

Memo



Date: November 12, 2009

To: Office of Administrative Hearings

From: Sanne Magnan, M.D. Ph.D.
Commissioner, Minnesota Department of Health

Subject: **Request for Approval of Minnesota Administrative Rules, Chapter 4764
Certification of Health Care Homes**

INTRODUCTION

Health care homes, which are known nationally as “medical homes,” are a cornerstone of the nation-leading comprehensive health care reforms that the Minnesota legislature adopted in 2008. 2008 Minn. Laws Ch. 358. Health care homes innovate primary care by having primary care providers, families, and patients work in partnership to improve the health and quality of life for individuals, especially those with chronic and complex conditions. Health care homes place the patient and family at the center of care, develop proactive approaches through care plans and enhanced patient access to health care professionals, and offer greater continuity of care through increased care coordination.

Under Minnesota Statutes, section 256B.0751, the Commissioners of Health and Human Services are authorized to adopt new, expedited rules to certify clinics and clinicians that provide primary care services as health care homes. This authorization coincides with momentum that has been building for several years in Minnesota as interest in developing health care homes has gained. Indeed, the Minnesota Department of Health (“the Department” or “MDH”) recently conducted a certification-readiness survey, which reflects that many of Minnesota’s primary care clinics have already adopted many practices that the health-care-homes movement advocates. In a June 2009 report, the National Academy for State Health Policy identified Minnesota as one of ten leading states in the advancement of health care homes. Companion legislation to the certification-enabling legislation bolsters further development of health care homes by requiring that publicly funded and private health care plans pay a care coordination fee to certified clinics and clinicians.

In response to the enabling legislation, the Department has adopted Minnesota Rules, Chapter 4764 (“the Rule”). The Rule’s introductory part describes its purpose, which is to require health care homes to deliver services that meet five broad thematic standards. The Rule’s main body contains detailed requirements that implement these five broad standards. Each standard has more than one set of requirements to address an applicant’s particular circumstances, i.e. whether the applicant is seeking certification: (a) for the first time, (b) after one year of experience as a health care home, or (c) after two or more years of experience. These requirements become progressively more rigorous and focus more heavily on performance outcomes rather than the initial infrastructure as the applicant moves along the experience

continuum. Finally, the Rule contains procedural requirements, including provisions for a variance, for revocation or voluntary certification surrender, and for an appeal when the Department declines to certify or recertify.

The Department of Health and the Department of Human Services (“DHS”) fulfill different roles for the Rules. MDH will take full responsibility for program development and enforcement. The Rule will be grouped with MDH’s rules. During the rulemaking process, the DHS participated extensively with MDH in the policy decisions and language development. DHS is authorized under companion legislation to develop policies for care coordination fee payments, which are currently underway. In light of these roles, MDH requests approval of the Rule.

As described below, Chapter 4764 satisfies each of the standards of review of Minnesota Rules 1400.2100, as applied to expedited rulemaking. Although this was an expedited process, the Department offered many opportunities for public input before and during rule development. The Department carefully considered the written comments submitted during the comment period following publication of the proposed rule in the State Register. Many comments came from provider organizations representing various sectors of the health care field, whose members will seek certification. The Department made changes suggested by the commenters to clarify the requirements and make them more workable, but did not make substantial changes to the proposed rule. Specific changes from the proposed rule are described in appropriate sections below.

I. THE DEPARTMENT COMPLIED WITH ALL PROCEDURAL REQUIREMENTS OF CHAPTER 14 AND PROVIDED ADDITIONAL OPPORTUNITIES FOR STAKEHOLDER INPUT.

A. The Rule Was Adopted In Compliance With All Procedural Requirements Of Chapter 14, As Required By Minnesota Rules 1400.2100 (A).

The Department met each of the following procedural requirements:

- The Revisor’s Office certified the form of the Rule on June 29, 2009. Minnesota Statutes, section 14.07, subdivision 2 (2008). *See* Revisor’s official version of the proposed rule, attached as Exhibit 1.
- The Department of Health mailed the *Notice of Intent to Adopt Expedited Rules without a Hearing* (“*Notice of Intent*”), attached as Exhibit 2, to its agency rulemaking mailing list on July 1, 2009, more than 33 days before close of the rule’s comment period on August 6, 2009, and published the Notice of Intent and Rule in the State Register on July 6, 2009. The Department of Human Services also mailed the *Notice of Intent* to its agency rulemaking list on July 1, 2009. Minnesota Statutes, section 14.389, subdivision 2 (2008); Minnesota Rules 1400.2085, subpart 2 (2007). *See* Certificate of Mailing the Notice of Intent to Adopt Expedited Rules and the Certificate of Accuracy of the Mailing List for the Department of Health, and

Certificate of Mailing the Notice of Intent to Adopt Expedited Rules and the Certificate of Accuracy of the Mailing List for the Department of Human Services, attached as Exhibit 3.

- The Department gave additional notice to notify as many interested parties as possible, as described in the Certificate of Additional Notice, attached as Exhibit 4.
- The Department is submitting all written comments received during the comment period with this filing, attached as Exhibit 5. Minnesota Statutes, section 14.389, subdivision 2 (2008).
- The Department modified the Rule in response to comments received during the comment period, without making it substantially different than the proposed rule. Minnesota Statutes, section 14.05, subdivision 2 (b) and (c), and 14.389, subdivision 3. *See* Chart of Public Comments with MDH's Response, which catalogues by Rule parts and subparts all comments with brief summaries of the Department's response, attached as Exhibit 9.
- The Revisor's Office approved all modifications to the rule on November 9, 2009. Minnesota Rules 1400.2410, subpart 2 (G) (2007). *See* Revisor's approved modifications to the proposed Rule, attached as Exhibit 6.
- The Commissioner of Health, Dr. Sanne Magnan, adopted the rule by order on November 12, 2009. The order of adoption is included in this filing. Minn. Rules 1400.2090 (2007). *See* Order Adopting Rule, attached as Exhibit 7.

B. The Department Provided Additional Opportunities For Stakeholder Input and Met Its Statutory Duty to Consult With Organizations that Work on Health Care Homes and Various Members of the Health Care Field.

Although the Department developed this rule through an expedited process, the Department actively sought additional public engagement before and during rulemaking. In addition, the Department fulfilled the enabling statute's procedural requirement to "consult with national and local organizations working on health care home models, physicians, relevant state agencies, health plan companies, hospitals, other providers, patients, and patient advocates." Minnesota Statutes, section 256B.0751, subdivision 2(b). The Department's community-engagement process included the following major events:

- **December 2008: Public Input for Initial Report.** The Department commissioned the Institute for Clinical Systems Improvement ("ICSI") to make recommended health-care-home elements and performance outcomes that the Department could use to evaluate applicants for health care home certification. ICSI assembled a large work group to perform the task, broadly composed of Minnesota health plan companies, health care providers, physicians, patient advocates and patients, state government agencies, and national organizations involved in the development of medical homes initiatives. The work group sought input from 104 health care organizations or professionals and compiled 523 comments on draft evaluative criteria. The work group also reviewed available evidence suggested by the commenters.

- **December 18, 2009: Advisory Group Review of Domains.** The Department assembled an advisory group of stakeholders that included Minnesota health plan companies, health care providers and associations, physician organizations, individual physicians, governmental agencies, patient advocates, patients and family members of patients. From this group, the Department assembled five affinity groups to address one topical area, or “domain,” a piece. The Department identified the domains based on the “Chronic Care Model,” which is attributable to respected authorities described in section III-A below. The affinity groups identified thirty-seven broad objectives and requirements that supported each.

- **December 30, 2008 to January 7, 2009: Public Web-Based Survey.** The Department solicited public input on the main objectives and requirements through a web-based survey. The Department received input from 273 medical clinics, health care professionals, and consumers. For each requirement, the survey gathered data on the following factors: ability to implement the requirement; the effect of the requirements on care delivery; and the requirement’s impact on patient experience, patient health, and cost of care.¹

- **January 9, 2009: Advisory Group Refinement of Requirements.** The Department divided the advisory group into smaller stakeholder groups, comprised of groups of patient and family members, public and private health plan payers, primary care providers, and governmental agencies. These stakeholder groups selected and prioritized the most important broad goals and requirements. They did so based on the enabling legislation, the public survey data, the efficacy of the requirement to impact the “triple aim” goals, and based on whether each requirement was foundational, transformational, or unneeded.

- **January 13, 2009: Conference Entitled, “Developing a Health Care Home in Minnesota - A National Perspective.”** The Department hosted a public conference to inform the health care community and the advisory group about national work on medical homes and the progress in Minnesota on health care homes. Key national leaders from the Center for Medicare and Medicaid Services (“CMS”²), the National Committee for Quality Assurance (“NCQA”³), and the Center for Medical Home Improvement (“CMHI”⁴) made presentations.

¹ The latter three health-care-performance measures are salient throughout Rule development and in the Rule. The three target areas were originally identified by the Massachusetts-based Institute for Healthcare Improvement (“IHI”), and have gained widespread recognition. As stated by the IHI, to address serious and significant problems in the United States’ health care system, new designs for health care delivery “can and must be developed to simultaneously accomplish three critical objectives . . . [These are:] improve[ment in] the health of the population; enhance[ment of] the patient experience of care; and reduc[tion], or at least control, [of] the per capita cost of care.” *See* <http://www.ihl.org/IHI/Programs/StrategicInitiatives/TripleAim.htm?TabId=6>. This so-called “triple-aim” approach is consistent with objectives in the enabling statute. Minnesota Statutes, section 256B.0751, subd. 2(a) (8) requires the Department to develop rules that measure patient experience and cost. Minnesota Statutes, section 256B.0751, subd. 6 requires the Commissioner to collect data on cost and health outcomes.

² The CMS is an agency of the U.S. Department of Health and Human Services and was formerly known as the Health Care Financing Administration. The CMS developed a demonstration project for health care homes which is in the process of being carried out.

³ The NCQA is a private, 501(c)(3) not-for-profit organization dedicated to improving health care quality. It was founded in 1990. NCQA has helped to build consensus around important health care quality issues by working

The conference included a round-table panel discussion with questions from the audience. The event was attended by 125 health care professionals.

- **January 14, 2009: Refinement of Requirements with Expert Input.** The smaller stakeholder groups continued to prioritize the requirements based on the same factors used on January 9. The visiting national experts from CMS, NCQA, and CMHI joined the work groups and provided input.
- **January 28, 2009: Advisory Group Ranks Requirements.** The advisory group assembled as a whole, discussed the pros and cons of each requirement, and voted to prioritize them. The work culminated in five broad categories of aspirational goals with specific requirements to support each category. The product was now ready for and underwent review by senior management staff in the Departments of Health and Human Services. The five major categories ultimately formed the basis for what are now the five broad “standards” in the Rule.
- **April 10, 2009: Advisory Group Addresses Certification.** The advisory group addressed how the standards and requirements could be measured and verified to evaluate an applicant for certification.
- **April 27, 2009: Department Proposes Draft Rules and Provides Informal Comment Period.** The Department presented draft rules to the public and explained the principles and process that supported their development. The presentation was attended in person and via telephone conference by approximately 130 health care professionals. The Department provided an informal comment period of one week to obtain input on the draft rules. The Department received about 40 pages of comments and made many changes to the draft rules in response.
- **July 1, 2009: Formal Rulemaking Begins According to Chapter 14.**
- **August 27, 2009 to 2010: Advisory Group on Performance Outcomes.** The Department has assembled an advisory group that has started to advise the Department on implementation of the Rule requirements on measurement of performance outcomes.

with large employers, policymakers, doctors, patients and health plans to decide what’s important, how to measure it, and how to promote improvement. The NCQA is a leading authority, if not *the* leading authority, on medical home criteria.

⁴ The CMHI is an organization founded in 1993 by Dr. W. Carl Cooley, Medical Director, and Ms. Jeanne W. McAllister, B.S.N., M.S., M.H.A., Director. The mission of the Center for Medical Home Improvement (CMHI) is to promote high quality primary care in the medical home and secure health policy changes critical to the future of primary care.

II. THE RULE IS NOT SUBSTANTIALLY DIFFERENT THAN THE PROPOSED RULE.

The Rule satisfies Minnesota Rules 1400.2100 (C) because the Rule is not substantially different than the proposed rule. Although the Department made certain changes following publication and the close of the comment period, the changes do not result in a substantially different rule. They were foreseeable in the scope of the subject matter announced in the notice. The Department made the changes in response to comments to clarify the Rule and modify the Rule in light of policy considerations. The specific changes are detailed in section III below.

III. THE RULE COMPLIES WITH THE REQUIREMENTS OF THE ENABLING STATUTE AND OTHER APPLICABLE LAW.

The Rule satisfies Minnesota Rules 1400.2100 (D) because the Rule complies with its enabling statute and other applicable law and does not exceed, conflict with, or grant the agency discretion beyond what is allowed by law. Compliance with the enabling statute requirement pertaining to Department consideration of existing standards, the authority for each part of the Rule, and any changes to the proposed rule are described below.

A. The Department Met Its Statutory Duty to Consider Existing Medical Home Standards.

The enabling statute requires that during rule development, the Department “consider existing standards developed by national independent accrediting and medical home organizations.” Minnesota Statutes, section 256B.0751, subdivision 2. The Department considered numerous sources of authority and reviewed many existing rules. Indeed, the Rule reflects much of the consensus that has been building about medical homes. The Department relied most heavily on the following existing standards:

- Joint Principles of the Patient-Centered Medical Home (“Joint Principles”). The American College of Physicians (“ACP”), American Academy of Family Physicians (“AAFP”), American Academy of Pediatrics (“AAP”), and American Osteopathic Association (“AOA”) jointly developed these standards. In March 2007, these organizations adopted a consensus statement endorsing the Joint Principles.
- Physician Practice Connections – Patient Centered Medical Home (2008) (“PPC-PCMH”) program of the NCQA, with input from the ACP, AAFP, AAP, and AOA. The Joint Principles provided the basis for the NCQA PPC-PCMH.
- PPC-PCMH CMS Version (October 6, 2008) designed by the NCQA specifically for use by CMS.
- AAFP/ TransforMED Medical Home Model (November 2008).
- Measuring the Medical Home in Adult Primary Care, 2008,

- The Medical Home Index: Measuring the Organization and Delivery of Primary Care for Children with Special Health Care Needs, 2001 (revised 2006).

In addition, the Department considered the following information regarding existing standards:

- The “Chronic Care Model,” developed by Edward Wagner, M.D., M.P.H.; Director, MacColl Institute for Healthcare Innovation, Group Health Cooperative of Puget Sound; and colleagues from the “Improving Chronic Illness Care” program, which is a national program of The Robert Wood Johnson Foundation. The Chronic Care Model contains some of the core principles of medical homes, including motivational, proactive patient-centered care and outcomes-based practices.
- “Report on the Current ‘State of the Art’ for Medical/ Health Care Homes,” a comprehensive report of existing guidelines and literature on medical homes, prepared by the Institute for Clinical Systems Improvement under contract to the Department.
- Materials designed to advance the understanding and adoption of the NCQA’s PPC-PCMH that were prepared by the Patient Centered Primary Care Collaborative. The collaborative is a coalition of major employers, consumer groups, patient quality organizations, health plans, labor unions, hospitals, physicians and many others who have joined together to develop and advance the patient-centered medical home model, 2006.
- Tools and guidance documents prepared by the CMHI to develop supports for primary care practices to improve their “medical homeness.”
- Documents and a self-assessment tool for clinics concerning the PPC-PCMH, prepared by the American Academy of Family Medicine.
- Information including health care definitions from the Agency for Healthcare Research and Quality (“AHRQ”), which is an agency of the U.S. Department of Health and Human Services. The AHRQ has expertise in evidence-based practices, quality indicators, quality measures, and other core concepts of the medical home model, and is a knowledgeable resource on medical homes.

B. THE RULE COMPLIES WITH ITS ENABLING STATUTE AND OTHER LAW.

As explained below, the Department’s authority to adopt the Rule is derived from the enabling legislation and other applicable law.

1. Part 4764.0010 APPLICABILITY AND PURPOSE.

Subpart 1 provides notice that the Rule applies to an eligible provider that is an applicant or is certified as a health care home. The definition of “eligible provider” reflects that clinics and clinicians (and local trade area clinicians, which are addressed in the appropriate section below) may apply for certification. *See* part 4764.0020, subpart 15. The term applicant is defined, under part 4764.0020, subpart 2, as an eligible provider that seeks certification or recertification. Thus, the rule governs clinics or clinicians that seek certification or recertification.

Arguably, the language in subpart 1 is redundant because the term applicant means an eligible provider, and a health care home that is certified is plainly an eligible provider. In other words, using the term eligible provider was unnecessary because this circumstance would have been implicit. The Department’s objective was to plainly inform any reader at the outset, without the reader’s needing to refer to the definitions, that an entity or individual must be eligible to apply for certification and that the Rule governs applicants.

Subpart 2 states that the Rule establishes procedures and standards for certification of health care homes.

The Rule contains procedures that apply to the following: an application for certification or recertification; a request for a variance; an appeal to challenge the denial of certification or recertification; and revocation, reinstatement, and surrender of certification.

The enabling statute directs the Department to develop standards according to a set of ten criteria. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (1) – (10). Based on these criteria and with considerable stakeholder involvement, the Department identified five broad, overarching objectives for certification. The Rule refers to these as “standards.”

Subpart 2, items A through E, set out the standards in general terms. The Department, however, will not rely on these provisions for enforcement purposes. Rather, the standards are stated in broad terms here to introduce them, but are implemented through the specific requirements stated in part 4764.0040.

2. Part 4764.0020 DEFINITIONS.

Most of the proposed definitions are terms commonly used in the health care industry, accrediting organizations for medical homes, and patient- and family-centered care organizations, or are defined in Minnesota statutes. Maintaining consistency with established and standard health care industry language assures that the Rule will be understandable to its primary audience and reduce administrative burden.

Subpart 1 provides notice that the definitions apply throughout Rule 4764.

Subpart 2. “Applicant” refers to the definition of eligible provider (subpart 15) to describe the category of persons or an entity that has applied for certification or recertification under parts 4764.0010 to 4764.0070. Because the term describes the very group to which the Rule applies, the term is used repeatedly in the Rule to refer to the regulated party.

Subpart 3. The definition of “care coordination” is based on the definition used by the Academy of Pediatrics and the Agency for Healthcare Research and Quality. The definition synthesizes principles from the two existing definitions and emphasizes aspects of care coordination that are pertinent in the Rule. The definition contains four terms that are defined elsewhere in the Rule: participant, personal clinician, local trade area physician, and health care home team.

Subpart 4. “Care coordination payment system” is defined as a system established under Minnesota Statutes, section 256B.0753, subdivision 1, or section 62U.03 (a), to compensate health care homes. Under the former, State health care programs make payments for per-person care coordination by certified health care homes. Under Minnesota Statutes, section 62U.03 (a), private health plan companies pay a care coordination fee on behalf of members who choose to enroll in certified health care homes, using payment conditions and terms consistent with the system developed under Minnesota Statutes, section 256B.0753. The term is defined for ease of reference to the payment systems in the Rule.

Subpart 5 defines the term “care coordinator.” The definition is consistent with the definition contained in standards adopted by the Academy of Pediatrics, the Academy of Family Physicians, and the American College of Physicians.

Subpart 6 defines the term “care plan.” The definition is consistent with commonly accepted usage and meaning in the medical and health care industries.

Change: In response to public comment that reflected confusion about whether the definition included an electronic document, the Department added the phrase “including an electronic document.”

Subpart 7 defines the term “chronic condition.” A person with a chronic condition is one of two categories that are a primary focus under the Rule. The other category is persons with a complex condition.⁵ Due to the importance of persons with a chronic condition under the statute and Rule, the Department broadly surveyed medical definitions to define the term so that it will function usefully for health care homes. The Department also considered the interrelationship between the terms “chronic condition” and “complex condition.”

⁵ The enabling statute requires that the Rule “focus initially on patients who have or are at risk of developing chronic health conditions.” Minnesota Statutes, section 256B.0751, subd. The statute also requires that health care homes “ensure that health care homes develop and maintain appropriate comprehensive care plans for their patients with complex or chronic conditions” and “offer their health care home services to all their patients with complex or chronic health conditions.” Minnesota Statutes, section 256B.0751, subds. 2 (a) (7) and 3 (b).

Subpart 8 defines “clinic” as 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. The enabling statutes use the term “clinic.” Minnesota Statutes, section 256B.0751, subdivision 3, spells out the requirements for clinicians certified as health care homes: (a) A personal clinician or a primary care *clinic* may be certified as a health care home. If a primary care *clinic* is certified, all of the primary care clinic’s clinicians must meet the criteria of a health care home. [Emphasis supplied.]

So many comments questioned what constitutes a clinic that the Department defined clinic as described above. The definition is designed to encompass the many ways that Minnesota providers configure clinics. For health care homes certification, the key is that the clinicians in the entity implement health care homes standards and criteria consistently under a common set of operating policies and procedures. That way MDH can ensure that each of the clinic’s clinicians meets the criteria for certification.

Change: For clarity, the Department changed “recognized” to “recognizable” as a better way of expressing the internal integrity required for practice groups allowed to become certified health care homes.

Subpart 9. The definition of “Commissioner” reflects that the Department of Health will implement and enforce the Rule. The term is defined for ease of reference in the Rule.

Subpart 10. The definition of “Commissioners” comes from Minnesota Statutes, section 256B.0751, subdivision 1(c). The definition is restated in the Rule for the convenience of the reader, rather than using a citation to the statute.

Subpart 11 defines the term “complex condition.” For the same reasons previously addressed with respect to a “chronic condition,” the Department conducted a broad survey of medical definitions to define complex condition that would function usefully and pragmatically for health care homes. The Department selected a definition based largely on that used by the National Academy of Science to define “serious and complex medical condition.” (Institute of Medicine (1999)). In response to informal public comment received before the formal comment period, the Department expanded the definition to include a single medical condition that is complex.

Subpart 12 defines “comprehensive care plan.” The term is used in the enabling statute, which requires that the Rule “ensure that health care homes develop and maintain appropriate comprehensive care plans for their patients with complex or chronic conditions.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (7) The definition contains two other defined terms, namely, care plan and external care plan. The definition reflects the difference between a care plan and a comprehensive care plan, the latter of which includes information from external care plans created outside the health care home.

Subpart 13 defines “continuous.” The term is defined to clarify requirements in the Rule about patient access to clinic staff in part 4764.0040, subpart 1, item B, subitem (1).

Subpart 14 defines “cost-effectiveness.” The definition relies on measurements of quality, cost, and resource use. This is consistent with the enabling statute, which requires the Department to adopt rules that “incorporate measures of quality, resource use, [and] cost of care.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (8).

Change: Subpart 15 adds a new definition for “direct communication,” which 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.” The Department received so many questions and comments about its proposed requirement that the clinician and care coordinator reside at the same location that, as discussed at 4764.0040, subpart 5, item C below, the Department reconsidered the requirement altogether. The essence of the previous proposal is the importance of establishing personal relationships among the participant, the clinician, and care coordinator. Accomplishing this important part of health care homes requires that there be direct communication among the parties. This is not a function that health care homes can accomplish by delegation to outside services, such as a nurse phone line or off-site phone bank. It does not, however, require that parties share the same physical space. Rather it, requires the personal acquaintance that being in the same space engenders, such as the exchange of nonverbal cues and body language. After such a relationship is established, the parties can accomplish the needed face-to-face contact from time to time by video conferencing. Consequently, expressing this concept required a definition for the term “direct communication.” To avoid the possibility of confusion about whether an interpreter might be an intermediary, the Department added the sentence eliminating the doubt.

Subpart 16 (formerly 15) “Eligible provider” is a defined phrase for ease of reference in Part 4764.0030, subpart 1, item A, which refers to eligible providers as the category of entities or persons that may apply for certification as a health care home. The definition includes three categories of entities or persons: a personal clinician, local trade area clinician, or clinic that provides primary care services. The enabling statute states that: “A personal clinician or primary care clinic may be certified as a health care home.” Minnesota Statutes, section 256B.0751, subdivision 3 (a). The Department meets this requirement by including both clinicians and clinics in the definition of eligible provider.

Local trade area clinicians, as defined in subpart 23, are included in the definition of eligible providers to ensure that patients who regularly receive health care services in local trade areas outside of Minnesota will have access to health care home services. This meets the specified criteria to “provide patients with consistent, ongoing contact with a personal clinician or a team of clinical professionals to ensure continuous and appropriate care for the patient’s condition.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (4).

The three categories referenced in the definition are all qualified by the phrase, “that provides primary care services.” This is because a primary objective of the enabling statute, if not *the* primary objective, is to “emphasize, enhance, and encourage the use of primary care.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (1). The Department promotes the provision of primary care services by permitting only clinicians or clinics that provide them to become certified as a health care home and therefore receive payment for care coordination.

Subpart 17 (formerly 16). The definition clarifies what is encompassed in “end-of-life care.” The Department selected a definition that The National Institutes of Health’s “State-of-the-Science Conference Statement on Improving End-of-Life Care” (December 2004) and the World Health Organization have endorsed.

Change: In response to a commenter’s suggestion, the Department expanded the definition by adding the word “cultural.”

Subpart 18 (formerly 17). The definition of “evidence-based guidelines” is consistent with its common usage and meaning in the medical industry. (*See*, for example, “comprehensive database of evidence-based clinical practice guidelines,” compiled by the National Guideline Clearinghouse™ (“NGC”), an initiative of the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.)

Change: Because commenters expressed concerns that including “expert consensus” made the definition vague, the Department removed the phrase.

Subpart 19 (formerly 18). The definition clarifies the term “external care plan” for ease of reference to information contained in care plans that are separate from the care plan created and developed by the health care home.

Change: In response to a comment, the Department added the phrase “behavioral health plan.” The Department replaced the phrase “a plan by a social worker or case manager” with the phrase “a case management plan” to simplify the language.

Subpart 20 (formerly 19). The term “family” is defined broadly to allow the patient to identify family members without regard to actual blood relationships or legal formalities. The principles of “patientcentered care” and “shared decision making” compel caregivers to recognize a patient’s right to identify their significant relationships and to select meaningful participants for care-related activities and discussions. The definition also reflects the statutory directive in section 256B.0751, subdivision 2 (a) (3) to allow a legal guardian or health care agent to actively participate, as appropriate.

Change: The Department added the word “spouse” to the enumerated list stating possible meanings for the term for an adult’s family, to be consistent with those for a minor. The Department replaced the word “and” with the word “or” in item number (4) stating a possible meaning for the term family for a minor, in response to public comment that the definition was too narrow for a minor.

Subpart 21 (formerly 20). The Minnesota legislature created the term “health care home.” Nationally, the term “medical home” is used. By using health care home, the legislature sought to broaden the term to emphasize the health of the population and other aspects of the community. *See* Minnesota Statutes, section 256B.0751, subdivision 6 (Commissioner to collect health data and certified homes must meet outcome standards). The definition is simple and functional to reflect the possibilities of who or what can be a certified health care home.

Subpart 22 (formerly 21). The definition of a “health care home learning collaborative” is based on a set of approaches that use the “Breakthrough Series” model for improvement, developed by the Institute for Healthcare Improvement. According to the model, this involves a series of meetings to learn about best practices, quality methods, and ideas for change, and the opportunity to share experiences about changes made in the provider’s own local setting. Minnesota is recognized as a leader in the area of quality improvement through collaborative learning. (“Integrating Best Practices in Using Collaborative Learning,” Wilder Research, July 2009.)

Subpart 23 (formerly 22). The definition of “health care home team” is consistent with care team definitions from national medical home organizations, including the Center for Medical Home Improvement and the American Academy of Pediatrics.

Change: In response to public comment inquiring about the breadth of the term, the Department concluded that a health care team may include any number of other specialists to meet the needs of a participant, including a therapist, nutritionist, diabetes educator, or health care educator. The Department therefore added the phrase, “and may include other health professionals based on the participant’s needs.”

Subpart 24 (formerly 23). “Local trade area clinician” recognizes providers who are licensed for practice outside of the state, but who regularly see Minnesota patients because their practice is located close to the state’s borders in an area that commonly serves Minnesota populations. The definition incorporates the term “local trade area” from the rules governing the state health care programs to ensure common understanding and consistency. The regulations governing state health care programs provide that the services delivered by health practitioners in local trade areas are equivalent to services delivered by in-state providers and are distinguished from the services of other out-of-state providers. *See* Minnesota Rules, parts 9505.0190, .0215 and .5025. This treatment of local trade area services in the state health care program rules facilitates patient access to services and complies with 42 CFR 431.52 (b) (4) . The definition of “local trade area clinician” specifies the same categories of health care provider described in the definition of “personal clinician” in the authorizing legislation. *See* Minnesota Statutes, section 256B.0751, subdivision 1(e).

Subpart 25 (formerly 24). Minnesota Statutes, section 256B.0751, subdivision 6 (a) states that for continued certification, health care homes must meet outcome standards. An “outcome” is a measurement to gauge the results of treatment for a particular disease or

condition, or a change in patient status. Outcome measures may include subjective measures, such as a patient's perception of restored function, functional status, and quality of life; and objective measures, such as mortality, morbidity, and health status. The definition is simple and straightforward and recognizes the "triple aim" objectives.

Subpart 26 (formerly 25) defines "participant" to refer to a person who has selected to receive health care through a health care home. By including the participant's family in the definition, the Department preserved the patient-centered emphasis on both the participant and the participant's family whenever the term participant is used, without the need to state both, which would have become cumbersome. The term participant should be distinguished from patient, who may or may not participate in the health care home. This distinction becomes important to address health outcomes in patient populations.

Subpart 27 (formerly 26). The enabling statute requires that the standards for certification must encourage "patient-centered care." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). Doing the concept justice is difficult without couching requirements in aspirational terms that are difficult or impossible to measure and enforce. To meet the statute's directives, the Department included measurable components.

Change: In response to public comment that the Department should place greater emphasis on the patient's role in decision-making, the Department added the adjective "patient-driven" to describe shared decision-making. In response to comments that using the words "consider" and "listen" were ambiguous and diluted the importance of the patient's input, the Department removed the language "by listening to and considering."

Subpart 28 (formerly 27). "Personal clinician" is defined in the enabling statute at Minnesota Statutes, section 256B.0751, subdivision 1 (e). Rather than simply incorporating the statutory definition by referring to the statute's citation, the Department chose to state the definition in the Rule for the convenience of persons reading the Rule.

Change: Effective August 1, 2009, physician assistants must be licensed for the first time in Minnesota. Minn. Laws 2009, Chapter 159. Previously, physician assistants had been registered. The Department therefore replaced the term "registered" with the word "licensed" to keep the Rule consistent with current law.

Subpart 29 (formerly 28). The definition of "preventive care" is consistent with commonly accepted usage and meaning in the medical industry. (*See, i.e.*, medical dictionary definition at <http://www.mondofacto.com/facts/dictionary?preventive+health+services>.)

Change: The Department added "treatment" to the list of examples to make it explicit that, when appropriate, treatment falls within the scope of "preventive care." The American Cancer Society suggested this change, using the example of nicotine replacement therapy that prevents problems from developing.

Subpart 30 (formerly 29). The definition of “pre-visit planning” describes the functions of the planning process for clarity.

Subpart 31, (formerly 30). The definition of “primary care” is consistent with commonly accepted usage and meaning in the medical industry. The definition is a key one because the Rule allows only entities that provide primary care services to become certified as a health care home under part 4764.0030, subpart 1, item A. (“Eligible provider” is defined in subpart 15.). The Department sought to avoid defining primary care so narrowly that it would exclude specialty providers from becoming certified. The definition therefore permits a specialty provider that actually offers and delivers traditional primary care services to qualify as a primary care provider as a part of its practice.

Subpart 32 (formerly 31) defines “primary care services patient population.” This is a key concept because the clinical performance outcomes requirements are measured based on this population. The definition clarifies that this population includes all persons receiving primary care services from the clinic or clinicians that compose the certified health care home. The advisory group on performance outcomes is developing details for this concept.

Subpart 33 (formerly 32). The “referral” is a clinical order or other document for recommending specialty care to the participant. It is an important component of tracking care and ensuring continuity of care between the primary care provider and specialist. The definition tailors the traditional understanding of the term to the health care home context.

Change: In response to public comment that reflected confusion about whether the definition included an electronic document, the Department added the phrase “including an electronic document.” The Department also inserted the phrase “a consultation for” in front of “an evaluation” to elaborate on the nature of a referral and make it clear that a referral recommends a specialist to provide consultative services in the manner ordered in the referral.

Subpart 34 (formerly 33). “Shared decision-making” is a core concept in patient- and family-centered care. The enabling statute requires the Department to adopt certification requirements that are patient-centered and encourage the use of patient decision-making aids. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3) and (10). On the continuum of a health care practitioner making health care choices for a patient, on one end, and the patient making health care choices, on the other end, the definition is intended to move actual practice along the continuum toward patient choice.

Change: The Department received comments including recommended language from the Health Care Homes Consumer and Family Council, one of the Department’s rule development advisory committees. The Council commented that the definition did not sufficiently take into account knowledge that the family and patient bring to a medical visit. The Department adopted the language that the Council recommended.

Subpart 35 (formerly 34). The definition of “specialist” refers to sources of medical information that must be obtained outside the health care home. The definition is needed for clarity when the Rule addresses a participant’s right to choose a specialist and when the Rule describes care coordination.

Change: Based on a comment from the Minnesota Medical Association, the Department restructured the language to reflect medical specialties and subspecialties that by tradition pertain to medical doctors and doctors of osteopathic medicine. The Department also listed examples of other health care professionals who have specialized training and might be called upon to provide appropriate care.

Subpart 36 (formerly 35). The Department adopted the “state health plan” definition in the enabling statute.

Subpart 37 (formerly 36). The Department defined “statewide measurement reporting system” for clarity and ease of reference according to the requirements in Minnesota Statutes, section 62U.02.

Change: The Department changed the definition from “statewide *measurement* reporting system” to “statewide *quality* reporting system” and deleted the reference to Minnesota Statutes, section 62U.02. The statewide system is commonly referred to as the “quality reporting system” so this change conforms the definition to that usage. The Department relies on Minnesota Statutes, section 256B.0751, subdivision 6 for its authority to collect the data so the previous reference to 62U was eliminated to avoid confusion.

Subpart 38 (formerly 37). The definition of “variance” is consistent with the legal meaning of the term and its usage in Minnesota Statutes, section 14.055, which addresses the use of a variance in rules. The definition also contains specific references to the Rule, and reflects that a variance may be obtained with respect to any requirement in parts 4764.0010 to 4764.0070.

3. Part 4764.0030 Certification and Recertification Procedures.

Part 4764.0030 describes who may apply for certification and what an applicant must submit to apply for certification or recertification. It also sets out the Rule requirements that apply to an applicant for initial certification, for recertification after the health care home has been certified for one year, and an applicant for recertification after the health care home has been certified for two or more years. This part also states the substance and timing for the Commissioner’s decision regarding an application.

Subpart 1, item A, describes who may apply for certification. As addressed above “eligible provider” includes the category of entities or persons that may apply for certification as a health care home. The definition refers to a personal clinician, a local trade area clinician, or a clinic that provides primary care services. *See* Part 4764.0020, subpart 15. The authority and rationale for this definition are also described above.

Item A also requires an eligible provider to be “supported by a care team and systems according to the requirements in part 4764.0040.” The enabling statute states that: “[i]n order to be certified as a health care home, a clinician or clinic must meet the standards set by the Commissioner.” Minnesota Statutes, section 256B.0751, subdivision 3 (a). When the Department certifies an individual clinician, the individual is not certified in isolation. Rather, the person is certified with the infrastructure – e.g., the clinical care team, the use of a dedicated care coordinator, a patient registry, a system of communications, and the adoption of relevant policies – through which the requirements of part 4764.0040 are met. When a clinician leaves a particular clinic, the clinician loses that team infrastructure and those systems, which were an integral part of the clinician’s ability to meet the Rule requirements. The next clinic that employs or associates with the clinician may not have the systems and supports needed to replace those of the former clinic and so that the clinician could comply with the certification requirements.

Item A therefore conveys that the removal of the “care team and systems [that meet] the requirements in part 4764.0040” from the clinician, which occurs when a clinician leaves a clinic, renders the clinician lacking in an essential component that made the clinician eligible for certification. Stated another way, the certification of an individual clinician is not necessarily portable between clinics. Rather, the moving clinician would need to apply for certification again.

Item B limits clinic certification to those in which all of its clinicians meet the requirements. This comes directly from the authorizing legislation, which states, “[i]f a primary care clinic is certified, all of the primary care clinic’s clinicians must meet the criteria of a health care home.” Minnesota Statutes, section 256B.0751, subdivision 3 (a). Although duplicative of the statute, this requirement carries such fundamental importance to the certification process that it merits inclusion in the Rule.

Item B references clinicians and local trade area clinicians because the provision is intended to encompass all clinicians. The remaining references in the Rule to a clinician therefore refer to both types of clinician.

Change: The Department changed the structure of the first sentence in item B in response to a comment that the requirement was confusing because it was stated in the negative. Another public comment expressed concern about how a clinic’s normal personnel changes would affect its certification as a clinic, so the Department added new sentences to the end of item B to address these circumstances. Based on the shift in focus in item B with the new sentences, the Department modified the headnote to better describe the contents of items A and B.

Subpart 2 describes the required contents of an application for certification as a health care home. When the Department evaluates whether to certify an applicant, the Department must determine whether a clinic or clinician “meets the standards set by the Commissioners.” Minnesota Statutes, section 256B.0751, subdivision 3 (a). The Department could not carry out this directive without information so it therefore has implicit authority to obtain information required to make this determination from the applicant. Because certification is voluntary, an

applicant may, at any time, withdraw its request for certification and decline to furnish the information sought.

Item A requires an applicant to submit a completed self-assessment that describes how the applicant meets the standards in part 4764.0040. In addition to furnishing specific information to the Department, the self-assessment enhances the applicant's ability to evaluate whether it meets the certification requirements, and is therefore ready to submit its application for certification.

Item B requires an applicant to submit a completed and signed application form. The application form provides the Department with basic information about the applicant needed by the Department to administer the certification program. The application consists of four sections, namely: applicant demographic information; additional clinician information; clinic's patient profile; and representations and signature. The applicant must also complete a self-assessment and attach the necessary documents.

Item C permits the Commissioner to obtain other documentation to show that the applicant meets the certification standards. As noted above, the scope of the Commissioner's authority is limited to what the Commissioner needs to thoroughly and accurately evaluate an application for certification. Because of the complexity the Commissioner faces in evaluating applicants' diversity in practice and procedures, on the one hand, and the need for administrative economy, on the other, the flexibility that this item entails streamlines the process as possible.

Subpart 3 provides that the Commissioner may both conduct an on-site review and request additional documentation. The Department needs this level of quality control to verify the validity of information an applicant submits. Without the ability to conduct an on-site review, the Department's authority to certify would be considerably weakened, thus defeating MDH's ability to properly protect public resources. An added benefit is that on-site reviews and additional information foster the learning contemplated by the statute as the Department and providers work together.

Subpart 4 precisely defines when an application is complete. This is important because the Department's receipt of a completed application triggers the running of a 90-day time-frame for the Commissioner to notify the applicant of the certification outcome. *See* subpart 7, item A.

Subpart 5 requires an applicant to submit a letter of intent that requests recertification at least 60 days before the expiration of a year from its last certification. Some health care homes will choose to allow their certification to lapse, rather than seek recertification. The Rule therefore requires an applicant to initiate the recertification process through the letter of intent. The letter also has a second, administrative purpose. When the Department receives a letter of intent, the Department will furnish to the health care home password-protected access to an online assessment tool and application form.

Subpart 5 also states the steps that a certified health care home must take to retain its certification, that is, to be recertified. Several provisions of the enabling statute provide the

authority for subpart 5. First, “[i]n order to maintain their status as health care homes, clinicians or clinics must renew their certification annually.” Minnesota Statutes, section 256B.0751, subdivision 3 (a). In addition, the enabling statute states that: “For continued certification under this [statute], health care homes must meet process, outcome, and quality standards as developed and specified by the Commissioners.” Minnesota Statutes, section 256B.0751, subdivision 6 (a).

The Department meets these objectives through progressively rigorous standards and requirements that are set forth in part 4764.0040. As the provider gains additional years of experience performing as a health care home, the standards require further development toward having the desired characteristics of a model health care home. The Rule therefore contains different requirements for initial certification, recertification after one year of experience, and recertification after two or more years as a health care home. The standards that apply to initial certification and recertification after the first year focus primarily on the adoption and implementation of policies, systems, and infrastructure. As the applicant moves along the spectrum of experience operating as a health care home, the standards increasingly move away from developing components and toward measurable performance outcomes. *See* part 4764.0040.

Subpart 5, items A and B, have an important relationship to part 4764.0040 because they preview and clarify which requirements in part 4764.0040 govern the applicant at different stages of recertification. Part 4764.0040 is organized so that there are at least two subparts that correspond to each standard.⁶ The subpart headnotes identify the standard that is implemented through the requirements in the subpart. For each standard, the first related subpart states the requirements for initial certification, and the second subpart states the requirements for recertification at the end of the first year of certification. For the performance reporting and quality improvement standard only, there is a third subpart that pertains to an applicant at the end of the second year of certification, and all subsequent years.

Part 4764.0030, subpart 5 clarifies how part 4764.0040 applies to an applicant for recertification. Item A addresses health care homes that have been certified for one year and seek recertification. The item explains that, in addition to meeting the requirements in part 4764.0040 that the applicant previously met for initial certification, the applicant must also meet the additional requirements that apply after the applicant’s first year of certification.

Item B addresses health care homes that have been certified for two or more years and seek recertification. The item clarifies that the health care home must continue to meet the requirements in part 4764.0040 that it previously met for initial certification and for recertification at the end of the first year. In addition, the applicant must meet the requirements specific to the end of the second year and later years, contained in part 4764.0040, subpart 11. Also, item B states that the applicant’s outcomes from its primary-care-services patient population must achieve the benchmarks that the Commissioner establishes under subpart 6. (The Commissioner’s authority to establish benchmarks is addressed below regarding subpart 6.)

⁶ As previously explained, part 4764.0010, subpart 2 previews in general terms the five broad standards that are implemented through the requirements in part 4764.0040.

Item B reflects three areas in which an applicant's performance outcomes must meet benchmarks; namely, patient health, patient experience, and cost-effectiveness. As previously noted in section I-B (footnote one), the Massachusetts-based Institute for Healthcare Improvement originally identified these three areas, which have gained widespread recognition and acceptance in the Minnesota medical community as key to achieving transformational improvement in health care. These "triple aims" make up the objectives that the Minnesota legislature adopted in the enabling statute. Minnesota Statutes, section 256B.0751, subdivisions 2(a) (8) and 6.

The Rule provision also specifies that the outcomes are measured based on the applicant's entire primary-care services population. The outcomes are not based on the applicant's health-care-home participant population alone. *See* part 4764.0020, subpart 31 (primary-care services population means all patients receiving primary care services from the clinic or clinicians that compose the health care home, whether or not the patient is a recipient of care coordination services in the health care home). In response to public comment from the informal comment period, the Department deliberately chose to measure outcomes based on the entire primary care services population. The Department's decision responded to concerns expressed about the potential for health care homes to engage in an unseemly practice of "cherry-picking" healthy participants for the health care home to score well on health outcomes measurements. As proposed and adopted, the Rule has a different desired effect. Because performance outcomes are based on the health of the entire primary care services population, a health care home has an incentive to recruit as many participants as possible into the health care home to put the practices required in a health care home to use to result in improved health outcomes for its participants.

Subpart 6 provides that the Department must announce annually the benchmarks that a health care home must achieve in its performance outcomes after the end of the second year of certification and in all subsequent years. As explained below, the provision recognizes the Commissioner's need to obtain information, data, and public input, before announcing the first benchmarks. The provision also recognizes the need for benchmarks to evolve over time as both the industry and the Department gain experience in outcomes measurement.

Consequently, the Commissioner cannot issue specific, permanent benchmarks to incorporate into the Rule now. That approach would be premature and preclude consideration of additional data and information that has not yet developed. For example, statewide data for all certified health care homes will show information and trends that the Commissioner should take into account when establishing the benchmarks and this data is, obviously, not yet available. Further, the Institute for Healthcare Improvement is embarking on an initiative that is specifically designed to achieve the three critical objectives among health entities that are volunteering to use its model. *See* <http://www.ihl.org/IHI/Programs/StrategicInitiatives/TripleAim.htm?TabId=6>. Outcomes from that initiative will inform the selection of benchmarks. With President Obama's administration's focusing at present on curbing rapidly rising health care costs, the relationship between costs and patient outcomes becomes apparent in the national consciousness. Additional studies, analysis,

and data from across the country can therefore be anticipated. In this vein, the Patient Centered Primary Care Collaborative has established six national advisory boards to develop outcomes measures for medical homes in the areas of the patient experience, patient health outcomes, cost-effectiveness, overall value, physician and team satisfaction, and medical “homeness.” Moreover, the Department’s advisory group on performance outcomes will influence the development of performance targets. That group will continue to convene into 2010. It includes clinics and clinicians that will be certified, and specialists in the measurement of performance outcomes.

Change: The Department removed the first sentence from subpart 6 because the sentence duplicated the requirement that is stated in a different manner in subpart 5, item B, subitems (1) and (2). (The Department also changed the headnote to “Benchmarks” to reflect the more narrow focus of the amended subpart.) In addition, the Department replaced the phrase “announced annually” with “that the Commissioner announces annually” to convert the language to the active voice.

Change: As explained above in the discussion for 4620.0020, subpart 4, the Department removed the reference to Minnesota Statutes, section 62U.02 in the Rule to eliminate confusion about the statewide reporting system. The Department relies on Minnesota Statutes, section 256.0751, subdivision 6 for collecting the data needed to perform the necessary evaluations of health care homes performance.

Subpart 6 limits the Department’s discretion to establish benchmarks by requiring benchmarks to be based on one or more of the six factors set forth in items A through F. Item A permits the Department to establish benchmarks that reflect outcomes improvement over time. This measurement requires a comparison of a health care home’s current quality measures with its past quality measures. Item B permits the Commissioner to select a benchmark based on a comparison of the quality outcomes for a particular health care home to outcomes for other health care homes. The bases for developing benchmarks identified in items A and B both support the statutory objective to adopt standards that focus on the delivery of high quality health care services. Minnesota Statutes, section 256B.0751, subdivision 2(a) (2), subdivision 2 (a) (8), and subdivision 6 (a).

Subitem C provides for benchmarks based on state or federal law. For example, if Congress adopts health care reform legislation that includes specific, measurable cost-containment measures, that measurement technique and the related outcomes could have a bearing on benchmarks for cost-effectiveness. Item D permits benchmarks based on best practices developed by a scientifically based outcomes-development organization, which meets the Department’s statutory objective to “encourage the use of scientifically based health care.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (10). Item E permits benchmarks based on measures established by a national accrediting body or professional organization, which supports the statutory directive that the Department consider standards adopted by national accrediting organizations or health care homes organizations in the development of the Rule. Minnesota Statutes, section 256B.0751, subdivision 2 (a).

Subitem F permits benchmarks that would improve the quality or enhance the use of data currently being collected. The provision provides the authority to adopt new measures to improve the usefulness the outcomes data being collected as the Department gains experience with the data, while limiting the Commissioner's discretion to measurements that pertain to the usefulness of data already being collected.

Subpart 7 establishes a timetable for the Department's decision on an application for certification as a health care home and advises the applicant of its rights when the applicant is certified, or when certification is denied, respectively.

Item A provides that the Department will notify an applicant in writing about whether the applicant is certified within ninety days of receiving a completed application. This requirement benefits the applicant by establishing a predictable, consistent process.

Item B restates the basic statutory principle that a health care home is eligible to receive care coordination payments if the health care home is certified or recertified. *See* Minnesota Statutes, section 256B.0753, subdivision 1. The Rule refers to reimbursement by a "care coordination payment system," a phrase that the Rule defines in part 4764.0020, subpart 4, as a system established under Minnesota Statutes, section 256B.0753, subdivision 1, or Minnesota Statutes, section 62U.03, paragraph (a). According to these statutes, DHS will pay the fee for a participant who is a state health care program recipient, and the pertinent health plan company will pay the fee for a participant who is a member of the health plan.

Item C requires the Department to state its reasons in writing if the Department denies the application for certification or recertification. This requirement benefits the applicant because it ensures that the applicant is informed of the basis for denial. Item C also provides notice to the applicant that the applicant has a right to an administrative appeal if its application is denied.

4. Part 4764.0040 Health Care Home Standards.

Subpart 1 states the standard to promote broad participant access to a health care home and communications between the health care home team, the participant, and other providers.

Change: In response to public comment indicating that the phrase "active recruitment" of patients into a health care home was ambiguous, and to eliminate any potential vagueness created by the adjective "effective" to describe communication, the Department removed these words from subpart 1.

The first sentence of the subpart requires the applicant to have a system that supports communication among the members of the health care home team, the participant, and other providers. First, by requiring communication between the provider and the patient, the Department satisfies the criteria for these standards to "encourage patient-centered care." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). The Rule in part 4764.0020, subpart 26 defines patient-centered care as delivering health care through patient-driven, shared decision making that is based on participation, cooperation, trust, and respect for participant

perspectives and choices. These health care objectives can only be achieved with provider-patient communication to build mutual trust, share information and experiences, and empower the patient to participate in health care decisions.

The first sentence of the subpart also requires the applicant to adopt a system that supports communication with other providers. Modern medical care frequently involves a need for services from specialty and subspecialty providers. Effective communication between the health care home, the patient, and other providers implements a model of the health care home as a base from which a patient's care is comprehensively coordinated, so that the patient does not experience fragmented health care. As a result, the Rule requirement meets the statutory criteria that the rules must encourage patient-centered care. The requirement is also consistent with the statute's directives that the rules require the use of a care coordinator and a comprehensive care plan, since both functions involve management of patient's overall care, including specialty care. *See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (5) and (6).*

Item A requires an applicant to offer health care home services to its patients who have or are at risk of developing complex or chronic conditions and are interested in participation. The provision incorporates a requirement from the enabling statute, which provides that “[c]linicians or clinics certified as health care homes must offer their health care home services to all their patients with complex or chronic health conditions who are interested in participation.” *Minnesota Statutes, section 256B.0751, subdivision 3 (b).*

Change: Upon further consideration of the broad reach of the above-noted statutory directive, including the term “all,” the Department removed language that would have limited the Rule requirement to those patients who, in the clinician's judgment could benefit from a health care home. Consistent with the statutory language, the Department also added the word “all” to describe the group of patients to whom the requirement related to offering services applies.

Item A expands the category of persons to whom a health care home must offer its services from what is required in the statutory provision previously noted. Specifically, the Rule goes beyond that particular provision because the Rule also addresses persons *at risk for developing* complex or chronic conditions. The expansion is based on a different statutory provision, *Minnesota Statutes, section 256B.0751, subdivision 2 (a) (7)*, which requires the Department to adopt requirements that “focus initially on patients who have *or are at risk of developing* chronic health conditions” (emphasis added). Furthermore, the Department included persons at risk of developing complex conditions for consistency in the treatment of persons with chronic and complex conditions to emphasize the preventive nature of health care homes.

Item B lists the features of a system that meets the minimum requirements needed to provide enhanced patient access to services, and beneficial communication between a health care home and a participant. Subitem (1) requires a system that informs participants that they have continuous access to designated clinic staff, an on-call provider, or a phone triage system. “Continuous” is defined in the Rule to mean twenty-four hours per day, seven days per week, and 365 days per year. *See part 4764.0020, subpart 13.*

The Rule requirement follows the statutory objective that health care homes “provide patients with a consistent, ongoing contact with a personal clinician or team of clinical professionals to ensure continuous and appropriate care for the patient’s condition.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (5). Moreover, the requirement will likely result in more appropriate use of health care resources and, consequently, reduced cost. *See* Minnesota Statutes, section 256B.0751, subdivision 2 (a) (8) (rule requirements must measure resource use and cost of care) and subdivision 6 (Commissioner must evaluate impact of health care homes on cost). When participants are able to reach a health care professional at all times, one who can screen information to identify situations that warrant a participant’s immediate appointment with a health professional, unnecessary emergency room visits and hospitalizations might be avoided. Studies support this outcome. Many hospital visits result not from the severity of the patient’s condition, but the unavailability of a less intensive and costly health care delivery option. Furthermore, because acute conditions can be addressed earlier when appropriate, this might also result in better health outcomes.

The continuous access requirement in subitem (1) may be met through telephone contact. The method of access may be through clinic staff, an on-call provider, or a phone triage system. For example, a health care home could contract with a local hospital emergency room to furnish call-response services outside of normal business hours.

Subitem (2) requires that whatever system a health care homes designs to meet the continuous access requirement, the person receiving the participant’s contact must have continuous access to the participant’s medical record information.⁷ Access to the participant’s diagnoses, prescriptions, and other pertinent information completes the participant’s available information so that the person taking initial information from a participant can draw a more comprehensive profile from the defined data elements and will be in much better position to respond appropriately to the participant’s specific health needs. As with the continuous access requirement, this promotes the best use of health care resources, another statutory objective. The requirement also promotes the use of “efficient, and effective health care services” because it increases the likelihood that the correct response is made at the right time. *See* Minnesota Statutes, section 256B.0751, subdivision 2 (a) (9) and (2).

Subitem (2) also lists the minimum required contents for a medical record. The medical record must contain contact information for the participant and the personal clinician. With this information, the person performing triage for participants contacting a health care home when the clinic is not normally open can, if warranted, contact the appropriate health professional directly so that the professional makes direct contact with the participant. The requirement helps “to ensure continuous and appropriate care for the patient’s condition.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (4).

⁷ “Medical record” for these purposes refers to the limited information specified in the Rule and not the more extensively defined medical record governed by the Minnesota Health Records Act, Minnesota Statutes, section 144.291.

The medical record must contain the participant's racial or ethnic background and primary language. This comports with the statutory directive that the Rule requirements "encourage. . . providing care that is appropriate to the patient's race, ethnicity, and language." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). If the participant's primary language is other than English, having this information reflected in the medical record alerts health professionals quickly to a potential communication barrier.

Other information that the Rule requires in the medical record is information about enrollment in a health care home and the patient's preferred means. Communicating with the participant according to his or her preferred means is consistent with the principles of patient-centered care and shared decision-making, in which the patient has a distinct voice in the manner of health care delivery. *See* Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2).

Unit (c) requires that the medical record state the participant's consents and restrictions about releasing the patient's medical information. Although the private or public nature of information in a medical record is generally governed by applicable law, the participant's specific consents or restrictions may override the law that would otherwise apply by default. This permits patient-centered care, and, when the pertinent consent is given, family-centered care, in which the patient controls to whom information is released. Compliance with the Rule creates a mechanism for recording and referencing which persons should share in the exchange of medical information.

Change: In response to a comment that interpreted the previous language to restrict the group of persons to whom a participant could consent to release of medical information, the Department removed the phrase "to specific family members." The change broadens the requirement, but also simplifies compliance, because the Rule now requires a health care home to include any consents and releases in a medical record. The Department also enhanced simplified the language by replacing the words "regarding the release of" with "for releasing."

Finally, to ensure that the medical record requirements result in "high quality, efficient, and effective care," unit (d) requires the medical record to contain basic health information that is essential or important to properly assess the participant's need for service. This information is: the participant's diagnoses, allergies, medications related to chronic and complex conditions, and whether a care plan has been created. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2)

Subitem (3) requires that the recipient of a patient contact determine when to schedule an appointment for the patient depending on the acuity of the patient's condition and a protocol. The protocol must address whether an appointment must be scheduled within one business day to avoid unnecessary emergency room visits and hospitalizations. These requirements meet the statutory directive to develop a rule that "ensure[s] continuous and appropriate care for the patient's condition." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (4). The use of a protocol to avoid unnecessary emergency room visits and hospitalizations is consistent with the enabling statute's objectives to improve the propriety of resource use and reduce the cost of care.

See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (8) (standards must measure resource use and cost of care) and subdivision 6 (Commissioner must evaluate impact of health care homes on cost). *See also* Minnesota Statutes, section 256B.0753, subdivision 3 (anticipating cost savings resulting from implementation of health care homes).

Item C requires that the applicant collect information about participants' cultural background, racial heritage and primary language, and generally describe how the applicant will apply this type of information to improve care. Through this requirement, the Department meets the enabling statute's requirement that the health care home standards "encourage . . . providing care that is appropriate to the patient's race, ethnicity, and language." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). By requiring the applicant to obtain this information and explain how it will be used, the Rule lays the groundwork for the applicant's ability to provide culturally relevant care, an evidence-based practice shown to improve both the likelihood the participant will adhere to medical advice and the resulting health care outcomes.

Change: The Department replaced the word "use" with "apply" because apply is a more specific term that connotes that the information on culture, race and language will serve a fruitful purpose.

Item D requires the applicant to document that the applicant is using the participant's preferred means of communication, if available in the clinic. This fulfills the companion Rule requirement, noted above, to record the preferred means of communication in the medical record. As with that practice, the Rule requirement here carries out the enabling statute's requirement that the rules encourage patient-centered care. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). The Rule excepts the use of a preferred means of communication from the requirement when the means is not available within the applicant's technological capability. An example is when a patient prefers communication via electronic mail but the clinic does not have encryption software or other measures to protect sensitive medical information from disclosure.

Item E requires the applicant to inform participants that they may choose a specialty care resource without regard to whether the specialist is a member of the same provider group or network as the participant's health care home. The requirement meets the statutory requirement to adopt rules that "encourage . . . active participation by the patient . . . as appropriate in decision making" and "encourage . . . patient decision-making aids that provide patients with information about treatment options and their associated benefits, risks, costs, and comparative outcomes." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (10). This is because the Rule requires the applicant to share adequate information with the patient so the patient can make an informed decision about which specialty provider to select.

Ideally, the Rule will motivate the applicant to furnish objective information about optimal treatment and care options available through various providers, rather than basing a referral solely on which specialty provider is within the health care home's network. The Rule thus responds to the statutory requirement to adopt standards that focus on delivering high-quality health care services. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2). The

Rule requirement is also in keeping with a separate objective of the comprehensive 2008 health care reform legislation, which is to improve consumer health care choices through information-sharing about the quality of services available from different providers. *See* Minnesota Statutes, section 62U.04, subdivision 1 (Commissioner required to provide comparative cost and quality information to consumers).

The Rule requires the applicant to inform patients that it is the patient's responsibility to determine whether their insurance covers the specialty provider. Participants need to know that obtaining this information is the patient's responsibility because coverage information is important to make an informed decision about health care options. Lack of insurance coverage typically results in out-of-pocket expenses for a patient to cover the cost of medical care.

Another concern this item is designed to address is the commonly expressed concern throughout the entire rule development about "gate keeping," that is, the possibility that a provider will refer a participant to a particular professional who might be in the same clinic or a related clinic, leaving the participant with the impression that the participant must accept the provider's recommendation. The Department has included Item G to counter any such tendency.

Item F requires the applicant to comply with existing applicable law on information privacy and security. Some of the other Rule requirements pertain to storing and accessing patients' medical information, such as the requirements in item B that a medical record contain specified information and be accessible to certain on-call providers or off-hours representatives. Despite any new obligations under the Rule, though, item F affirms that the responsibility to determine compliance with both the Rule and applicable law ultimately rests with the provider.

Subpart 2 states the requirements for recertification that implement the standard regarding broad participant access to a health care home and meaningful communication between the health care home and participant. The requirements pertain when a health care home seeks recertification after it has been certified for one year.

To comply with subpart 2, the applicant must demonstrate that the applicant encourages participants to take an active role in managing the participants' health care. This requirement is another measure to "encourage patient-centered care, including active participation by the patient and family. . . as appropriate in decision making and care plan development." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). As previously noted, family involvement appears in the Rule through the definition of the word participant in Part 4764.0020, subpart 25, which means the patient and, where applicable, the patient's family.

Change: To address some questions from commenters about how to show improved participant involvement, and also to clarify that the requirement in subpart 2 is to show that the health care home has communicated with the participant about a potential barrier to health education, the Department replaced the word "improved" with the word "demonstrated." To further clarify the requirement, the Department replaced the word "addressing" with the more specific words "identifying and responding to." The Department also replaced the word

“impediment” with the word “barrier” because impediment is sometimes construed to mean a disability, which is not the intended meaning.

As just noted, subpart 2 requires the applicant for recertification to show that the applicant has demonstrated participant involvement and communication by identifying and responding to any of three barriers to health education. The barriers identified can be the participant’s readiness for change, literacy level, or other barriers to learning. The Rule requirement meets the statutory criteria that the standards focus on delivering effective health care services, and, here also, that the rules encourage patient-centered care. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2) and (3). Services that are designed to respond to the unique barrier experienced by the participant help the participant overcome the barrier, and are therefore more effective. Similarly, identifying and responding to any one type of barrier demonstrates a patient-centered focus to overcome the barrier. For example, an applicant could adopt a policy to routinely identify a participant’s literacy level, and respond to the outcome by use of greater reliance on verbal communication for participants with a low literacy level.

Subpart 3 addresses the standard regarding use of a searchable, electronic patient registry. The enabling law requires that the rules “ensure the use of health information technology and systematic follow-up, including the use of patient registries.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (9). The first sentence of subpart 3 states the two primary functions of an electronic registry: to contain participant information and track patient care. These general functions are implemented through the specific requirements set out in items A and B.

Item A requires that the registry 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 gaps in care. The Rule requirement supports the statutory objective of requiring technology use and systematic follow-up by requiring the applicant to have a patient registry that can perform as an automated, electronic system for health care management. Automating the management and follow-up of patient care also addresses the efficiency of health care services. It permits some functions to be performed by a computer to support the work of health care professionals, and can therefore preserve their time for direct patient care. *See* Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2) (standards must focus on efficient health care services).

Item B states that for each participant, the registry must contain the participant’s name, age, gender, contact information, and any identification number assigned by the health care provider. This requirement establishes a minimum threshold of basic information about participants that must be in the registry. This minimum threshold gibes with common understanding in the health care industry regarding the phrase “patient registry.”

Item B also requires the registry to contain sufficient data elements to issue a report that shows gaps in care for specific subgroups of participants with a chronic or complex condition. This requirement encompasses two elements from the enabling statute: finding gaps for

continuity-of-care purposes and managing chronic and complex conditions. First, the rules must “ensure continuous and appropriate care for the patient’s condition.” To accomplish that objective, a health care home needs to identify any gaps in care, so that the health care homes can address them and keep the patient’s needs fulfilled. This is what “continuous and appropriate care” means.

Second, the registry must contain sufficient data elements to issue a report identifying gaps in care for groups of participants with a chronic or complex condition furthers the objective to “focus initially on patients who have or are at risk of developing chronic health conditions.” Minnesota Statutes, section 256B.0751, subdivisions 2 (a) (4) and (7). A report concerning persons with chronic health conditions and various subgroups within it will reveal where improvements can be made for these patients as a group, dovetailing with the continuity requirement discussed in the paragraph above.

Change: In subpart 3, item B, subitem (2), the Department replaced the words “specific subgroups” with “groups” to more accurately describe a broader, more general perspective on the requirement to sort the data by groups. The adoption and effective use of electronic health information systems can play a significant role in transforming the health care system and in supporting healthier communities.

A comment received during the public comment period expressed a concern that smaller clinics might not have the resources to retrofit existing technology to meet the Rule requirement regarding an electronic patient registry. The Department views this type of circumstance as one for which the Department would give serious consideration to an applicant’s require for a variance. For example, smaller clinics might use other types of computer-generated spreadsheets or databases such as Excel or Access for its electronic patient registry. Nevertheless, providers will have to accommodate the significant mandates that were enacted in the 2007 and 2008 Legislative sessions that affect all health care providers (*see* Minnesota Statutes, section 62J.495-497). That statute requires:

- All health care providers and hospitals must have an interoperable electronic health record (EHR) system by 2015.
- The State of Minnesota must develop a statewide implementation plan to meet the 2015 interoperable EHR mandate.
- The State of Minnesota must establish uniform health data standards by 2009.
- All health care providers and payers must establish and use an e-prescribing system by January 1, 2011.

Subpart 4 specifies that when a health care home seeks recertification at the end of the first year, it must use the patient registry to identify gaps in care for participants and implement

remedies to prevent gaps in care. The Rule requirement goes a step beyond the requirement for initial certification because it requires that the health care home use the registry to follow up and correct the situation when gaps in care are identified. The Rule provision implements the criterion in Minnesota Statutes, section 256B.0751, subdivision 2 (a) (9) that the rules require the use of health information technology and systematic follow-up, including the use of patient registries. The automated, electronic patient registry amounts to health information technology. The required functions, to identify gaps and implement remedies, meet the statutory criterion that health care homes provide systematic follow-up.

The Rule provides two examples of how to remedy gaps in care through using a patient registry: appointment reminders and pre-visit planning. Appointment reminders increase the likelihood that participants will keep the appointment as scheduled and arrive on time, so the Rule requirement promotes the efficiency of the health care. This meets one of the statutory criteria for the rules. *See* Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2). The use of patient reminders and pre-visit planning also promotes the statutory criterion that the rules focus on the participant's ongoing contact with a clinician or team of clinical professionals to ensure continuous and appropriate care. *See* Minnesota Statutes, section 256B.0751, subdivision 2 (a) (4). Pre-visit planning is a standard requirement for medical homes, as seen in programs for the National Committee for Quality Assurance's Physician Practice Connections- Patient-Centered Medical Home and CMS' Medical Home demonstration project. Other remedies to gaps in care that can be implemented through an automated patient registry are helping to see that follow-up appointments are made and prescriptions filled.

Subpart 5 requires the applicant for certification to adopt a system of care coordination that promotes patient and family-centered care. This is in keeping with the enabling statute, which directs the Department to adopt rules that "encourage patient-centered care, including active participation by the patient and family." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). Many care groups view the patient-provider relationship as the very essence of the health care home model.

Item A requires the applicant to adopt a system of collaboration in which the personal clinician, care coordinator, and health care home participant collaborate about the participant's health care. Item A, subitem (1) specifically requires that one or more members of the health care home team set health care goals for the participant and identify resources to achieve the goals. In Part 4764.0020, subpart 22, the health care home team is defined to include the personal clinician and care coordinator, and, depending on the size of the health care home, sometimes other professionals who plan and deliver care in a coordinated way through the health care home. The team approach with relevant professionals participating ensures that care is integrated and coordinated across all elements of the health care system, rather than fragmented. This is a patient-centered, rather than health care system-centered, approach. In addition, such group collaboration to identify resources to achieve goals enhances the quality of the information provided to the participant because it is based on multiple perspectives addressing all of the participant's health needs. The approach is consistent with the statutory criterion that the rules

encourage the use of patient decision-making aids that provide the patient with information about treatment options. *See* Minnesota Statutes, section 256B.0751, subdivision 2 (a) (10).

Subitem (2) requires the applicant to adopt a system in which the personal clinician and the care coordinator ensure consistency and continuity of care. This mirrors the statutory requirement that the Department develop standards that “ensure continuous and appropriate care for the patient’s condition.” *See* Minnesota Statutes, section 256B.0751, subdivision 2 (a) (4).

Subitem (3) requires the applicant to adopt a system in which the participant collaborates with the health care home team about how often the participant will communicate with the care team, with the participant’s other health care providers, and community resources. Through this requirement, the Department carries out the statutory criteria that the standards should “provide patients with a consistent, ongoing contact with a personal clinician or team of clinical professionals to ensure continuous and appropriate care.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2). By establishing a particular frequency of communications between the participant and the care team, and between the participant and other providers, the continuity of care is enhanced. Because the care team collaborates with the participant to make these care planning decisions, the Rule requirement also furthers the statutory criteria that the standards encourage patient-centered care and active participation by the patient. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3).

Change: The Department replaced the words “team will initiate” with “participant will have,” and correspondingly replaced the word “participant” with “care team,” to reflect that sometimes communication between the participant and care team can and should be initiated by the participant. The change also shifts the focus to the participant’s, rather than the applicant’s, contact with providers and community resources. Further, “and” was replaced with “or” regarding the entities for which this type of care planning is required to permit greater flexibility for the health care home to meet the requirement based on the participant’s actual needs. These changes clarify the participant’s role in his or her own care.

Item B requires that the applicant for certification use health care home teams to provide and coordinate participant care, including communication and collaboration with specialists. Requiring health care home team professionals to communicate and collaborate with specialists meets the statutory criteria that these professionals “ensure continuous and appropriate care for the patient’s condition.” *Id.* The Rule requirement affirms the role of the health care team to coordinate the spectrum of health care professionals with whom the participant interacts.

Change: The Department added “and inform the participant of this designation” to make sure that the participant knows who his or her personal clinician and care coordinator are.

Item B also requires the participant to select one personal clinician and one care coordinator as the primary contact for each role. The Rule requirement meets the statutory criteria that the standards encourage patient-centered care. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). Consistent with the definition of patient-centered care in part

4764.0020, subpart 26, this concept involves health care that is based on mutual trust and respect. It also requires listening to and considering participant perspectives and choices. To truly realize this concept of health care, there must be an ongoing relationship between the participant, and one primary caregiver and coordinator.

Change: A number of commenters indicated that the proposed requirement in item C to locate a clinician and care coordinator at the same site would preclude small clinics from sharing a care coordinator and therefore made compliance with the Rule more expensive and perhaps unrealistic. In response, the Department eliminated the requirement, and replaced it with a requirement that preserves the primary advantage of co-location, that is, face-to-face communication among the three key persons in the health care home team.

As just noted, item C requires at least some face-to-face communication between the participant and clinician, the participant and care coordinator, and the clinician and care coordinator. Relationships evolve differently when face-to-face contact is made, so that a person can see and respond to the physical demeanor and nonverbal cues of the other. The face-to-face contact between the participant and clinician, and between the participant and the care coordinator, is an important aspect of building a patient-centered relationship that is grounded in knowing one another. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). In much the same way, the requirement that the care coordinator and clinician have some face-to-face contact enhances the communications and cohesiveness of the care team. With a dedicated care coordinator who is more engaged in the care team based on personal relationships, the clinician has a greater ability and confidence to rely on the coordinator to meet the needs of the participant, therefore freeing the clinician to practice to the fullest extent of his or her license in accordance with Minnesota Statutes, section 256B.0751, subdivision 2 (a) (6).

Change: Item D previously required the applicant to provide the care coordinator with dedicated time and space to perform the care coordination responsibilities. As was the case with the now-eliminated co-location requirement, several commenters expressed a concern that requiring dedicated space would hinder small clinics' ability to share a care coordinator. The Department responded by eliminating the dedicated space requirement. The Department also replaced the word "functions" with "responsibilities" because the latter more accurately describes the role of the care coordinator.

As just noted, item D requires the applicant to adopt a system in which the care coordinator receives dedicated time to perform care coordination responsibilities. This requirement responds to the statutory criteria that the rule requirements must "enable and encourage utilization of a range of qualified health care professionals, including dedicated care coordinators, in a manner that enables providers to practice to the fullest extent of their license." See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (6). The legislature's use of the adjective "dedicated" to describe care coordinators shows that the rules must require a health care home to make a genuine commitment to furnishing a new, meaningful service to fulfill the requirement. At the very least, health care homes must permit a care coordinator to concentrate exclusively on the task of care coordination for some uninterrupted periods of time. This frees up

time for licensed professionals to practice to the fullest extent of their license, focusing on the specialized activities that they are best suited and trained to carry out.

Item E requires the applicant to adopt a system in which the applicant documents the specified care coordination elements in the participant's chart or care plan. The five specified elements relate to treatment from a specialist or in a specialized setting, laboratory tests, and prescriptions for medicine – and the result or outcome for each. Requiring the documentation confirms that the health care home team tracks the care services and the care outcomes for the participant across the health care system. This better situates the health care home team to provide knowledgeable, informed guidance to the participant. The team can thus avoid duplication of services; hospitalizations; unnecessary office visits, tests, or procedures; and inconsistent decisions. The achievement of any of these results promotes a health care home's delivery of "efficient and effective" health care services. See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2).

Subpart 6 states the requirements for the standard for care coordination that an applicant must meet to be recertified at the end of the first year of certification. The requirements pertain to the adoption and implementation of patient and family-centered principles.

Item A requires the applicant to ensure that participants are given the opportunity to fully engage in planning their health care and to share in decisions about their health care. It requires the applicant to obtain and document participants' feedback regarding their role in the health care home. This provision originates from the statutory criterion that the rules encourage the patient to "active[ly] participate. . . as appropriate in decision making and care plan development." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). The Rule's feedback requirement serves to measure and verify for both the applicant and the Department whether the applicant has successfully implemented the patient-centered approach.

Change: In response to a suggestion from the Center for Cross-Cultural Health, and to more accurately convey the two types of assistance to which item B refers, the Department replaced the phrase "community and public health resources" with "community-based organizations and public health resources."

Item B requires the applicant to identify and work with community-based organizations and public health resources to put help in place for a participant when appropriate. This requirement applies only after an organization has operated as a health care home for a year, and reflects further development of the patient-provider relationship. The requirement meets the statutory criterion that the standards encourage patient-centered care because identifying appropriate community resources for a participant involves knowing the patient's needs, where he or she lives, and how the needs can be met by available resources. Through appropriate referrals to non-medical, community-based services, such as aging or disability services, social services, or transportation, a participant's quality of life is enhanced. This, in turn, can facilitate improvement in health and, in some cases, lead to a participant's more efficient and effective use of medical resources. See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2)

(standards must focus on the delivery of efficient and effective health care resources) and 2 (a) (8) (standards must incorporate measures of resource use and cost of care).

Item C imposes a requirement directly from the statute. The Rule requires that the health care home team permit and encourage its health care professionals to practice at a level that fully uses their training and skills. The provision originates from the statutory requirement that the rules use “health care professionals . . . in a manner that enables providers to practice to the fullest extent of their license.” See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (6).

Item D requires an applicant to engage participants in planning for transitions among providers and between life stages. A health care home has an important, central role in planning for transitions between providers because the health care home coordinates services across specialties and subspecialties. The enabling statute reflects this role in the requirements that the rules ensure the health care home’s “ongoing” contact with the participant, the development of a “comprehensive” care plan, and the provision of care-coordination services. See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (4), (5), and (6).

The portion of the Rule requirement that requires the health care home to engage the participant in planning for life transitions also meets the statutory criterion to develop standards that encourage patient-centered care and participant engagement. See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). The focus on life transitions is consistent with the role of the health care home as the central point of continuity, such as the transition from a pediatrician to an internal medicine physician. The Rule provision also carries out the objective in Minnesota Statutes, section 256B.0751, subdivision 2 (a) (5) that requires the rules to ensure that health care homes engage in comprehensive care planning, which would include life transitions.

Subpart 7 establishes the certification requirements for the standard for comprehensive care plans. The care plan represents the fruits of the collaborative labors exerted between the patient and family, and the primary and subspecialty care providers. Care plans are required in many existing standards for medical homes. The Physician Practice Connections-Patient-Centered Medical Home guidelines adopted by the National Committee for Quality Assurance, and the demonstration design and qualifying criteria for the medical home demonstration project conducted by the CMS both require them.

Item A requires health care homes to 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. By focusing on persons with chronic conditions, the Rule requirement furthers the legislature’s directive to “focus initially on patients who have or are at risk of developing chronic health conditions.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (7). The requirement also supports the enabling statute’s requirement that the standards “ensure that health care homes develop and maintain appropriate comprehensive care plans for their patients with complex or chronic conditions.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (5). If a health care home concludes that a participant will not benefit from a care plan, then no care plan is appropriate for the participant. Plan preparation in

that circumstance would amount to a waste of resources. See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2) and (8).

Change: In item A, subitem (1), the Department added the requirement that the applicant must “ensure and verify joint understanding of the care plan.” The Department made the change because a participant cannot meaningfully participate in care plan development without understanding the care plan. In response to a suggestion from the Public Policy Committee of the Minnesota Dietetic Association, the Department added “dietician” to the list of examples of health care team members. As noted by that Association, many patients with chronic health conditions could benefit from including therapeutic diet counseling and education in a care plan that addresses obesity, heart disease, high blood pressure, diabetes, and other conditions.

The Rule requires that, in developing and implementing the care plan, the health care home must do a number of things. Item A, subitems (1) and (2) require the health care home to actively engage the participant and appropriate members of the health care team in the development of the care plan. The requirement “encourage[s] patient-centered care, including active participation by the patient. . . in. . . care plan development.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3). The same is true for the requirement that the applicant ensure that measures have been taken to see that the participant and care team jointly understand what the plan means and then to verify that the understanding results. Confirming that everyone shares a common understanding of the plan is an obvious key to the plan’s success.

The Rule provision requires that “appropriate” health care team members be in the team that develops the care plan. The Rule provides examples including a pharmacist or social worker. The Rule thus reflects that the composition of the care team depends on the participant’s particular needs. This is consistent with developing standards that are patient-centered and appropriate for the patient’s condition. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3) and (4). It is also consistent with ensuring that the patient receives relevant information from a variety of perspectives to make informed medical decisions. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (10).

Subitem (3) requires the applicant to include an assessment of the participant’s health risks and chronic conditions in the care plan. This requirement comes directly from the enabling statute, which requires the Department to develop standards that “ensure that health care homes develop and maintain appropriate care plans for their patients with complex or chronic conditions, including an assessment of health risks and chronic conditions.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (5).

Change: The Department rewrote this subitem to read, “incorporate pertinent elements of the assessment that has been performed by a qualified member of the health care team about health risks and chronic conditions.” The Department altered the subitem to more clearly explain which duties providers’ individual staff members are responsible for in developing care plans. An appropriate member of the health care team performs the assessment. The care coordinator, who does not have to be the assessing member, then incorporates pertinent elements of that

assessment into the care plan. Efficiency occurs by limiting the health care professionals' time to where the professionals' involvement is truly needed.

Subitem (4) requires an applicant to, jointly with the participant, review, evaluate, and, if appropriate, amend the care plan at specified intervals appropriate to manage the participant's health and measure progress toward goals. The Rule requirement implements the care plans framework that is evident in the enabling statute, that is, that care plan development is an ongoing, rather than a static, activity. Specifically, the statute refers to care plan "development," and to the need to ensure that care plans are "develop[ed] and maintain[ed]." See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (31) and (5). In addition, the Rule requirement carries out the statutory directive to develop standards that "ensure the use of . . . systematic follow-up." See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (9).

Subitem (5) requires the health care home to provide a copy of the care plan to the participant when it is created or amended. The participant's possessing a copy facilitates the participant's ability to ask questions of the care team, better comprehend the direction of care, and fully engage in later plan development. This meets the statutory criteria that the rules encourage the patient to actively engage in care plan development and require the applicant to use aids that provide the participant with information on which to base decisions. See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (3) and (10).

Change: With respect to item A, subitem (6), the Department responded to a comment from the Minnesota Medical Association, which pointed out that the meaning of the word "significant," used to modify "medical services and procedures," is not readily ascertainable. The Department removed the word."

Subitem (6) calls for health care homes to use and document the use of available evidence-based guidelines for medical services and procedures. The Rule provision implements a statutory objective to adopt rules that "encourage the use of scientifically-based health care." Minnesota Statutes, section 256B.0751, subdivision 2 (a) (10).

Item B states that an applicant for certification must use a care plan that contains goals and an action plan for each of four care activities. Subitem (1) requires the care plan to include goals and an action plan for preventive care. Preventive care is typically provided during the course of primary care services. By requiring that the applicant document preventive care measures, and explain deviations from standard protocols, the Rule meets the statutory directive to develop rules that enhance primary care services. The services are enhanced because the required documentation in the care plan clarifies for members of the care team, including the participant, which preventive care measures are established as a goal and how the participant can meet the goal. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (1).

The Rule next requires in subitems (2), (3), and (4) that the health care home include in the participant's care plan goals and an action plan for: the ongoing care of a chronic condition, an exacerbation of a known chronic condition, and, if appropriate, palliative end-of-life care and

health care directives. All of these requirements implement the statutory directive to adopt rules that “ensure that health care homes develop and maintain appropriate comprehensive care plans for their patients with complex or chronic conditions.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (5).

Change: The Department replaced the word “advance” with “health care” in subitem (4) so that this term coincides with Minnesota probate law, which uses the term “health care directives” in Minnesota Statutes, chapter 145C.

Item C requires the applicant to update the goals in the care plan with the participant as frequently as the participant’s condition warrants. By ensuring that goals and plans are updated periodically, the participant has current and therefore relevant information about the participant’s preventive goals and what actions should be taken to achieve them. Since a person’s condition usually changes over time, otherwise a care plan could quickly become outdated. The Rule requirement furthers the enabling statute’s directives to focus on high-quality, effective health care services. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (2).

Subpart 8 requires that for recertification at the end of a health care home’s first year of certification, the health care home must ask each participant with a care plan whether the participant has any external care plans. If so, the health care homes must create a comprehensive care plan by consolidating appropriate information from the external plans into the participant’s care plan. Through this requirement, the Department furthers the statutory objective that the care plan be “comprehensive.” Minnesota Statutes, section 256B.0751, subdivision 2 (a) (5). Because the professionals who prepare external care plans often have expertise outside of that available in a health care home, using those care plans draws on that expertise. The Rule provision therefore enables the use of a wide range of qualified health care professionals, another objective of the enabling statute. See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (6). Moreover, by requiring references to outside, existing care plans, the Rule minimizes duplication of efforts and ensures that valuable planning that has already taken place elsewhere can be reinforced in a health care home. These results are consistent with providing efficient health care services. *Id.*, subdivision 2 (a) (2).

Subpart 9 states the requirements for initial certification that relate to the performance measurement and quality improvement standard. As previously addressed, the Rule focuses on achievement of benchmarks in three critical areas; namely, the health of an applicant’s primary care services population, patient experience in the health care system, and cost-effectiveness of health care resources. See *infra*, section III.B.3, addressing part 4764.0030, subpart 5, item B (Again, acknowledging these areas are how the Rule incorporates the “triple-aim” approach). Subpart 9 states the steps an applicant must take to improve these outcomes.

Item A contains requirements regarding an applicant’s adoption of a quality improvement process. The Department derives its authority for this requirement from the statutory criteria that the rules focus on delivering high-quality health care services and enhance primary care services. Minnesota Statutes, section 256B.0751, subdivision 2 (a) (1) and (2). To achieve these broad

goals, certified health care homes must take ongoing steps to materially improve their services. The adoption of a quality improvement system places a health care home in a better position to do so. The applicant's adoption of a quality improvement system also enhances the likelihood that a certified health care home will continue to meet performance standards over time, and consequently retain its certification. *See* Minnesota Statutes, section 256B.0751, subdivision 6 (for "continued certification," health care homes must meet process, outcome, and quality standards specified by the Commissioner).

Item A also requires that the quality improvement team be comprised of at least one of the clinicians from the health care home, at least one care coordinator, two or more participants in the health care home, and, in a clinic, at least one managerial or administrative representative. With these knowledgeable health care professionals on the team, it is equipped to figure out how to improve performance outcomes and what systematic or procedural changes might be needed to do so.

Change: The Department's focus for measuring performance outcomes is on the certified clinic or clinician's entire primary care services population, not just on the outcomes for the health care homes participants. As explained above, and consistent with public comment, this is to neutralize any potential incentive to selectively recruit participants for the health care home that might enhance performance outcomes, leaving out the more medically challenging patients. The Department therefore corrected language in item A by replacing the word "participant" with "patient" in two places where the word at issue describes a type of quality indicator.

The Department also added language to item A to further clarify the requirements for the structure of the quality improvement team in response to public response. Some clinics were interpreting the draft rule requirement to mean that each health care home team, small or large, needed to establish its own quality team, which might result in some clinics having 25–50 teams, placing an undue financial burden on those larger organizations. The Rule instead requires that clinics establish quality teams with appropriate care team membership to strategically carry out their quality improvement activities using a system that reflects how the clinic structures its quality work, which is why the Department inserted the qualifying measure that the team "*reflects the structure of the clinic.*"

The quality improvement team's composition "*includes the following persons at the clinic level, at a minimum:*

- (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.* [emphasis added to new language]

Consistent with the definition of “clinic” in Part 4764.0020, subpart 8, the phrase “at the clinic level” will typically mean at the same site. The other language change, in subitem (3), acknowledges that while clinics must demonstrate a concerted effort to recruit participants, participants cannot be forced to take representative roles, no matter how important to the success of health care homes their contributions might be. The importance of participant participation cannot be understated.

Change: The Department added a new letter B:

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

The Department added this to accommodate the fact that, since not all members of health care home teams can participate in the quality team, the clinic must establish a structured feedback method for the quality team to exchange information with these other health care home team members not on the quality team and with other staff. Without implementation of quality improvement activities, a quality improvement team means little, and the requirement for this two-way communication facilitates such implementation.

Item C (re-lettered item B) requires the applicant to show that it is capable of performance measurement at the time of certification. Quality improvement activities with data collection, tracking and analysis have been a common methodology in clinics for many years and most clinics already have some level of requirements for collecting and analyzing data. An applicant must have this capability to submit outcomes data to the Department, as required by the enabling statute. Minnesota Statutes, section 256B.0751, subdivision 6. Thus, the requirement to perform this basic function at the time of certification ensures that the health care home is commencing movement along the continuum toward later measurement and reporting of several indicators.

Item D (re-lettered item C) requires the applicant to participate in a health care home collaborative. The Rule provision is authorized by Minnesota Statutes, section 256B.0751, subdivision 3 (c), which requires health care homes to participate in a collaborative to exchange information related to quality improvement and best practices.

Change: The Department rewrote this item so health care homes’ requirements now read: 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:*

Both small rural clinics and large urban organizations commented, concerned about the burden of practice representatives attending the required learning collaborative. Clinics were interpreting this standard also to mean, as with the quality team above, that every team unit small or large needed to send the defined personnel, which might result too in some clinics in 25–50 teams and other clinics the whole clinic team. The Department envisioned participation by health care home

team members but never meant to place a burden on clinics or negatively impact patient care. Clinics are required to assign members of the practice team to the learning collaborative in such a way that participation will be structured in a flexible and constructive manner. They assign such members that advance the clinics' learning and reflect their organizational structure.

The rewritten learning-collaborative structure mirrors the representative capacities in the quality teams to make sure the same perspectives are reflected in this important information-sharing system. The composition is spelled out in renumbered subitems (1) requiring a health care home to have one or more clinicians, (2) one or more care coordinators, and (3) and one or more management or administrative representatives, if a clinic, participate in a collaborative. The persons performing in each of these roles will have different perspectives regarding the value of information shared in the collaborative and whether it might be useful in their health care home. The legislature's interest in home health care collaboratives is part of the broader set of statutory objectives to enhance primary care services, including the quality of services, through information sharing about best practices and quality improvement. See Minnesota Statutes, section 256B.0751, subdivision 2 (a) (1) and (2), and subdivision 5.

Subitem (4) completes the collaborative by providing for the participants' perspective. It requires a health care home to encourage participants to participate in a collaborative, with the goal of having two or more participants take part. A participant has an important, perhaps the most important, vantage point for whether best practices used in other health care homes might enhance the practices in the health care home in which he or she participates. The Rule merely establishes a goal for participation because a health care home cannot dictate whether a participant will choose to participate.

In subitem (1), "personal" was added before "clinician" for clarity.

In item E (re-numbered subitem (3)), the Rule requires the health care home to adopt procedures for the collaborative participants to share information from the collaborative with the health care home and other staff and to elicit related feedback. The Rule requirement ensures that there is an established communication path to do so, which makes it easier for collaborative participants to share new, innovative ideas and propose adoption of successful practices used elsewhere, and to refine those ideas based on broadly representative feedback. This also supports the broad, statutory objective of enhancing the quality of primary care services.

Change: The Department changed this item's construction so that it is parallel with subpart 9, items A–D by deleting "the health care home must provide participants" and inserting "establishing."

Subpart 10 states the requirements that health care homes must meet at the end of the first year for the standard on performance reporting and quality improvement. Item A requires participation in the statewide quality reporting system by submitting outcomes for quality indicators identified by the Commissioner. The Commissioner is relying on a community advisory board to advise her.

Thus, the requirement in item A supports the objective in the enabling statute that the Commissioner must obtain data to evaluate the impact of health care homes on health care quality, cost, and outcomes. Minnesota Statutes, section 256B.0751, subdivision 6 (a). Because the Rule requirement applies after a health care home has been certified for one year, no reporting is required during a health care home's first year of certification.

Change: Item A requires that certified health care homes participate in the statewide quality reporting system. Since the Department relies on its authority under Minnesota Statutes, section 256.0751, subdivision 6, and while Minnesota Statutes, section 62U.02 provides overlapping authority, the Department removed this latter citation to prevent confusion. The Department further clarified the requirement for the health care homes submitting their quality-indicators data by adding the phrase "in the manner prescribed by the commissioner" so that the Department receives the data in a form it can evaluate.

Change: As previously noted, the Department's focus for measuring performance outcomes is on the certified clinic or clinician's entire primary care services population, not just those for the health care homes participants. As explained, this is to remove any potential incentive to selectively recruit participants for the health care home that might enhance performance outcomes, leaving out the more medically challenging patients. The Department therefore corrected language in subpart 10, item B, subitems (1) and (2) by replacing by replacing the word "participant" with "patient" where the word at issue describes a type of quality indicator.

While no reporting is required at initial certification, reporting is required at the end of the first year for recertification. Item B requires a health care home to measure, analyze and track at least one quality indicator from each of the three critical areas of performance measurement during the first year. As previously addressed, the three areas are patient health, patient experience, and cost-effectiveness. The Rule provision acquaints a health care home with the steps that it must take to report performance outcomes in the following year, which is within the Commissioner's authority to obtain.

Change: The Department added a new item C that reads: C. submit health care homes data in the manner prescribed by the Commissioner that is needed by the Commissioner needs to fulfill the health care homes evaluation requirements of Minnesota Statutes, section 256B.0752, subdivision 2.

Upon further consideration, the Department realized that the Commissioner needs to collect two distinct forms of data: the patient data for performance outcomes for evaluating individual health care homes' performance and the data the Commissioner needs to evaluate health care homes' effectiveness to fulfill the Commissioner's own evaluation requirements of Minnesota Statutes, section 256B.0752. Consequently, the Department added another requirement to make it clear that health care homes must report this additional data in the manner prescribed by the Commissioner.

Subpart 11 states the requirements related to performance reporting and quality improvement at the end of the second year of certification as a health care home, and in subsequent years. These requirements build on the requirements for the prior year. Item A requires the applicant to continue participating in the statewide quality reporting system, in accordance with a provider's statutory obligation to do so under Minnesota Statutes, section 62U.02. The provision affirms that a health care home must report performance data to the Commissioner in each year of certification to enable the Commissioner to fulfill her statutory duty to evaluate the impact of health care homes in Minnesota. Minnesota Statutes, section 256B.0751, subdivision 6 (a).

Item B requires the applicant for recertification to meet the benchmarks established by the Commissioner under part 4764.0030, subpart 6, in the applicant's primary care services population. As previously addressed, the Rule provision marks a transition in the Rules from the requirements for initial certification and recertification after the first year, which focus on development of infrastructure to support operation as a health care home, to performance outcomes. The Rule requirement advances the enabling statute's directive to the Commissioner to enhance primary care services and the quality of health care delivery under Minnesota Statutes, section 256B.0751, subdivision 2 (a) (1) and (2), because each health care home, to continue to be certified, must achieve certain minimum performance outcomes.

Change: For simplicity and clarity, the Department divided the requirements in subpart 11 into two items, A and B. The Department also modified the language in item B so that it is consistent with the language used to reference the same requirement in part 4764.0030, subpart 5, item B, subitem (2).

5. Part 4764.0050 VARIANCE

Under Minnesota Statutes, section 14.055, authorization for individual variances applies to all rules. Circumstances might exist in which individual applicants are unable to comply with specific requirements in the Rule. In other situations an applicant may need no longer demonstrate compliance with every applicable certification requirement because the applicant's superior performance outcomes reflect the success of its health care home operation. When these circumstances exist, this Rule part provides a means for applicants to receive a variance.

Subpart 1 informs applicants when to apply for a variance. The subpart states that an applicant may request a variance or the renewal of a variance at the time of certification or recertification. The provision also notifies applicants what to include in a petition for a variance. The applicant must include the items set forth in Minnesota Statutes, section 14.056, and an explanation of why the requirements as applied to the applicant would not serve any of the rule's purpose, or why 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 cause prejudice to any entity or person.

The Department derives its authority to grant a variance from Minnesota Statutes, section 14.055. The Rule adopts the same two categories of variances that are stated in the statute. First, if the Commissioner finds that the Rule requirements as applied to the applicant would not serve any of the rule's purposes, the Commissioner must grant a variance. Minnesota Statutes, section 14.055, subdivision 3. Second, 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 cause prejudice to any entity or person, then the Commissioner has discretion to determine whether or not to grant a variance. Minnesota Statutes, section 14.055, subdivision 4.

Change: In the first sentence, the Department removed the phrase “and the Commissioner may grant or renew” and added the phrase “or renew a variance” to clarify that the applicant should initiate a request for a variance, or the renewal of a variance, as appropriate. The Department also removed the phrase “to an applicant who demonstrates good cause” because the requirements in items A and B speak for themselves, making the extra phrase that summarized the bases for a variance superfluous and possibly confusing. The Department also changed the language in items A and B regarding the Commissioner's authority to grant a variance to clarify that one type of variance is mandatory, and the other permissive.

Subpart 2 provides that the Commissioner may impose conditions on the granting of a variance according to Minnesota Statutes, section 14.055. That statute permits an agency to “attach any conditions to the granting of a variance that the agency determines are needed to protect public health.” Although the Rule is designed to broadly enhance public health outcomes through the adoption of proven care delivery practices, the Rule does not regulate a specific, known risk that could pose a material threat to public health. As a result, it is probably unlikely the Commissioner will determine that a condition on a variance is needed to protect public health.

But the Commissioner has authority to adopt reasonable parameters to circumscribe a variance. Specifically, Minnesota Statutes, section 14.056, subd. 5, provides that an agency that grants a variance needs to issue an order “specifying the scope and period of any variance granted.” Consistent with this authority, the Rule subpart states that the Commissioner may limit the duration of a variance, or may renew a variance. The Commissioner also has statutory authority to describe and limit the scope of a variance pursuant to this subpart. *Id.*

Subpart 3 provides for the Commissioner to grant a discretionary variance if the applicant meets or surpasses benchmarks for superior achievement in its outcomes data and makes a showing of progress regarding characteristics of a health care home reflected in part 4764.0040. The provision provides an incentive to health care homes to go beyond meeting minimum benchmarks in its outcomes data by rewarding superior achievement. The Rule provision carries out the requirement in the enabling statute that the Department must evaluate the effectiveness of health care homes and motivate the delivery of high-quality health care. Minnesota Statutes, section 256B.0751, subdivisions 2 (a) (2), and 6 (a) and (b).

The variance for superior achievement would exempt the applicant from the requirements of part 4764.0030, subpart 5, item B. That provision lists the requirements for recertification of a health care home after the second year of certification and beyond. These requirements are demonstrating that the applicant meets the requirements for initial certification, for recertification after the first year as a health care home, and for recertification after the second year and subsequent years, and meets the benchmarks for performance in the applicant's outcomes data. For an applicant that receives a variance for surpassing the benchmarks, an applicant would only need to show its achievement of surpassing the benchmarks by a specified amount, and that it is making progress on the five standards, and would not need to demonstrate continuing compliance with any of the other certification requirements.

Subpart 3 requires the Commissioner to announce the benchmarks for superior achievement on an annual basis, just as the Commissioner is required to do for the standard benchmarks that are announced according to part 4764.0030, subpart 6. The Commissioner is also required to use the same factors that are used to establish the standard benchmarks.

Items A through E state what an applicant must do to qualify for the variance. Item A states that the applicant must meet the benchmarks for superior outcomes in the three key quality indicators: patient experience in the health care system, patient health outcomes, and health care cost, based on data submitted to the statewide quality measurement system.

Change: So that item A conforms to the rest of the rule, the Department changed the phrase "statewide quality *measurement* system" to "statewide quality *reporting* system."

Item B explains that the applicant must submit a signed statement affirming that it continues to comply with the applicable requirements in part 4764.0040. So, even though the applicant does not need to *demonstrate* its compliance, the certification requirements in part 4764.0040 still apply, and the applicant must confirm that it remains in compliance.

Item C states that the applicant must show continued progress regarding four of the five health care home standards (not including the performance reporting and quality improvement standard.) To do so, the applicant must identify a new approach that advances its practices with respect to each standard. Through this provision, the Commissioner fosters innovation as a viable approach to improve the quality of health care. The enabling statute also encourages innovation. See Minnesota Statutes, section 256B.0751, subd. 5 (purpose of required participation in collaborative is to "exchange information related to quality improvement and best practices"). See also Minnesota Statutes, section 62U.04, subd. 1 (Commissioner required to "develop a plan to . . . encourage greater [health care] provider innovation and collaboration.")

Item D states that an applicant is required to provide any additional documentation required by the Commissioner. This authority is commensurate with the Commissioner's ability to decide whether to grant a variance. The Commissioner needs to gather sufficient information to make an informed decision. When an applicant seeks a variance, it implicitly agrees to provide required information. An applicant can withdraw its request at any time.

Item E requires continued participation in a health care collaborative. This is consistent with the statutory provision requiring health care home participation in a collaborative. Minnesota Statutes, section 256B.0751, subdivision 3 (c).

Subpart 4 provides for a variance from one or more Rule requirements to permit an applicant to undertake services of a type or in a manner that is experimental or innovative, as long as the new practice does not undermine the enabling statute's criteria for the Rule and may improve the applicant's health care home services. The Rule provision motivates the improvement of health care home services through original or cutting-edge practices. As addressed above regarding subpart 3, the enabling statute and a companion statute also encourage innovation among health care providers to improve care.

Subpart 5 provides a means for applicants seeking recertification to obtain a variance if the applicant is unable to meet the minimum benchmarks for health care outcomes in its primary care services patient population. To obtain the variance, the applicant must demonstrate two circumstances: that there is reasonable justification for the applicant's inability to meet the benchmarks, and that the applicant has a plan to achieve measurable improvement in the following year or a time frame specified. The procedure preserves the Department's objective to motivate the applicant to improve performance outcomes, but relaxes the requirements when there is a reasonable explanation for noncompliance and the applicant plans a specific approach to achieve compliance. This measure balances the drive for improvement against the weight of particular patient populations for which the desired outcomes are less realistic. Nevertheless, the health care homes must continue striving by adjusting their course accordingly.

6. Part 4764.0060 APPEALS.

This section provides a means for applicants to appeal the denial of an application for certification or recertification if an applicant believes that it has been improperly denied.

Subpart 1 requires the Commissioner to notify an applicant in writing of the reasons for the Commissioner's denial of an application for certification or recertification. Providing this information benefits the applicant because it provides the applicant with an opportunity to consider the Department's rationale. The applicant is therefore in a better position to respond by either challenging the Commissioner's rationale, or correcting deficiencies that are identified.

The Rule informs the applicant that the applicant can appeal from an adverse decision regarding its application for certification or recertification. The Department's authority to provide a second, independent review of the initial, adverse decision is inherent in the authority to make the initial decision.

The Rule also states that an applicant has 30 days from the date of receiving notice of the decision to appeal the decision. The Commissioner's decision to adopt a deadline for appeal adds predictability and certainty to the process.

Subpart 2 provides that the applicant may appeal by submitting either a written statement of the applicant's grounds for disputing the decision, or a corrective action plan that

describes the corrective steps taken, a plan for continued improvement, and, if applicable, reasons the applicant is unable to comply with requirements for certification or recertification.

If the applicant submits a statement of the grounds for appeal, then the Department's designee is able to fully consider the applicant's rationale before making a final agency decision.

The option that permits the applicant to correct deficiencies in the application benefits the applicant because it provides the applicant with a new opportunity for certification. Requiring the applicant to identify corrective action steps that it has taken, and those that it plans to take, requires the applicant to be specific about how it will correct deficiencies and is a useful document that the Department can use later to hold the applicant accountable to following through on its plans.

The Rule also permits the applicant to describe the cause for deficiencies or inability to comply. The Commissioner's designee thus is better able to make a fair final agency decision. The Commissioner's designee is also better able to treat similarly situated applicants in a similar manner. An example of pertinent information that could be submitted is that an applicant's population is not as healthy as desired because the applicant is located in a core, urban area of a large city, and data shows this population to be more vulnerable.

Subpart 3 permits the applicant to request a meeting with the Commissioner's designee to discuss disputed facts and findings, to present the applicant's corrective action plan, or both. The Rule provision benefits the applicant because it provides an avenue for the applicant to persuade the Commissioner's designee about the merits of the applicant's position and to respond to any questions the designee may have.

Subpart 4 states that the Commissioner will notify an applicant of the final agency decision regarding the appeal 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. It is helpful to an applicant for planning purposes to know a definitive timeframe within which the Commissioner must act.

7. Part 4764.0070 REVOCATION, REINSTATEMENT, AND SURRENDER.

Subpart 1 states that when the Commissioner denies an appeal that challenges a denial of recertification, or the applicant does not timely appeal a denial of recertification, then any previous certification is revoked, the provider is no longer certified, and the provider cannot receive payments for health care coordination according to Minnesota Statutes, section 256B.0753 and 62U.03. This subpart clarifies the consequences of an adverse outcome in an appeal, or of an applicant's decision not to appeal the denial of recertification.

Subpart 2 confirms that an applicant may apply for recertification even if a past application for recertification was denied.

The Rule also states that when an applicant was previously certified for one year or longer at the time certification was revoked, the applicant must meet the requirements for recertification, rather than the requirements for initial certification. The requirements are progressive and are based on the number of years of experience a provider has as a health care home. It is therefore only fair to recognize a provider's experience as a health care home by allowing the applicant to meet the more advanced standards.

This subpart also informs providers that they may seek technical or program assistance from the Department, or from a health care home learning collaborative, to assist the provider to become recertified.

Subpart 3 lays out the procedure for a certified health care home that seeks to surrender its certification. The subpart states that the health care home may do so by providing 90-days advance notice to participants and to the Commissioner. The advance notice permits participants to adjust to the change before it is implemented by seeking out a different health care home if desired.

Finally, the Rule subpart confirms that if a health care home voluntarily surrenders its certification, then, after the 90-day notice period, the health care home cannot receive care coordination payments under Minnesota Statutes, section 256B.0753 or 62U.03. The provision confirms the consequence of a health care home's decision to surrender its certification so that a health care home can make an informed decision about whether to do so.

IV. THE RULE IS CONSTITUTIONAL AND LEGAL.

Statutes are presumed to be constitutional. *Associated Builders and Contractors v. Ventura*, 610 N.W.2d 293 (Minn. 2003). As shown above, Rule 4764 does not exceed its statutory authority. Accordingly, there is no question regarding the Rule's constitutionality or legality.

V. THE RULE DOES NOT DELEGATE AUTHORITY TO AN OUTSIDE AGENCY, PERSON OR GROUP.

All authority under the Rule remains exclusively with the Commissioner of Health. The Rule does not delegate authority to an outside agency, person, or group. The Department will establish a collaborative for the purpose of health care homes and government agencies, including the Department, to share experiences and develop knowledge of best practices; but this falls squarely within the auspices of the enabling legislation. See Minnesota Statutes, section 256B.0751, subdivision 5.

VI. THE RULE FITS WITHIN THE DEFINITION OF "RULE."

The rule is a statement of general applicability and future effect, adopted to implement and make specific the requirements of Minnesota Statutes, section 256B.0751 as they relate to

standards of certification for health care homes. It will therefore have the force and effect of law. Minnesota Statutes, section 14.02, subdivision 4 (2008); Minnesota Rules 1400.2100, subpart G.

VII. THE RULE DOES NOT REQUIRE A HEARING OR NOTICE OF WITHDRAWAL OF HEARING.

Minnesota Statutes, section 256B.0751, subdivision 2, paragraph (c), grants the Department the authority to use the expedited rulemaking process under section 14.389 without reference to subdivision 5. Because no hearing is required, the requirement of notice of withdrawal of a hearing request is inapplicable. Minnesota Statutes, section 14.25, subdivision 2 (2008); Minnesota Rules 1440.2100, subpart H.

CONCLUSION

The Department has established that each of the standards of review applicable to expedited rulemaking has been satisfied. The Department has acted within its authority and followed all of the procedural requirements to develop the standards for certification and the related procedures in the Rule. Therefore, the Departments respectfully request that the Rule be approved.

cc: Calvin R. Ludeman, Commissioner, Minnesota Department of Human Services