presented and concordance between patient values and the care received, and patient and practitioner satisfaction with the shared decision-making process;

(c) As a condition of participating in the demonstration project, a participating practice site must bear the cost of selecting, purchasing, and incorporating the chosen decision aids into clinical practice.

(3) The health care authority may solicit and accept funding and
in-kind contributions to support the demonstration and evaluation, and
may scale the evaluation to fall within resulting resource parameters.

Sec. 3. RCW 7.70.060 and 1975-'76 2nd ex.s. c 56 s 11 are each
amended to read as follows:

(1) If a patient while legally competent, or his or her
representative if he or she is not competent, signs a consent form
which sets forth the following, the signed consent form shall
constitute prima facie evidence that the patient gave his or her
informed consent to the treatment administered and the patient has the
burden of rebutting this by a preponderance of the evidence:

((1))) (a) A description, in language the patient could reasonably
be expected to understand, of:
((a)) (i) The nature and character of the proposed treatment;
((b)) (ii) The anticipated results of the proposed treatment;
((c)) (iii) The recognized possible alternative forms of
treatment; and
((d)) (iv) The recognized serious possible risks, complications,
and anticipated benefits involved in the treatment and in the
recognized possible alternative forms of treatment, including
nontreatment;
((2))) (b) Or as an alternative, a statement that the patient
elects not to be informed of the elements set forth in (a) of this
subsection ((1) of this section)).

(2) If a patient while legally competent, or his or her
representative if he or she is not competent, signs an acknowledgement
of shared decision making as described in this section, such
acknowledgement shall constitute prima facie evidence that the patient
gave his or her informed consent to the treatment administered and the
patient has the burden of rebutting this by clear and convincing
evidence. An acknowledgement of shared decision making shall include:

(a) A statement that the patient, or his or her representative, and
the health care provider have engaged in shared decision making as an
alternative means of meeting the informed consent requirements set
forth by laws, accreditation standards, and other mandates;

(b) A brief description of the services that the patient and
provider jointly have agreed will be furnished;
(c) A brief description of the patient decision aid or aids that have been used by the patient and provider to address the needs for (i) high-quality, up-to-date information about the condition, including risk and benefits of available options and, if appropriate, a discussion of the limits of scientific knowledge about outcomes; (ii) values clarification to help patients sort out their values and preferences; and (iii) guidance or coaching in deliberation, designed to improve the patient's involvement in the decision process;

(d) A statement that the patient or his or her representative understands: The risk or seriousness of the disease or condition to be prevented or treated; the available treatment alternatives, including nontreatment; and the risks, benefits, and uncertainties of the treatment alternatives, including nontreatment; and

(e) A statement certifying that the patient or his or her representative has had the opportunity to ask the provider questions, and to have any questions answered to the patient's satisfaction, and indicating the patient's intent to receive the identified services.

(3) As used in this section, "shared decision making" means a process in which the physician or other health care practitioner discusses with the patient or his or her representative the information specified in subsection (2) of this section with the use of a patient decision aid and the patient shares with the provider such relevant personal information as might make one treatment or side effect more or less tolerable than others.

(4) As used in this section, "patient decision aid" means a written, audio-visual, or online tool that provides a balanced presentation of the condition and treatment options, benefits, and harms, including, if appropriate, a discussion of the limits of scientific knowledge about outcomes, and that is certified by one or more national certifying organizations.

(5) Failure to use a form or to engage in shared decision making, with or without the use of a patient decision aid, shall not be admissible as evidence of failure to obtain informed consent. There shall be no liability, civil or otherwise, resulting from a health care provider choosing either the signed consent form set forth in subsection (1)(a) of this section or the signed acknowledgement of shared decision making as set forth in subsection (2) of this section.
Washington House Bill 1311 (2011)
CERTIFICATION OF ENROLLMENT

ENGROSSED SUBSTITUTE HOUSE BILL 1311

62nd Legislature
2011 Regular Session

Passed by the House April 15, 2011
Yea 58  Nay 38

____
Speaker of the House of Representatives

Passed by the Senate April 6, 2011
Yea 38  Nay 11

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President of the Senate

Approved

CERTIFICATE

I, Barbara Baker, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is ENGROSSED SUBSTITUTE HOUSE BILL 1311 as passed by the House of Representatives and the Senate on the dates hereon set forth.

____
Chief Clerk

FILED

Governor of the State of Washington

Secretary of State
State of Washington
AN ACT Relating to establishing a public/private collaborative to improve health care quality, cost-effectiveness, and outcomes in Washington state; amending RCW 70.250.010 and 70.250.030; adding a new section to chapter 70.250 RCW; creating a new section; and repealing RCW 70.250.020.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. Sec. 1. (1) The legislature finds that:

(a) Efforts are needed across the health care system to improve the quality and cost-effectiveness of health care services provided in Washington state and to improve care outcomes for patients.

(b) Some health care services currently provided in Washington state present significant safety, efficacy, or cost-effectiveness concerns. Substantial variation in practice patterns or high utilization trends can be indicators of poor quality and potential waste in the health care system, without producing better care outcomes for patients.

(c) State purchased health care programs should partner with private health carriers, third-party purchasers, and health care
providers in shared efforts to improve quality, health outcomes, and
cost-effectiveness of care.

(2) The legislature declares that collaboration among state
purchased health care programs, private health carriers, third-party
purchasers, and health care providers to identify appropriate
strategies that will increase the effectiveness of health care
delivered in Washington state is in the best interest of the public.
The legislature therefore intends to exempt from state antitrust laws,
and to provide immunity from federal antitrust laws through the state
action doctrine, for activities undertaken pursuant to efforts designed
and implemented under this act that might otherwise be constrained by
such laws. The legislature does not intend and does not authorize any
person or entity to engage in activities or to conspire to engage in
activities that would constitute per se violations of state and federal
antitrust laws including, but not limited to, agreements among
competing health care providers or health carriers as to the price or
specific level of reimbursement for health care services.

(3) The legislature intends that the Robert Bree collaborative
established in section 3 of this act provide a mechanism through which
public and private health care purchasers, health carriers, and
providers can work together to identify effective means to improve
quality health outcomes and cost-effectiveness of care. It is not the
intent of the legislature to mandate payment or coverage decisions by
private health care purchasers or carriers.

Sec. 2. RCW 70.250.010 and 2009 c 258 s 1 are each amended to read
as follows:
The definitions in this section apply throughout this chapter
unless the context clearly requires otherwise.

(1) "Advanced diagnostic imaging services" means magnetic resonance
imaging services, computed tomography services, positron emission
tomography services, cardiac nuclear medicine services, and similar new
imaging services.

(2) "Authority" means the Washington state health care authority.

(3) "Collaborative" means the Robert Bree collaborative established
in section 3 of this act.

(4) "Payor" means ((public purchasers and)) carriers licensed under
chapters 48.21, 48.41, 48.44, 48.46, and 48.62 RCW.
"Public purchaser" means the department of social and health services, the department of health, the department of labor and industries, the authority, and the Washington state health insurance pool. "Self-funded health plan" means an employer-sponsored health plan or Taft-Hartley plan that is not provided through a fully insured health carrier.

"State purchased health care" has the same meaning as in RCW 41.05.011.

NEW SECTION. Sec. 3. A new section is added to chapter 70.250 RCW to read as follows:

(1) Consistent with the authority granted in RCW 41.05.013, the authority shall convene a collaborative, to be known as the Robert Bree collaborative. The collaborative shall identify health care services for which there are substantial variation in practice patterns or high utilization trends in Washington state, without producing better care outcomes for patients, that are indicators of poor quality and potential waste in the health care system. On an annual basis, the collaborative shall identify up to three health care services it will address.

(2) For each health care service identified, the collaborative shall:

(a) Analyze and identify evidence-based best practice approaches to improve quality and reduce variation in use of the service, including identification of guidelines or protocols applicable to the health care service. In evaluating guidelines, the collaborative should identify the highest quality guidelines based upon the most rigorous and transparent methods for identification, rating, and translation of evidence into practice recommendations.

(b) Identify data collection and reporting necessary to develop baseline health service utilization rates and to measure the impact of strategies adopted under this section. Methods for data collection and reporting should strive to minimize cost and administrative effort related to data collection and reporting wherever possible, including the use of existing data resources and nonfee-based tools for reporting.

(c) Identify strategies to increase use of the evidence-based best practice approaches identified under (a) of this subsection in both
state purchased and privately purchased health care plans. Strategies considered should include, but are not limited to: Identifying goals for appropriate utilization rates and reduction in practice variation among providers; peer-to-peer consultation or second opinions; provider feedback reports; use of patient decision aids; incentives for appropriate use of health care services; centers of excellence or other provider qualification standards; quality improvement systems; and service utilization and outcomes reporting, including public reporting. In developing strategies, the collaborative should strongly consider related efforts of organizations such as the Puget Sound health alliance, the Washington state hospital association, the national quality forum, the joint commission on accreditation of health care organizations, the national committee for quality assurance, the foundation for health care quality, and, where appropriate, more focused quality improvement efforts, such as the Washington state perinatal advisory committee and the Washington state surgical care and outcomes assessment program. The collaborative shall provide an opportunity for public comment on the strategies chosen before finalizing their recommendations.

(3) If the collaborative chooses a health care service for which there is substantial variation in practice patterns or a high or low utilization trend in Washington state, and a lack of evidence-based best practice approaches, it should consider strategies that will promote improved care outcomes, such as patient decision aids, provider feedback reports, centers of excellence or other provider qualification standards, and research to improve care quality and outcomes.

(4) The governor shall appoint twenty members of the collaborative, who must include:

(a) Two members, selected from health carriers or third-party administrators that have the most fully insured and self-funded covered lives in Washington state. The count of total covered lives includes enrollment in all companies included in their holding company system. Each health carrier or third-party administrator is entitled to no more than a single position on the collaborative to represent all entities under common ownership or control;

(b) One member, selected from the health maintenance organization having the most fully insured and self-insured covered lives in Washington state. The count of total lives includes enrollment in all
companies included in its holding company system. Each health
maintenance organization is entitled to no more than a single position
on the collaborative to represent all entities under common ownership
or control;

(c) One member, chosen from among three nominees submitted by the
association of Washington health plans, representing national health
carriers that operate in multiple states outside of the Pacific
Northwest;

(d) Four physicians, selected from lists of nominees submitted by
the Washington state medical association, as follows:

(i) Two physicians, one of whom must be a practicing primary care
physician, representing large multispecialty clinics with fifty or more
physicians, selected from a list of five nominees. The primary care
physician must be either a family physician, an internal medicine
physician, or a general pediatrician; and

(ii) Two physicians, one of whom must be a practicing primary care
physician, representing clinics with less than fifty physicians,
selected from a list of five nominees. The primary care physician must
be either a family physician, an internal medicine physician, or a
general pediatrician;

(e) One osteopathic physician, selected from a list of five
nominees submitted by the Washington state osteopathic medical
association;

(f) Two physicians representing the largest hospital-based
physician systems in the state, selected from a list of five nominees
submitted jointly by the Washington state medical association and the
Washington state hospital association;

(g) Three members representing hospital systems, at least one of
whom is responsible for quality, submitted from a list of six nominees
from the Washington state hospital association;

(h) Three members, representing self-funded purchasers of health
care services for employees;

(i) Two members, representing state purchased health care programs;

and

(j) One member, representing the Puget Sound health alliance.

(5) The governor shall appoint the chair of the collaborative.

(6) The collaborative shall add members to its membership or
establish clinical committees for each therapy under review by the
collaborative for the purpose of acquiring clinical expertise needed to accomplish its responsibilities under this section and RCW 70.250.010 and 70.250.030. Membership of clinical committees should reflect clinical expertise in the area of health care services being addressed by the collaborative, including clinicians involved in related quality improvement or comparative effectiveness efforts, as well as nonphysician practitioners. Each clinical committee shall include at least two members of the specialty or subspecialty society most experienced with the health service identified for review.

(7) Permanent and ad hoc members of the collaborative or any of its committees may not have personal financial conflicts of interest that could substantially influence or bias their participation. If a collaborative or committee member has a personal financial conflict of interest with respect to a particular health care service being addressed by the collaborative, he or she shall disclose such an interest. The collaborative must determine whether the member should be recused from any deliberations or decisions related to that service.

(8) A person serving on the collaborative or any of its clinical committees shall be immune from civil liability, whether direct or derivative, for any decisions made in good faith while pursuing activities associated with the work of collaborative or any of its clinical committees.

(9) The guidelines or protocols identified under this section shall not be construed to establish the standard of care or duty of care owed by health care providers in any cause of action occurring as a result of health care.

(10) The collaborative shall actively solicit federal or private funds and in-kind contributions necessary to complete its work in a timely fashion. The collaborative shall not accept private funds if receipt of such funding could present a potential conflict of interest or bias in the collaborative's deliberations. Available state funds may be used to support the work of the collaborative when the collaborative has selected a health care service that is a high utilization or high-cost service in state purchased health care programs or the health care service is undergoing evaluation in one or more state purchased health care programs and coordination will reduce duplication of efforts. The collaborative shall not begin the work
described in this section unless sufficient funds are received from private or federal resources, or available state funds.

(11) No member of the collaborative or its committees may be compensated for his or her service.

(12) The proceedings of the collaborative shall be open to the public and notice of meetings shall be provided at least twenty days prior to a meeting.

(13) The collaborative shall report to the administrator of the authority regarding the health services areas it has chosen and strategies proposed. The administrator shall review the strategies recommended in the report, giving strong consideration to the direction provided in section 1 of this act and this section. The administrator's review shall describe the outcomes of the review and any decisions related to adoption of the recommended strategies by state purchased health care programs. Following the administrator's review, the collaborative shall report to the legislature and the governor regarding chosen health services, proposed strategies, the results of the administrator's review, and available information related to the impact of strategies adopted in the previous three years on the cost and quality of care provided in Washington state. The initial report must be submitted by November 15, 2011, with annual reports thereafter.

Sec. 4. RCW 70.250.030 and 2009 c 258 s 3 are each amended to read as follows:

(1) No later than September 1, 2009, all state purchased health care programs shall, except for state purchased health care services that are purchased from or through health carriers as defined in RCW 48.43.005, implement evidence-based best practice guidelines or protocols applicable to advanced diagnostic imaging services, and the decision support tools to implement the guidelines or protocols, identified under ((RCW 70.250.020)) section 3 of this act.

(2) By January 1, 2012, and every January 1st thereafter, all state purchased health care programs must implement the evidence-based best practice guidelines or protocols and strategies identified under section 3 of this act, after the administrator, in consultation with participating agencies, has affirmatively reviewed and endorsed the recommendations. This requirement applies to health carriers, as
defined in RCW 48.43.005 and to entities acting as third-party administrators that contract with state purchased health care programs to provide or administer health benefits for enrollees of those programs. If the collaborative fails to reach consensus within the time frames identified in this section and section 3 of this act, state purchased health care programs may pursue implementation of evidence-based strategies on their own initiative.

NEW SECTION. Sec. 5. RCW 70.250.020 (Work group--Members--Duties--Report--Expiration of work group) and 2009 c 258 s 2 are each repealed.

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Washington State Senate Bill 1311 Report
SENATE BILL REPORT
ESHB 1311

As of March 10, 2011

Title: An act relating to establishing a public/private collaborative to improve health care quality, cost-effectiveness, and outcomes in Washington state.

Brief Description: Improving health care in the state using evidence-based care.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Cody, Jinkins, Bailey, Green, Clibborn, Appleton, Moeller, Frockt, Seaquist and Dickerson).

Brief History: Passed House: 3/04/11, 62-35. Committee Activity: Health & Long-Term Care: 3/14/11.

SENATE COMMITTEE ON HEALTH & LONG-TERM CARE

Staff: Mich'l Needham (786-7442)

Background: The Health Care Authority (HCA) administers state employee health benefit programs through the Public Employees Benefits Board, as well as health care programs targeted at low-income individuals, such as the Basic Health Plan and the Community Health Services Grants. In addition, the HCA coordinates initiatives related to state-purchased health care, such as the Prescription Drug Program and the Health Technology Assessment Program. Through the Prescription Drug Program, the state contracts for independent reviews of prescription drugs to compare the safety, efficacy, and effectiveness of drug classes from which recommendations are made by a clinical committee for the development of a preferred drug list. The Health Technology Assessment program reviews scientific, evidence-based reports about the safety and effectiveness of medical devices, procedures, and tests, and a clinical committee determines whether or not the state should pay for them.

Legislation passed in 2009 (Engrossed Substitute House Bill 2105) established a workgroup to be appointed by the HCA, responsible for identifying evidence-based best practices guidelines and decision support tools related to advanced diagnostic imaging services. The workgroup included physicians and private and public health care purchasers. All state-purchased health care programs that purchase services directly were required to implement the guidelines by September 1, 2009. The workgroup expired on July 1, 2010.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.
Summary of Bill: The Robert Bree Collaborative (Collaborative) is established to provide a mechanism for public and private health care purchasers, health carriers, and providers to work together to identify effective means to improve quality health outcomes and cost-effectiveness of care.

The Collaborative consists of 20 members appointed by the Governor. The members include:

- two representatives of health carriers or third party administrators;
- one representative of a health maintenance organization;
- one representative of a national health carrier;
- two physicians representing large multispecialty clinics with 50 or more physicians, one of which is a primary care provider;
- two physicians representing clinics with fewer than 50 physicians, one of which is a primary care provider;
- one osteopathic physician;
- two physicians representing the largest hospital-based physician groups in the state;
- three representatives of hospital systems, at least one of whom is responsible for quality;
- three representatives of self-funded purchasers;
- two representatives of state-purchased health care programs; and
- one representative of the Puget Sound Health Alliance.

The Governor must appoint the chair of the Collaborative, and the HCA must convene the Collaborative. The Collaborative must add members or establish clinical committees to acquire clinical expertise in particular health care service areas under review. No member may be compensated for his or her service. Members of the Collaborative and clinical committees are immune from civil liability for any decisions made in good faith while conducting work related to the Collaborative or its clinical committees. The Collaborative's proceedings must be open to the public and notice of meetings must be provided at least ten days in advance. The Collaborative may not begin its work unless there are sufficient federal or private funds or state funds available through other ongoing health care service review efforts.

The Collaborative must annually identify up to three health care services for which there are substantial variations in practice patterns or high utilization trends in Washington that do not produce better care outcomes and may be indicators of poor quality and potential waste in the health care system.

Upon the identification of such health care services, the Collaborative must identify evidence-based best practices to improve quality and reduce variation in the use of the service. The Collaborative must also identify data collection and reporting for the development of baseline utilization rates and ways to measure the impact of strategies to promote the use of the best practices. To the extent possible, the reporting should minimize cost and administrative effort and use existing data resources.

The Collaborative must also identify strategies to increase the use of the evidence-based practices. The strategies may include:

- goals for appropriate utilization rates;
- peer-to-peer consultation; provider feedback reports;
• use of patient decision aids;
• incentives for the appropriate use of health services;
• centers of excellence or other provider qualification standards;
• quality improvement systems; and
• service utilization and outcome reporting.

In the event that a health care service identified for review lacks adequate information about its benefits, the Collaborative may endorse coverage with evidence development to allow for the collection of additional data to inform patient-oriented outcomes. The Collaborative must strongly consider the efforts of other organizations when developing strategies. The Collaborative must report its findings and recommendations to the Governor and Legislature annually.

All state-purchased health care programs, including health carriers and third party administrators that contract with state programs, must implement the evidence-based practice guidelines and strategies by January 1, 2012, and every subsequent year. If the Collaborative does not reach consensus, state purchased health care programs may implement evidence-based strategies on their own initiative.

The statutory reference to the HCA workgroup that was established to identify evidence-based practices related to advanced diagnostic imaging services for all state-purchased health care programs is repealed.

**Appropriation:** None.

**Fiscal Note:** Requested on March 8, 2011.

**Committee/Commission/Task Force Created:** No.

**Effective Date:** Ninety days after adjournment of session in which bill is passed.
Vermont Senate Bill 129 (2010)
No. 49. An act relating to containing health care costs.

(S.129)

It is hereby enacted by the General Assembly of the State of Vermont:

*** Variation in Health Care Utilization ***

Sec. 1. STUDY OF HEALTH CARE UTILIZATION

(a)(1) The commissioner of banking, insurance, securities, and health care administration shall analyze variations in the use of health care provided both by hospitals and by physicians treating Vermont residents as measured across the appropriate geographic unit or units. The commissioner shall contract with the Vermont program for quality in health care (VPQHC) pursuant to 18 V.S.A. § 9416 and may contract or consult with other qualified professionals or entities as needed to assist in the analysis and recommendations. To the extent possible, the analysis shall include information already available in medical literature and the Vermont quality report.

(2) The purpose of the analysis is to identify treatments or procedures for which the utilization rate varies significantly among geographic regions within Vermont, where the utilization rates are changing faster in one geographic region than another, to determine the reasons for the variations and changes in utilization, and to recommend solutions to contain health care costs by appropriately reducing variation, including by promoting the use of equally or more effective, lower-cost treatments and therapies provided by all health
care professionals licensed in the state. The commissioner may examine the utilization rates of comparable, out-of-state hospitals or entities and regions if necessary to complete this analysis.

(3) The secretary of human services shall collaborate with the commissioner of banking, insurance, securities, and health care administration in the analysis required by this section. To the extent that the agency has data to contribute to the analysis that may not be shared directly, the agency shall provide the analysis to the commissioner of banking, insurance, securities, and health care administration.

(4) The commissioner and the secretary may begin the analysis with the following services:

(A) whose utilization is governed largely by patient preference, including:

(i) cataract surgery;

(ii) joint replacement;

(iii) back surgery; and

(iv) elective cardiac and vascular procedures.

(B) whose utilization appears to be governed largely by the available supply of the service, including:

(i) total physician visits, including to specialists and primary care physicians:
(ii) medical admissions to hospitals, including number of inpatient days and outpatient visits, including emergency room visits;

(iii) ambulatory-sensitive conditions;

(iv) advanced imaging;

(v) diagnostic tests; and

(vi) minor procedures.

(b)(1) In fiscal year 2010, the commissioner of banking, insurance, securities, and health care administration shall collect the same amount under subsection 9416(c) of Title 18 as was collected in state fiscal year 2009 for the expenses incurred under that section.

(2) In fiscal year 2010, the commissioner of banking, insurance, securities, and health care administration may redistribute up to $150,000.00 of the amount collected under subsection 9416(c) of Title 18 in order to ensure that the analyses and report required by this section are completed.

(c) No later than January 15, 2010, the secretary of human services and the commissioner of banking, insurance, securities, and health care administration shall provide a report to the house committee on health care and the senate committee on health and welfare containing a summary of their analysis of health care utilization, including explanations for variations or increases in spending and recommendations for containing health care costs by reducing variation, including promoting the use of equally or more effective lower cost
treatment alternatives, prevention, or other methods of appropriately changing utilization.

Sec. 2. UTILIZATION REVIEW AND REMEDIATION PLAN

No later than January 15, 2010, using the analysis required in Sec. 1 of this act as the primary source of analysis, the commissioner of banking, insurance, securities, and health care administration shall consult with the Vermont Association of Hospitals and Health Systems, Inc., the Vermont Medical Society, insurers, and others to recommend:

(1) A process to ensure appropriate utilization in treatments or procedures across Vermont, including:

(A) identifying inappropriately low or high utilization in a geographic region for which there is a method of changing utilization;

(B) prioritizing variation identified in a geographic region by considering the impact a change in inappropriately low or high variations could have on cost or quality and the potential to develop strategies to rectify inappropriate variations;

(C) determining the causes of inappropriately low or high utilization identified pursuant to the process developed under this subdivision in a particular geographic region;

(D) providing the information gathered pursuant to the process developed under this subdivision to the health care professionals and facilities in the geographic region and in a publicly available format; and
(E) monitoring the health care professionals and facilities in the geographic region’s progress.

(2) Modifications, if any, to existing regulatory processes, including the certificate of need process or the annual hospital budget process.

(3) Solutions to reduce inappropriate low or high utilization, including initiatives to improve public health and change reimbursement methodologies.

(4) Incentives for hospitals and health care professionals to change inappropriately low or high utilization.

* * * Administrative Cost * * *

Sec. 3. HEALTH PLAN ADMINISTRATIVE COST REPORT

(a) No later than December 15, 2009, the commissioner of banking, insurance, securities, and health care administration, in collaboration with the secretary of human services and the commissioner of human resources, shall provide a health plan administrative cost report to the health care reform commission, the house committee on health care, and the senate committee on health and welfare.

(b) The report shall:

(1) identify a common methodology based on the current rules for insurer reports to the department of banking, insurance, securities, and health care administration for calculating costs of administering a health plan in order to provide useful comparisons between the administrative costs of:

(A) private insurers;
(B) entities administering self-insured health plans, including the state employees’ and retirees’ health benefit plans; and

(C) offices or departments in the agency of human services; and

(2) compare administrative costs across the entities in Vermont providing health benefit plans.

* * * Shared Decision-making * * *

Sec. 4. SHARED DECISION-MAKING DEMONSTRATION PROJECT

(a) No later than January 15, 2010, the secretary of administration or designee shall present a plan to the house committees on health care and on human services and the senate committee on health and welfare for a shared decision-making demonstration project to be integrated with the Blueprint for Health. The purpose of shared decision-making shall be to improve communication between patients and health care professionals about equally or more effective treatment options where the determining factor in choosing a treatment is the patient’s preference. The secretary shall consider existing resources and systems in Vermont as well as other shared decision-making models. The plan shall analyze potential barriers to health care professionals participating in shared decision-making, including existing law on informed consent, and recommend solutions or incentives to encourage participation by health care professionals in the demonstration project.

(b) “Shared decision-making” means a process in which the health care professional and patient or patient’s representative discuss the patient’s health
condition or disease, the treatment options available for that condition or disease, the benefits and harms of each treatment option, information on the limits of scientific knowledge on patient outcomes from the treatment options, and the patient’s values and preferences for treatment with the use of a patient decision aid.

* * * Health Care Quality * * *

Sec. 5. BISHCA; REVIEW OF HEALTH QUALITY INITIATIVES

(a) The commissioner of banking, insurance, securities, and health care administration, in collaboration with the Vermont program for quality in health care, shall conduct a review of health care quality organizations in other states and countries to identify and evaluate quality improvement strategies, initiatives, and best practices. The review shall determine how other jurisdictions conduct health care quality reviews, including what types of organizations are providing health care quality analysis, the content of the analysis, the methods used by the organization to do the analysis, and other relevant information.

(b) No later than January 15, 2010, the commissioner shall provide a report to the house committee on health care and the senate committee on health and welfare, including his or her findings, a comparison of Vermont’s program with other jurisdictions, and any recommendations for modifying the program.
**Accountable Care Organization Pilot Project**

Sec. 6. ACCOUNTABLE CARE ORGANIZATION WORK GROUP

(a) It is the intent of the general assembly that all Vermonters receive affordable and appropriate health care at the appropriate time, and that health care costs be contained over time. In order to achieve this goal and to ensure the success of health care reform, it is essential to pursue innovative approaches to a system of health care delivery that integrates health care at a community level and contains costs through community-based payment reform, such as developing an accountable care organization. It is also the intent of the general assembly to ensure sufficient state involvement and action in designing and implementing an accountable care organization in order to comply with federal anti-trust provisions by replacing competition between payers and others with state regulation and supervision.

(b)(1)(A) The commission on health care reform shall convene a work group to support the development of an application by at least one Vermont network of community health care providers for participation in a national accountable care organization (ACO) state learning collaborative sponsored by the Dartmouth Institute for Health Policy and Clinical Practice and the Brookings Institution with the intent that at least one ACO pilot project be implemented in Vermont no later than July 1, 2010. The network of community health care providers shall include primary care professionals, specialists, hospitals, and other health care providers and entities.
(B) An accountable care organization is an entity that enables networks of community health care providers to become accountable for the overall costs and quality of care for the population they jointly serve and to share in the savings created by improving quality and slowing spending growth as described in Fostering Accountable Health Care: Moving Forward in Medicare by Fisher et al, Health Affairs w219, 2009.

(2) The commission shall research other opportunities to create proposals to establish an ACO pilot project or another similar payment reform pilot project, which may become available through participation in a demonstration waiver in Medicare, payment reform in Medicare, national health care reform, or other federal changes that support the development of accountable care organizations.

(c)(1) The commission shall solicit participation in the work group from a broad group of interested stakeholders, including the secretary of administration or designee, the commissioner of banking, insurance, securities, and health care administration or designee, the director of the office of Vermont health access or designee, representatives of private insurers, employers, consumers, and representatives of health care professionals and facilities interested in participating in the ACO pilot project.

(2) To the extent required to avoid federal anti-trust violations, the commissioner of banking, insurance, securities, and health care administration shall facilitate and supervise the participation of health care professionals,
health care facilities, and insurers in the planning and implementation of an accountable care organization. The department shall ensure that the application includes sufficient state supervision over these entities to comply with federal anti-trust provisions. The department shall propose to the commission any legislation necessary for implementation of the ACO pilot project.

(3) The director of the office of Vermont health access shall propose to the commission a plan for including Medicaid, VHAP, and Dr. Dynasaur in the accountable care organization, including a model for recapturing a portion of anticipated savings from participation in an ACO which would be reinvested with health care professionals and facilities. Notwithstanding section 1901 of Title 33, the commission, with consultation from the health access oversight committee may approve the director of Vermont health access’ plan for including Medicaid, VHAP, and Dr. Dynasaur in the ACO pilot project if it is necessary for the director to apply for the waiver amendment outside of the legislative session to ensure implementation of the ACO pilot project no later than July 1, 2010.

(d) The work group shall:

(1) identify local community health care professional and facility networks interested in participating in the ACO pilot project and assist them in qualifying as a site;
(2) develop a financial model for the community provider network involved in the accountable care organization to estimate the fiscal impact of the ACO pilot project on payers, the local community health care professional and facility network, and the state, including a model for recapturing a portion of anticipated savings from participation in an ACO which would be reinvested with health care professionals and facilities; and

(3) ensure that the ACO pilot project proposal is coordinated with the Blueprint for Health, existing medical home projects, and shared decision-making pilot projects.

(e) No later than January 15, 2010, the commission on health care reform shall report to the house committees on health care and human services and the senate committee on health and welfare on the ACO state learning collaborative application, the status of the development of an application by a Vermont network of health care providers, and any proposed legislation necessary for the implementation of the ACO pilot project.

(f) The work group shall cease to exist on January 1, 2011.

Sec. 7. ACCOUNTABLE CARE ORGANIZATION PILOT; MEDICAID WAIVER

If the plan provided for under Sec. 6(c)(3) of this act is approved by the commission on health care reform, the director of Vermont health access shall apply to the Centers on Medicare and Medicaid Services (CMS) for an amendment to the Global Commitment for Health Medicaid Section 1115
waiver to allow for participation in a national accountable care organization state learning collaborative sponsored by the Dartmouth Institute for Health Policy and Clinical Practice and the Brookings Institution.

* * * Health Care Administration * * *

Sec. 8. 18 V.S.A. § 9401 is amended to read:

§ 9401. POLICY

(a) It is the policy of the state of Vermont to ensure that all residents have access to quality health services at costs that are affordable. To achieve this policy it is necessary that the state ensure the quality of health care services provided in Vermont and, until health care systems are successful in controlling their costs and resources, to oversee cost containment.

(b) It is further the policy of the state of Vermont that the health care system should:

(1) Maintain and improve the quality of health care services offered to Vermonters.

(2) Utilize planning, market, and other mechanisms that contain or reduce increases in the cost of delivering services so that health care costs do not consume a disproportionate share of Vermonters’ incomes or the moneys available for other services required to insure the health, safety, and welfare of Vermonters.

(3) Encourage regional and local participation in decisions about health care delivery, financing, and provider supply.
(4) Promote market or other Utilize planning, market, and other mechanisms that will achieve rational allocation of health care resources in the state.

(5) Facilitate universal access to preventive and medically necessary health care.

(6) Support efforts to integrate mental health and substance abuse services with overall medical care.

Sec. 9. 18 V.S.A. § 9402 is amended to read:

§ 9402. DEFINITIONS

* * *

(6) “Health care facility” means all institutions, whether public or private, proprietary or nonprofit, which offer diagnosis, treatment, inpatient, or ambulatory care to two or more unrelated persons, and the buildings in which those services are offered. The term shall not apply to any facility operated by religious groups relying solely on spiritual means through prayer or healing, but includes all institutions included in subdivision 9432(7) 9432(10) of this title, except health maintenance organizations.

* * *

(10) “Health resource allocation plan” means the plan developed adopted by the commissioner and adopted by the governor of banking, insurance, securities, and health care administration under section 9405 of this title.
(11) “Home health agency” means a for-profit or not-for-profit nonprofit health care facility providing part-time or intermittent skilled nursing services and at least one of the following other therapeutic services made available on a visiting basis, in a place of residence used as a patient’s home: physical, speech, or occupational therapy; medical social services; home health aide services; or other non-nursing therapeutic services, including the services of nutritionists, dieticians, psychologists, and licensed mental health counselors.

* * *

(13) “Hospital” means an acute care hospital licensed under chapter 43 of this title and falling within one of the following four distinct categories, as defined by the commissioner by rule:

(A) Category A1: tertiary teaching hospitals.

(B) Category A2: regional medical centers.

(C) Category A3: community hospital systems.

(D) Category A4: critical access hospitals.

* * *

*** Certificate of Need ***

Sec. 10. 18 V.S.A. § 9434 is amended to read:

§ 9434. CERTIFICATE OF NEED; GENERAL RULES

(a) A health care facility other than a hospital shall not develop, or have developed on its behalf a new health care project without issuance of a
certificate of need by the commissioner. For purposes of this subsection, a “new health care project” includes the following:

* * *

(5) The offering of a health care service or technology having an annual operating expense which exceeds $500,000.00 for either of the next two budgeted fiscal years, if the service or technology was not offered or employed, either on a fixed or a mobile basis, by the health care facility within the previous three fiscal years.

(6) The construction, development, purchase, lease, or other establishment of an ambulatory surgical center.

* * *

Sec. 10a. 18 V.S.A. § 9434(b)(3) is amended to read:

(3) The offering of a health care service or technology having an annual operating expense which exceeds $500,000.00 for either of the next two budgeted fiscal years, if the service or technology was not offered or employed, either on a fixed or a mobile basis, by the hospital within the previous three fiscal years.

Sec. 11. 18 V.S.A. § 9440(c)(2) is amended to read:

(c) The application process shall be as follows:

* * *

(2)(A) Prior to filing an application for a certificate of need, an applicant shall file an adequate letter of intent with the commissioner no less than 30
days or, in the case of review cycle applications under section 9439 of this title, no less than 45 days prior to the date on which the application is to be filed. The letter of intent shall form the basis for determining the applicability of this subchapter to the proposed expenditure or action. A letter of intent shall become invalid if an application is not filed within six months of the date that the letter of intent is received or, in the case of review cycle applications under section 9439 of this title, within such time limits as the commissioner shall establish by rule. Except for requests for expedited review under subdivision (5) of this subsection, public notice of such letters of intent shall be provided in newspapers having general circulation in the region of the state affected by the letter of intent. The notice shall identify the applicant, the proposed new health care project, and the date by which a competing application or petition to intervene must be filed. In addition, a copy of the public notice shall be sent to the clerk of the municipality in which the health care facility is located. Upon receipt, the clerk shall post the notice in or near the clerk's office and in at least two other public places in the municipality.

(B) Applicants who agree that their proposals are subject to jurisdiction pursuant to section 9434 of this title shall not be required to file a letter of intent pursuant to subdivision (A) of this subdivision (2) and may file an application without further process. Public notice of the application shall be provided upon filing as provided for in subdivision (A) of this subdivision (2) for letters of intent.
Sec. 12. 18 V.S.A. § 9443 is amended to read:

§ 9443. EXPIRATION OF CERTIFICATES OF NEED

The commissioner shall adopt rules providing for the expiration of certificates of need.

(a) Unless otherwise specified in the certificate of need, a project shall be implemented within five years or the certificate shall be invalid.

(b) No later than 180 days before the expiration date of a certificate of need, an applicant that has not yet implemented the project approved in the certificate of need may petition the commissioner for an extension of the implementation period. The commissioner may grant an extension in his or her discretion.

(c) Certificates of need shall expire on the date the commissioner accepts the final implementation report filed in connection with the project implemented pursuant to the certificate.

(d) An action or expenditure that is related to a service or expenditure that was the subject of a certificate of need shall not be considered a material or nonmaterial change to that project if the original certificate of need expired, as provided in this section, at least two years before the action is proposed. The proposed action shall require a certificate of need only if the change itself would be considered a new health care project under section 9434 of this title.
Sec. 13. 18 V.S.A. § 9432 is amended to read:

§ 9432. DEFINITIONS

As used in this subchapter:

* * *

(2) “Annual operating expense” means that expense which, by generally accepted accounting principles, is incurred by a new health care service during the first fiscal year in which the service is in full operation after completion of the project.

(2)(3) “Applicant” means a person who has submitted an application or proposal requesting issuance of a certificate of need.

(2)(4) “Bed capacity” means the number of licensed beds operated by the facility under its most current license under chapter 43 of this title and of facilities under chapter 71 of Title 33.

(4)(5) “Capital expenditure” means an expenditure for the plant or equipment which is not properly chargeable as an expense of operation and maintenance and includes acquisition by purchase, donation, leasehold expenditure, or lease which is treated as capital expense in accordance to the accounting standards established for lease expenditures by the Financial Accounting Standards Board, calculated over the length of the lease for plant or equipment, and includes assets having an expected life of at least three years. A capital expenditure includes the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the
acquisition, improvement, expansion, or replacement of the plant and equipment.

(5)(6) “Construction” means actual commencement of any construction or fabrication of any new building, or addition to any existing facility, or any expenditure relating to the alteration, remodeling, renovation, modernization, improvement, relocation, repair, or replacement of a health care facility, including expenditures necessary for compliance with life and health safety codes.

(6)(7) “To develop,” when used in connection with health services, means to undertake activities which on their completion will result in the offer of a new health care project, or the incurring of a financial obligation in relation to the offering of a service.

(7)(8) “Health care facility” means all persons or institutions, including mobile facilities, whether public or private, proprietary or not for profit, which offer diagnosis, treatment, inpatient, or ambulatory care to two or more unrelated persons, and the buildings in which those services are offered. The term shall not apply to any institution operated by religious groups relying solely on spiritual means through prayer for healing, but shall include but is not limited to:

* * *

(8)(9) “Health care provider” means a person, partnership, corporation, facility, or institution, licensed or certified or authorized by law to provide
professional health care service in this state to an individual during that individual’s medical care, treatment, or confinement.

(9)(10) “Health services” mean activities and functions of a health care facility that are directly related to care, treatment, or diagnosis of patients.

(11) “Material change” means a change to a health care project for which a certificate of need has been issued which:

(A) constitutes a new health care project as defined in section 9434 of this title; or

(B) increases the total costs of the project by more than 10 percent of the approved amount.

(12) “Nonmaterial change” means a modification that does not meet the cost threshold of a material change as defined in subdivision (11) of this section, but otherwise modifies the kind, scope, or capacity of a project for which a certificate of need has been granted under this subchapter.

(10)(13) “Obligation” means an obligation for a capital expenditure which is deemed to have been incurred by or on behalf of a health care facility or health maintenance organization.

(11)(14) “To offer,” when used in connection with health services, means that a health care provider holds itself out as capable of providing, or as having the means for the provision of, specified health services.

(12) “Annual operating expense” means that expense which, by generally accepted accounting principles, is incurred by a new health care
service during the first fiscal year in which the service is in full operation after completion of the project.

Sec. 14. 18 V.S.A. § 9444 is amended to read:

§ 9444. REVOCATION OF CERTIFICATES; MATERIAL CHANGE

(a) The commissioner may revoke a certificate of need for substantial noncompliance with the scope of the project as designated in the application, or for failure to comply with the conditions set forth in the certificate of need granted by the commissioner.

(b)(1) In the event that after a project has been approved, its proponent wishes to materially change the scope or cost of the approved project, all such changes are subject to review under this subchapter. If a change itself would be considered a new health care project as defined in section 9434 of this title, it shall be considered as material. If the change itself would not be considered a new health care project as defined in section 9434 of this title, the commissioner may decide not to review the change and shall notify the applicant and all parties of such decision. Where the commissioner decides not to review a change, such change will be deemed to have been granted a certificate of need.

2) Applicants shall notify the commissioner of a nonmaterial change to the approved project. If the commissioner decides to review a nonmaterial change, he or she may provide for any necessary process, including a public
hearing, before approval. Where the commissioner decides not to review a change, such change will be deemed to have been granted a certificate of need.

* * * CONSUMER INFORMATION * * *

Sec. 15. CONSUMER HEALTH CARE PRICE AND QUALITY INFORMATION; WEBSITE

On the front page of Vermont’s state government website, the secretary of administration or designee shall prominently post a link, worded in a clear and understandable manner, to the price and quality information for consumers. The price and quality information shall be available in an easy-to-use format that is understandable to the average consumer.

Sec. 16. IMPLEMENTATION

Sec. 12 of this act, amending section 9443 of Title 18, shall apply to certificates of need issued on or after July 1, 2009.

Approved: May 28, 2009
4764.0010 APPLICABILITY AND PURPOSE.

Subpart 1. Applicability. Parts 4764.0010 to 4764.0070 apply to an eligible provider that is an applicant or is certified as a health care home.

Subp. 2. Purpose. Parts 4764.0010 to 4764.0070 establish the standards and procedures for certification of health care homes. The purpose of the standards is to require health care homes to deliver services that:

A. facilitate consistent and ongoing communication among the health care home and the patient and family, and provide the patient with continuous access to the patient's health care home;

B. use an electronic, searchable patient registry that enables the health care home to manage health care services, provide appropriate follow-up, and identify gaps in patient care;

C. include care coordination that focuses on patient and family-centered care;

D. include a care plan for selected patients with a chronic or complex condition, involve the patient and, if appropriate, the patient's family in the care planning process; and

E. reflect continuous improvement in the quality of the patient's experience, the patient's health outcomes, and the cost-effectiveness of services.

4764.0020 DEFINITIONS.

Subpart 1. Scope. The terms used in parts 4764.0010 to 4764.0070 have the meanings given them in this part.

Subp. 2. Applicant. "Applicant" means an eligible provider that has applied for certification or recertification under parts 4764.0010 to 4764.0070.

Subp. 3. Care coordination. "Care coordination" means a team approach that engages the participant, the personal clinician or local trade area clinician, and other
members of the health care home team to enhance the participant's well-being by
organizing timely access to resources and necessary care that results in continuity of
care and builds trust.

Subp. 4. **Care coordination payment system.** "Care coordination payment system"
means a system established under Minnesota Statutes, section 256B.0753, subdivision 1,
or 62U.03, paragraph (a), to compensate health care homes.

Subp. 5. **Care coordinator.** "Care coordinator" means a person who has primary
responsibility to organize and coordinate care with the participant in a health care home.

Subp. 6. **Care plan.** "Care plan" means an individualized written document,
including an electronic document, to guide a participant's care.

Subp. 7. **Chronic condition.** "Chronic condition" means a medical condition that
has lasted at least six months, can reasonably be expected to continue for at least six
months, or is likely to recur.

Subp. 8. **Clinic.** "Clinic" means an operational entity through which personal
clinicians or local trade area clinicians deliver health care services under a common set of
operating policies and procedures using shared staff for administration and support. The
operational entity may be a department or unit of a larger organization as long as it is a
recognizable subgroup.

Subp. 9. **Commissioner.** "Commissioner" means the commissioner of health.

Subp. 10. **Commissioners.** "Commissioners" means the commissioners of health
and human services.

Subp. 11. **Complex condition.** "Complex condition" means one or more medical
conditions that require treatment or interventions across a broad scope of medical, social,
or mental health services.
Subp. 12. **Comprehensive care plan.** "Comprehensive care plan" means the care plan for a participant plus all available and relevant portions of any external care plans created for that participant.

Subp. 13. **Continuous.** "Continuous" means 24 hours per day, seven days per week, 365 days per year.

Subp. 14. **Cost-effectiveness.** "Cost-effectiveness" means the measure of a service or medical treatment against a specified health care goal based on quality and cost, including use of resources.

Subp. 15. **Direct communication.** "Direct communication" means an exchange of information through the use of telephone, electronic mail, video conferencing, or face-to-face contact without the use of an intermediary. For purposes of this definition, an interpreter is not an intermediary.

Subp. 16. **Eligible provider.** "Eligible provider" means a personal clinician, local trade area clinician, or clinic that provides primary care services.

Subp. 17. **End-of-life care.** "End-of-life care" means palliative and supportive care and other services provided to terminally ill patients and their families to meet the physical, nutritional, emotional, social, spiritual, cultural, and special needs experienced during the final stages of illness, dying, and bereavement.

Subp. 18. **Evidence-based guidelines.** "Evidence-based guidelines" means clinical practice guidelines that are recognized by the medical community for achieving positive health outcomes and are based on scientific evidence and other authoritative sources, such as clinical literature.

Subp. 19. **External care plan.** "External care plan" means a care plan created for a participant by an entity outside of the health care home such as a school-based individual education plan, a case management plan, a behavioral health plan, or a hospice plan.
Subp. 20. **Family.**

A. For a patient who is 18 years of age or older, "family" means:

1. any person or persons identified by the patient as a family member;
2. legal guardian according to appointment or acceptance under Minnesota Statutes, sections 524.5-201 to 524.5-317;
3. a health care agent as defined in Minnesota Statutes, section 145C.01, subdivision 2; and
4. a spouse.

B. For a patient who is under the age of 18, "family" means:

1. the natural or adoptive parent or parents or a stepparent who live in the home with the patient;
2. a legal guardian according to appointment or acceptance under Minnesota Statutes, sections 260C.325 or 524.5-201 to 524.5-317;
3. any adult who lives with or provides care and support for the patient when the patient's natural or adoptive parents or stepparents do not reside in the same home as the patient; and
4. a spouse.

Subp. 21. **Health care home.** "Health care home" means a clinic, personal clinician, or local trade area clinician that is certified under parts 4764.0010 to 4764.0070.

Subp. 22. **Health care home learning collaborative or collaborative.** A "health care home learning collaborative" or "collaborative" means an organization established under Minnesota Statutes, section 256B.0751, subdivision 5, in which health care home team members and participants from different health care organizations work together in a
structured way to improve the quality of their services by learning about best practices and quality methods, and sharing experiences.

Subp. 23. **Health care home team or care team.** "Health care home team" or "care team" means a group of health care professionals who plan and deliver patient care in a coordinated way through a health care home in collaboration with a participant. The care team includes at least a personal clinician or local trade area clinician and the care coordinator and may include other health professionals based on the participant's needs.

Subp. 24. **Local trade area clinician.** "Local trade area clinician" means a physician, physician assistant, or advanced practice registered nurse who provides primary care services outside of Minnesota in the local trade area of a state health care program recipient and maintains compliance with the licensing and certification requirements of the state where the clinician is located. For purposes of this subpart, "local trade area" has the meaning given in part 9505.0175, subpart 22.

Subp. 25. **Outcome.** "Outcome" means a measurement of improvement, maintenance, or decline as it relates to patient health, patient experience, or measures of cost-effectiveness in a health care home.

Subp. 26. **Participant.** "Participant" means the patient and, where applicable, the patient's family, who has elected to receive care through a health care home.

Subp. 27. **Patient and family-centered care.** "Patient and family-centered care" means planning, delivering, and evaluating health care through patient-driven, shared decision-making that is based on participation, cooperation, trust, and respect of participant perspectives and choices. It also incorporates the participant's knowledge, values, beliefs, and cultural background into care planning and delivery. Patient and family-centered care applies to patients of all ages.

Subp. 28. **Personal clinician.** "Personal clinician" means a physician licensed under Minnesota Statutes, chapter 147, a physician assistant licensed and practicing under
Minnesota Statutes, chapter 147A, or an advanced practice nurse licensed and registered to practice under Minnesota Statutes, chapter 148.

Subp. 29. **Preventive care.** "Preventive care" means disease prevention and health maintenance. It includes screening, early identification, counseling, treatment, and education to prevent health problems.

Subp. 30. **Previsit planning.** "Previsit planning" means planning for the participant's visit by reviewing the participant's medical record and, if applicable, communicating with the participant before a health care appointment to review changes in the participant's condition and determine a plan for the visit.

Subp. 31. **Primary care.** "Primary care" means overall and ongoing medical responsibility for a patient's comprehensive care for preventive care and a full range of acute and chronic conditions, including end-of-life care when appropriate.

Subp. 32. **Primary care services patient population.** "Primary care services patient population" means all of the patients who are receiving primary care services from the health care home, regardless of whether a patient has chosen to participate in the health care home.

Subp. 33. **Referral.** "Referral" means a written document, including an electronic document, given by a provider to a participant recommending that the participant receive a consultation for evaluation, treatment, or services from a provider outside of the health care home.

Subp. 34. **Shared decision making.** "Shared decision making" means the mutual exchange of information between the participant and the provider to assist with understanding the risks, benefits, and likely outcomes of available health care options so the patient and family or primary caregiver are able to actively participate in decision making.
Subp. 35. **Specialist.** "Specialist" means a health care provider or other person with specialized health training not available within the health care home. This includes traditional medical specialties and subspecialties. It also means individuals with special training such as chiropractic, mental health, nutrition, pharmacy, social work, health education, or other community-based services.

Subp. 36. **State health care program.** "State health care program" has the meaning given in Minnesota Statutes, section 256B.0751, subdivision 1, paragraph (f).

Subp. 37. **Statewide quality reporting system.** "Statewide quality reporting system" means a system used by the commissioner to collect data necessary for monitoring compliance with certification standards and for evaluating the impact of health care homes on outcomes.

Subp. 38. **Variance.** "Variance" means a specified alternative or an exemption from compliance to a requirement in parts 4764.0010 to 4764.0070 granted by the commissioner according to the requirements of part 4764.0050.

4764.0030 **CERTIFICATION AND RECERTIFICATION PROCEDURES.**

Subpart 1. **Eligibility for certification.**

A. An eligible provider, supported by a care team and systems according to the requirements in part 4764.0040, may apply for certification as a health care home.

B. A clinic will be certified only if all of the clinic's personal clinicians and local trade area clinicians meet the requirements for participation in the health care home. It is the clinic's responsibility to notify the department when a new clinician joins a certified clinic and intends to become a certified clinician. The clinic has 90 days from the date of hiring the new clinician or until its next annual anniversary date to apply for recertification, whichever is sooner. A clinic may operate as a certified clinic with the new clinician acting as though certified until the new clinician is certified. If the clinician chooses not to
be certified, the clinic will no longer be certified, but the clinicians who were previously
certified as part of the clinic will automatically hold an individual certification only.

Subp. 2. **Contents of application.** The applicant must submit the following to
the commissioner:

A. a completed self-assessment in a form prescribed by the commissioner which
describes how the applicant meets the requirements in part 4764.0040;

B. a completed and signed application form prescribed by the commissioner;

and

C. any other information required by the commissioner to show that the
applicant meets the standards for certification or recertification.

Subp. 3. **On-site review and additional documentation.** The commissioner may
conduct an on-site review and may request additional documentation to determine whether
the applicant complies with certification or recertification requirements.

Subp. 4. **Completed application for certification.** An application for certification
or recertification is complete when the commissioner has received all information in
subpart 2; the on-site review, if any, has been completed; and the commissioner has
received any additional documentation requested under subpart 3.

Subp. 5. **How to seek recertification.** To retain certification, a health care home
must submit a letter of intent stating its desire to be recertified no later than 60 days before
the one-year anniversary of its last certification or recertification and do the following:

A. At the end of year one, an applicant must demonstrate:

   (1) the requirements for initial certification continue to be met; and

   (2) the requirements for the end of year one for each health care home

standard in part 4764.0040 are met.
B. At the end of year two and all subsequent years, unless the applicant obtains a variance for superior outcomes and continued progress on standards as provided in part 4764.0050, subpart 3, an applicant must demonstrate:

(1) the requirements for initial certification and recertification at the end of year one continue to be met; and

(2) the requirements for recertification at the end of year two in part 4764.0040, subpart 11, are met, including the requirement that the applicant's outcomes in its primary care services patient population achieve the benchmarks for patient health, patient experience, and cost-effectiveness established by the commissioner under subpart 6.

Subp. 6. **Benchmarks.** The commissioner must announce benchmarks for patient health, patient experience, and cost-effectiveness annually. The benchmarks must be based on one or more of the following factors:

A. an improvement over time as reflected by a comparison of data measuring quality submitted by the health care home in the current year to data submitted in prior years;

B. a comparison of data measuring quality submitted by the health care home to data submitted by other health care homes;

C. standards established by state or federal law;

D. best practices recommended by a scientifically based outcomes development organization;

E. measures established by a national accrediting body or professional association; and

F. additional measures that improve the quality or enhance the use of data currently being collected.
Subp. 7. Notice of decision and timelines.

A. The commissioner must notify an applicant in writing regarding whether the applicant is certified or recertified as a health care home within 90 days after receiving a completed application.

B. If the commissioner certifies or recertifies the applicant as a health care home, the health care home is eligible for per-person care coordination payments under the care coordination payment system.

C. If the commissioner denies the application for certification or recertification, the commissioner must notify the applicant in writing of the reasons for the denial. The applicant may file an appeal under part 4764.0060.

4764.0040 HEALTH CARE HOME STANDARDS.

Subpart 1. Access and communication standard; certification requirements. The applicant for certification must have a system in place to support effective communication among the members of the health care home team, the participant, and other providers.

The applicant must do the following:

A. offer the applicant's health care home services to all of the applicant's patients who:

(1) have or are at risk of developing complex or chronic conditions; and

(2) are interested in participation;

B. establish a system designed to ensure that:

(1) participants are informed that they have continuous access to designated clinic staff, an on-call provider, or a phone triage system;
11.1 (2) the designated clinic staff, on-call provider, or phone triage system representative has continuous access to participants' medical record information, which must include the following for each participant:

11.4 (a) the participant's contact information, personal clinician's or local trade area clinician's name and contact information, and designated enrollment in a health care home;

11.7 (b) the participant's racial or ethnic background, primary language, and preferred means of communication;

11.9 (c) the participant's consents and restrictions for releasing medical information; and

11.11 (d) the participant's diagnoses, allergies, medications related to chronic and complex conditions, and whether a care plan has been created for the participant; and

11.13 (3) the designated clinic staff, on-call provider, or phone triage system representative who has continuous access to the participant's medical record information will determine when scheduling an appointment for the participant is appropriate based on:

11.16 (a) the acuity of the participant's condition; and

11.17 (b) application of a protocol that addresses whether to schedule an appointment within one business day to avoid unnecessary emergency room visits and hospitalizations;

C. collect information about participants' cultural background, racial heritage, and primary language and describe how the applicant will apply this information to improve care;

D. document that the applicant is using participants' preferred means of communication, if that means of communication is available within the health care home's technological capability;
E. inform participants that the participant may choose a specialty care resource without regard to whether a specialist is a member of the same provider group or network as the participant's health care home, and that the participant is then responsible for determining whether specialty care resources are covered by the participant's insurance; and


Subp. 2. **Access and communication standard; recertification at the end of year one.** By the end of the first year of health care home certification, the applicant for recertification must demonstrate that the applicant encourages participants to take an active role in managing the participant's health care, and that the applicant has demonstrated participant involvement and communication by identifying and responding to one of the following: participants' readiness for change, literacy level, or other barriers to learning.

Subp. 3. **Participant registry and tracking participant care activity standard; certification requirements.** The applicant for certification must use a searchable, electronic registry to record participant information and track participant care.

A. The registry must enable the health care home team to conduct systematic reviews of the health care home's participant population to manage health care services, provide appropriate follow-up, and identify any gaps in care.

B. The registry must contain:

(1) for each participant, the name, age, gender, contact information, and identification number assigned by the health care provider, if any; and
(2) sufficient data elements to issue a report that shows any gaps in care for groups of participants with a chronic or complex condition.

Subp. 4. Participant registry and tracking participant care activity standard; recertification at the end of year one. By the end of the first year of health care home certification, the applicant for recertification must use the registry to identify gaps in care and implement remedies to prevent gaps in care such as appointment reminders and previsit planning.

Subp. 5. Care coordination standard; certification requirements. The applicant for certification must adopt a system of care coordination that promotes patient and family-centered care through the following steps:

A. collaboration within the health care home, including the participant, care coordinator, and personal clinician or local trade area clinician as follows:

   (1) one or more members of the health care home team, usually including the care coordinator, and the participant set goals and identify resources to achieve the goals;

   (2) the personal clinician or local trade area clinician and the care coordinator ensure consistency and continuity of care; and

   (3) the health care home team and participant determine whether and how often the participant will have contact with the care team, other providers involved in the participant's care, or other community resources involved in the participant's care;

B. uses health care home teams to provide and coordinate participant care, including communication and collaboration with specialists. If a health care home team includes more than one personal clinician or local trade area clinician, or more than one care coordinator, the applicant must identify one personal clinician or local trade area
clinician and one care coordinator as the primary contact for each participant and inform
the participant of this designation;

C. provides for direct communication in which routine, face-to-face discussions
take place between the personal clinician or local trade area clinician and the care
Coordinator;

D. provides the care coordinator with dedicated time to perform care
coodination responsibilities; and

E. documents the following elements of care coordination in the participant’s
chart or care plan:

(1) referrals for specialty care, whether and when the participant has been
seen by a provider to whom a referral was made, and the result of the referral;

(2) tests ordered, when test results have been received and communicated
to the participant;

(3) admissions to hospitals or skilled nursing facilities, and the result of
the admission;

(4) timely postdischarge planning according to a protocol for participants
discharged from hospitals, skilled nursing facilities, or other health care institutions;

(5) communication with participant’s pharmacy regarding use of
medication and medication reconciliation; and

(6) other information, such as links to external care plans, as determined by
the care team to be beneficial to coordination of the participant’s care.

Subp. 6. Care coordination standard; recertification at the end of year one. By
the end of the first year of health care home certification, the applicant for recertification
must enhance the applicant’s care coordination system by adopting and implementing the
following additional patient and family-centered principles:
A. ensure that participants are given the opportunity to fully engage in care planning and shared decision-making regarding the participant's care, and that the health care home solicits and documents the participant's feedback regarding the participant's role in the participant's care;

B. identify and work with community-based organizations and public health resources such as disability and aging services, social services, transportation services, school-based services, and home health care services to facilitate the availability of appropriate resources for participants;

C. permit and encourage professionals within the health care home team to practice at a level that fully uses the professionals' training and skills; and

D. engage participants in planning for transitions among providers, and between life stages such as the transition from childhood to adulthood.

Subp. 7. Care plan standard; certification requirements. The applicant for certification must meet the following requirements:

A. establish and implement policies and procedures to guide the health care home in assessing whether a care plan will benefit participants with complex or chronic conditions. The applicant must do the following in creating and developing a care plan:

(1) actively engage the participant and verify joint understanding of the care plan;

(2) engage all appropriate members of the health care team, such as nurses, pharmacists, dieticians, and social workers;

(3) incorporate pertinent elements of the assessment that a qualified member of the care team performed about the patient's health risks and chronic conditions;
(4) review, evaluate, and, if appropriate, amend the care plan, jointly with
the participant, at specified intervals appropriate to manage the participant's health and
measure progress toward goals;

(5) provide a copy of the care plan to the participant upon completion of
creating or amending the plan; and

(6) use and document the use of evidence-based guidelines for medical
services and procedures, if those guidelines and methods are available;

B. a participant's care plan must include goals and an action plan for the
following:

(1) preventive care, including reasons for deviating from standard
protocols;

(2) care of chronic illnesses;

(3) exacerbation of a known chronic condition, including plans for the
participant's early contact with the health care home team during an acute episode; and

(4) end-of-life care and health care directives, when appropriate; and

C. the applicant must update the goals in the care plan with the participant as
frequently as is warranted by the participant's condition.

Subp. 8. Care plan standard; recertification at the end of year one. By the end
of the first year of health care home certification, the applicant must ask each participant
with a care plan whether the participant has any external care plans and, if so, create a
comprehensive care plan by consolidating appropriate information from the external plans
into the participant's care plan.

Subp. 9. Performance reporting and quality improvement standard;
certification requirements. The applicant for certification must measure the applicant's
performance and engage in a quality improvement process, focusing on patient experience, patient health, and measuring the cost-effectiveness of services, by doing the following:

A. establishing a health care home quality improvement team that reflects the structure of the clinic and includes, at a minimum, the following persons at the clinic level:

(1) one or more personal clinicians or local trade area clinicians who deliver services within the health care home;

(2) one or more care coordinators;

(3) two or more participant representatives who were provided the opportunity and encouraged to participate; and

(4) if the health care home is a clinic, one or more representatives from clinic administration or management;

B. establishing procedures for the health care home quality improvement team to share their work and elicit feedback from health care home team members and other staff regarding quality improvement activities;

C. demonstrating capability in performance measurement by showing that the applicant has measured, analyzed, and tracked changes in at least one quality indicator selected by the applicant based upon the opportunity for improvement; and

D. participating in a health care home learning collaborative through representatives that reflect the structure of the clinic and includes the following persons at the clinic level:

(1) one or more personal clinicians or local trade area clinicians who deliver services in the health care home;

(2) one or more care coordinators;
(3) if the health care home is a clinic, one or more representatives from clinic administration or management; and

(4) two or more participant representatives who were provided the opportunity and encouraged to participate with the goal of having two participants of the health care home take part; and

E. establishing procedures for representatives of the health care home to share information learned through the collaborative and elicit feedback from health care home team members and other staff regarding information.

Subp. 10. Performance reporting and quality improvement standard;

recertification at the end of year one. By the end of year one of health care home certification, the applicant for recertification must:

A. participate in the statewide quality reporting system by submitting outcomes for the quality indicators identified and in the manner prescribed by the commissioner;

B. show that the applicant has selected at least one quality indicator from each of the following categories and has measured, analyzed, and tracked those indicators during the previous year:

(1) improvement in patient health;

(2) quality of patient experience; and

(3) measures related to cost-effectiveness of services; and

C. submit health care homes data in the manner prescribed by the commissioner to fulfill the health care homes evaluation requirements in Minnesota Statutes, section 256B.0752, subdivision 2.

Subp. 11. Performance reporting and quality improvement standard;

recertification at the end of year two and subsequent years.
A. By the end of the second year of certification as a health care home, and each
year thereafter, the applicant must continue to participate in the statewide quality reporting
system by submitting outcomes for the additional quality indicators identified and in the
manner prescribed by the commissioner.

B. To qualify for recertification, the applicant's outcomes in primary care
services patient population must achieve the benchmarks for patient health, patient
experience, and cost-effectiveness established under part 4764.0030, subpart 6.

4764.0050 VARIANCE.

Subpart 1. Criteria for variance. At certification or recertification, the applicant
may request a variance or the renewal of a variance from a requirement in parts 4764.0010
to 4764.0040. To request a variance, an applicant must submit a petition, according to the
requirements of Minnesota Statutes, section 14.056, and demonstrate that the applicant
meets the criteria in item A or B.

A. If the commissioner finds that the application of the requirements, as applied
to the circumstances of the applicant, would not serve any of the rule's purposes, the
commissioner must grant a variance.

B. If the commissioner finds that failure to grant the variance would result in
hardship or injustice to the applicant, the variance would be consistent with the public
interest, and the variance would not prejudice the substantial legal or economic rights of
any person or entity, the commissioner may grant a variance.

Subp. 2. Conditions and duration. The commissioner may impose conditions
on the granting of a variance according to Minnesota Statutes, section 14.055. The
commissioner may limit the duration of a variance and may renew a variance.

Subp. 3. Variance for superior outcomes and continued progress on standards.
The commissioner may grant a variance to the requirements in part 4764.0030, subpart
5, item B, based on superior achievement reflected in the outcomes data and continued progress on the health care home standards in part 4764.0040. The commissioner must annually announce benchmarks for superior achievement based on the factors in part 4764.0030, subpart 6. To receive the variance, the applicant must:

A. demonstrate that the applicant has met or surpassed the benchmarks for superior achievement in outcomes related to patient health, patient experience, and cost-effectiveness, as reflected in the data submitted by the applicant to the statewide quality reporting system;

B. submit a signed statement affirming that the applicant continues to comply with the requirements for initial certification, recertification at the end of year one, and recertification at the end of year two, according to part 4764.0040;

C. demonstrate continued progress on the health care home standards by identifying at least one approach that is new to the applicant for each of the five health care home standards in part 4764.0040, except for the standard for performance reporting and quality improvement;

D. provide any additional documentation of superior outcomes and continued progress on standards requested by the commissioner; and

E. continue to participate in a health care home learning collaborative.

Subp. 4. **Experimental variance.** The commissioner may grant a variance from one or more requirements to permit an applicant to offer health care home services of a type or in a manner that is innovative if the commissioner finds that the variance does not impede the achievement of the criteria in Minnesota Statutes, section 256B.0751, subdivision 2, paragraph (a), and may improve the health care home services provided by the applicant.

Subp. 5. **Variance for justifiable failure to show measurable improvement.** The commissioner may grant a variance to a health care home seeking recertification that fails
to show measurable improvement as required by parts 4764.0030, subpart 5, item B, subitem (3), and 4764.0040, subpart 11, if the applicant demonstrates the following:

A. reasonable justification for the applicant's inability to show required measurable improvement; and

B. a plan to achieve measurable improvement in the following year or a shorter time period identified by the commissioner.

4764.0060 APPEALS.

Subpart 1. Denial of certification or recertification and time for appeal. The commissioner must notify an applicant in writing of the reasons for denial of an application for certification or recertification. An applicant has 30 days from the date of receiving notice of the decision to appeal the decision.

Subp. 2. How to appeal. The applicant may appeal by submitting either item A or B, or both:

A. a written statement of the applicant's grounds for disputing the commissioner's decision; or

B. a corrective action plan that describes the following specific actions for improvement:

(1) the corrective steps that have been taken by the applicant;

(2) a plan for continued improvement; and

(3) if applicable, any reasons that the applicant is unable to comply.

Subp. 3. Optional request for meeting. Upon request, an applicant is entitled to a meeting with the commissioner's designee to discuss disputed facts and findings, present the applicant's corrective action plan, or both.
Subp. 4. Notice of decision and timeline. The commissioner must grant or deny the appeal and notify the applicant of the decision within 60 days after receipt of a completed appeal, or, if the applicant meets with the commissioner's designee, within 60 days after the meeting.

4764.0070 REVOCATION, REINSTATEMENT, AND SURRENDER.

Subpart 1. Revocation. If the commissioner denies an appeal or a health care home fails to appeal the commissioner's decision to deny recertification, the provider will no longer be certified as a health care home or be eligible to receive per-person care coordination payments.

Subp. 2. Reinstatement. A provider whose certification as a health care home has been revoked may apply for reinstatement. If the provider was previously certified for one year or longer at the time of revocation, it must meet the recertification requirements to be reinstated. During the 12 months following revocation of certification, the provider may obtain technical or program assistance from the Minnesota Department of Health and through a health care home learning collaborative to assist the provider to regain certification.

Subp. 3. Surrender. A health care home may voluntarily surrender the health care home certification by providing the commissioner and the health care home participants with 90 days' written notice. After the expiration of the 90-day notice period, a provider that has surrendered health care home certification is no longer eligible for per-person care coordination payments based on certification.
Minnesota Omnibus Bill:
Patient-Centered Decision-Making
A bill for an act

relating to human services; requiring patient-centered decision-making process

before certain procedures are reimbursed under medical assistance; proposing

coding for new law in Minnesota Statutes, chapter 256B.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. [256B.768] PATIENT-CENTERED DECISION MAKING.

(a) Effective January 1, 2012, the commissioner shall require active participation in

a patient-centered decision-making process before authorization is approved or payment

reimbursement is provided for the following:

(1) a surgical procedure for the following conditions: abnormal uterine bleeding,
benign prostate enlargement, chronic back pain, early stage breast and prostate cancers,
gastroesophageal reflux disease, hemorrhoids, spinal stenosis, temporomandibular joint
dysfunction, ulcerative colitis, urinary incontinence, uterine fibroids, or varicose veins; or
(2) bypass surgery for coronary disease, angioplasty for stable coronary artery
disease, and total hip replacement.

(b) A list of these procedures shall be published in the State Register by October
2011. The list shall be reviewed no less than every two years by the commissioner, in
consultation with the commissioner of health. The commissioner, in consultation with the
Health Services Policy Committee under section 256B.0625, subdivision 3c, may include
additional preference-sensitive procedures for which the clinical evidence does not clearly
support one treatment option over another and the appropriate course of treatment depends
on the values and preferences of the patient. The commissioner shall hold a public forum
and receive public comment prior to any changes to the list provided in paragraph (a).
Any changes made shall be published in the State Register.

(c) Prior to receiving authorization or reimbursement for the procedures identified
under this section, a health care provider must certify that the patient has participated in
a patient-centered decision-making process. The format for this certification and the
process for coordination between providers shall be developed by the Health Services
Policy Committee.

(d) For purposes of this section, "patient-centered decision making" means a process
that involves directed interaction between a health care professional and the patient or
the patient's legal representative to assist the patient in understanding the patient's health
condition, available treatment options, and the benefits and harms of each option, and in
deciding what treatment is best for the patient based on the patient's circumstances, values,
and preferences. The interaction may be conducted by a health care provider or through
the use of patient decision aids, or both.
2.13 (e) For purposes of this section, "patient decision aid" means a written, audiovisual, or online tool that provides a balanced presentation of the condition or treatment options, benefits, and harms, and is certified by one or more national certifying organizations or meets the certification requirements established under the Patient Protection and Affordable Care Act, Public Law 111-148, section 3506.

2.18 (f) This section does not apply if any of the procedures identified in this section are performed under an emergency situation.

2.20 Sec. 2. SHARED DECISION-MAKING RESOURCE CENTER.

2.21 (a) The commissioner of human services shall pursue a grant under the Patient Protection and Affordable Care Act, Public Law 111-148, for the establishment and support of a shared decision-making resource center to provide technical assistance to providers and to develop and disseminate best practices and the information to support and accelerate to adoption of patient decision aids and shared decision making.

2.26 (b) If a shared decision-making resource center is established, the resource center shall review the procedures listed in Minnesota Statutes, section 256B.768, and make recommendations to the commissioner on procedures that should be included in the list.
Maine Board of Licensure in Medicine
Informed Consent Guidelines
INFORMED CONSENT

Guidelines from the Maine Board of Licensure in Medicine

Obtaining and recording informed consent before major diagnostic, therapeutic, and invasive procedures is a physician’s professional and legal obligation. Patients have the legal right to grant or withhold informed consent, either personally or through lawful representatives.

The term “informed consent” first appeared in an amicus curiae brief filed by the American College of Surgeons in the case of Salgo v. Leland Stanford University in 1957. While not all physicians and not all patients desire to be involved in a shared decision making process, prevailing negligence law and the legal right to self-determination now require some documentation of informed consent for most major treatments and procedures. Physicians therefore have a legal motivation for obtaining and recording informed consent for major treatments and procedures, subject to recognized legal exceptions such as in providing emergency medical care to incapacitated patients. In addition to this legal motivation, the Board believes physicians ought to be motivated by a commitment to the ethical value of patient self-determination, or personal autonomy. Therefore, the Board offers these guidelines for physicians practicing in Maine.

The Goal

The goal of offering these guidelines is to help physicians move beyond a limited consent model that emphasizes primarily the physician's legal obligation to disclose information and the patient's legal right to make independent decisions. The Board advocates a different model that emphasizes communication and encourages a certain kind of transaction between patient and physician. The norms that govern such transactions are clarity, relevance, accuracy, and sincerity. There is no standard form, nor any uniform procedure that will fit all cases calling for informed consent in this model, but there is an underlying ethical obligation to make it possible for the patient and the physician to participate together in a transaction that takes into account the norms of clarity, relevance, accuracy, and sincerity.

The Board is concerned here with major diagnostic, therapeutic, and invasive procedures, and not so much with routine decisions about minor medical problems. In certain cases, physicians may simply explain that they see many people with a particular problem and regularly with success treat the problem in a particular way, then ask if the patient has any questions about the problem or the treatment. In these cases, if the patient

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1 Title 32 M.R.S.A. § 3269(3) authorizes the Board to “license and set standards of practice for physicians and surgeon practicing medicine in Maine.” However, nothing in this document is intended to affect the definition of “informed consent” for civil medical malpractice actions as defined by Title 24 M.R.S.A. § 2905.

2 154 Cal.App.2d 564.
makes statements or asks questions indicating discomfort, lack of understanding, or continuing uncertainty, then the following guidelines apply.

**Shared Decision Making**

The primary value of documented informed consent is that it represents the existence of a relationship between physician and patient that is based upon, or at least includes, an element of shared decision making. Shared decision making for the patient is not the same as mere acquiescence, or compliance based on partial or slanted information, or indifference due to habit or apathy, nor is it the same as conformity to custom – such as the custom of “following doctor’s orders.”

Shared decision making is a process for reaching a shared conclusion through informed judgment. Such a process is an educational ideal in the field of medical care, as it is throughout most institutions in a democratic society. The heart of the matter is the control of information: to the extent information about a problem can be shared, decisions about potential solutions can be shared. Physicians have privileged access to medical information through their education, experience, and expertise. This privilege carries with it the duty to disclose clearly such information as is relevant and is supported by accurate scientific information in a sincere manner for consideration by the patient. Furthermore, this duty is itself governed by the physician’s fiduciary obligation to protect the patient’s best interests.

Generally, physicians control the medically relevant information patients need in order to ask the questions they may want to ask but might not be able to formulate on their own. Successfully sharing that information is a matter of 1) the physician’s willingness to do so, and 2) the physician’s ability to apply the skills of communication required to do so. It is also a matter of 3) the patient’s willingness to participate in the process, and 4) the patient’s ability to understand the information, apply it to his or her situation, and then express a reasoned judgment based on the relevant medical information as well as on personal values, wishes, and goals. If there is any doubt about the patient’s ability in this regard, the physician should arrange an evaluation of the patient’s capacity by a qualified colleague.

The physician personally initiates the process of informing the patient by presenting the medically reasonable options relevant to the patient’s condition. The medical reasonableness of these options is tied to the available and reliable evidence base of expected benefit and risk for each alternative. The physician’s judgment about these options should be free of personal self-interest, and religious, political, racial, and gender bias.

The Board encourages physicians to remind patients of their right to have someone with them (an advocate of some kind) during these discussions, as patients can be overwhelmed, frightened, and confused when confronting an important medical decision.
Skills for Eliciting Informed Consent

By far the most important skill is empathetic listening, which is the capacity for acquiring objective knowledge about the perspective taken by another person. It is a way of listening that requires temporary suspension of one’s personal point of view while trying to assume another’s point of view. It is a means for gathering data. It is not synonymous with being compassionate or sympathetic, even though its mere presence can have a beneficial effect. The primary purpose of empathy in this sense is to become well informed about the patient’s point of view. It is important for the physician to find out what and how much the patient already knows and what more the patient wishes or needs to know, and to what extent the patient desires to participate in the decision making process. In disclosing medical information the physician can err in two ways – excess and deficiency. Empathetic understanding can help guard against going wrong in either of these ways.

Next is skill in disclosing and explaining. In trying to establish the basis for shared decision making, the physician discloses medical information relevant to the case at hand, and provides explanations of what that information means, in language that is intelligible to the patient.

It is important to distinguish between two useful but distinct kinds of explanation. The first is scientific explanation, which is making a case for why certain events are the way they are and for predicting future events. The second is semantic explanation, which by contrast is making the meaning of something clear to the listener. Semantic explanation is like translation or paraphrase, using different words and terms until the intended meaning is revealed and understood.

An explanation can be satisfactory from a formal (scientific) point of view, while at the same time failing to be satisfying from the patient’s point of view. Another way to put this point is that while a medical explanation of risks and benefits associated with treatment options can be scientifically sound, the listener may find it to be unintelligible, and therefore not useful as information upon which to grant or withhold consent. Informed consent depends on the physician’s success in providing both kinds of explanation.

Third is framing. Anything that can be said, can be said another way. Decisions are often influenced by the way alternatives are presented. For example, the outcome statistics for 100 middle-aged men undergoing surgery for lung cancer can be described as “90 survive the surgery . . . and of those 90, 34 are alive at the end of 5 years.” An alternative way of expressing (framing) the same results might be: “10 die from surgery. . . and 66 more die within 5 years.” Typically, for a patient choosing between surgery and radiation, surgery appears much less attractive when described using mortality rather than survival statistics. The difference between 10% mortality (for surgery) and 0% mortality (for radiation) is more impressive than the difference between 90% survival (for surgery) and 100% survival (for radiation). A physician may knowingly or unwittingly nudge a patient toward one option simply by the way the range of options is described, or framed. (Note that 5-year mortality statistics for radiation only have not been mentioned.)
Definition of Informed Consent

In conclusion, the Board recommends the following definition of informed consent be adopted and applied by Maine physicians.

Informed consent for treatment has been obtained when: 1) the physician has disclosed and explained to the patient’s satisfaction the process used to arrive at the medically reasonable and recommended intervention(s), which is based on reliable evidence of expected benefit and risk of each alternative, and which is free of any impermissible bias; 2) the patient, who has demonstrated capacity, has been given ample opportunity to ask questions about the process and the recommended intervention(s), to the extent the patient wishes, all questions then having been answered to the patient’s satisfaction; and 3) the patient gives consent in writing to major intervention(s) agreed to jointly with the physician.

Nota bene:

Obtaining informed consent is the physician’s personal responsibility. This responsibility cannot be wholly delegated. Other medical staff (PA’s, NP’s, Physicians in training and others) may usefully participate in the process, but no amount of shared videos, questionnaires, and pamphlets can substitute entirely for personal communicative transaction with the responsible physician. Finally, proof of informed consent cannot be reduced merely to a signature on a form. A note from the physician about the process of gaining that signature should be attached to the form.

When a Physician Assistant, with proper delegation, performs a diagnostic, therapeutic, or invasive procedure for which the standard of care indicates informed consent is required, the Board expects the Physician Assistant to take the same actions as are described in this document for the physician.

Approved: April 13, 2010