CHAPTER 13. MISCELLANEOUS INSURERS AND OTHER REGULATED ENTITIES

SUBCHAPTER E. HEALTH CARE COLLABORATIVES

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1. INTRODUCTION. The commissioner of insurance adopts new 28 Texas Administrative Code (TAC) Chapter 13, Subchapter E, §§13.401 – 13.404, 13.411 – 13.417, 13.421 – 13.426, 13.429, 13.431 – 13.432, 13.441, 13.451 – 13.455, 13.461, 13.471 – 13.474, 13.481 – 13.483, and 13.491 – 13.494. Sections 13.402 – 13.404, 13.413 – 13.416,

13.422 – 13.424, 13.429, 13.431, 13.441, 13.453, 13.461, 13.473, 13.474, 13.482, 13.483, 13.491, and 13.492 are adopted with changes to the proposed text published in the September 28, 2012, issue of the *Texas Register* (37 TexReg 7681). Sections 13.401, 13.411, 13.412, 13.417, 13.421, 13.425, 13.426, 13.432, 13.451, 13.452, 13.454, 13.455, 13.471, 13.472, 13.481, 13.493, and 13.494 are adopted without changes to the proposed text and will not be republished.

2. REASONED JUSTIFICATION. The commissioner adopts this new subchapter to implement Article 4 of Senate Bill 7, enacted by the 82nd Legislature, First Called Session, effective September 28, 2011. SB 7 adds Insurance Code Chapter 848 relating to health care collaboratives (HCCs).

The adopted sections provide the necessary framework for establishing HCCs and regulating their activity in the health care market in pursuit of innovative health care delivery systems and payment models to achieve better patient outcomes, improve health care transparency, and make efficient use of health care resources.

SB 7, Article 2, §2.01(b), includes a specific legislative finding that: ". . . certified [HCCs] will increase pro-competitive effects as the ability to compete on the basis of quality of care will overcome any anticompetitive effects." The adoption will support the legislative objectives in Insurance Code Chapter 848, Subchapters B and C, relating to the authority of an HCC to do business in this state; the powers and duties of an HCC; and the legislative goal of greater competition in health care services based on delivery of quality health care.

The Legislature stated a clear intention in SB 7, Article 2, §2.01(c), to exempt from antitrust laws and to provide immunity from federal antitrust laws through the state action doctrine an HCC authorized under Insurance Code Chapter 848, and its contract negotiations with payors. The Legislature further stated that it does not intend or authorize any person or entity to engage, or to conspire to engage, in activities that would constitute *per se* violations of federal antitrust laws.

Accordingly, the adopted sections require every initial and renewal application for an HCC certificate of authority to undergo independent department and attorney general antitrust review. This competition-related review must occur at least annually to ensure that

(1) there is no reduction of competition due to HCC size or composition,

(2) pro-competitive benefits outweigh anticompetitive effects of increases in market power, and

(3) HCCs do not violate the enumerated rights of physicians.

Review associated with the pro-competitive benefit analysis will be in accord with established antitrust principles of market power analysis.

Other essential aspects of the department's application review process will focus on solvency, organization, quality, and efficiency in service delivery.

Solvency and organization review standards are necessary to ensure that the HCC maintains financial solvency through sufficient capitalization and reserves, and that it complies with statutory formation and governance requirements.

Quality and efficiency review standards are necessary to ensure that the HCC

provides adequate networks; increases collaboration; promotes improved patient outcomes, safety, and coordination of services; reduces preventable events; and contains costs without compromising the quality of patient care.

If the commissioner determines that an application for a certificate of authority complies with all Insurance Code Chapter 848 certification requirements, the commissioner must forward the application and all items considered in making the determination to the attorney general. The attorney general must then conduct an independent antitrust review of the application to determine if the applicant meets the requirements of Insurance Code §848.057(a)(5) and (6). After making the determination, the attorney general must notify the commissioner of concurrence or nonconcurrence with the commissioner's determination.

Insurance Code §848.151 authorizes the commissioner and attorney general to adopt reasonable rules necessary and proper to implement the requirements of Insurance Code Chapter 848.

The adopted sections are necessary to implement Insurance Code §848.054 and §848.152, which require the commissioner to adopt rules governing application for a certificate of authority to organize and operate an HCC, and to prescribe the regulatory fees and assessments imposed on HCCs to cover reasonable expenses of the department and the attorney general in administering Chapter 848.

The adoption includes a number of requirements similar to those that apply to issuers of other network-based health plans, such as health maintenance organization (HMO) plans and preferred provider benefit plans. The adoption also includes

requirements that are more expansive, consistent with the consideration of antitrust issues and regulations.

Department outreach. In preparation for the proposal, the department invited and received extensive input from stakeholders. On January 30, 2012, the department held a public meeting to provide stakeholders the opportunity to discuss HCC rule development, including: the application process, such as organizational and financial documents, networks, and antitrust issues; the regulatory fees and assessments associated with the organization and operation of an HCC; and the renewal process. Representatives from the Office of the Attorney General attended the meeting.

On April 16, 2012, the department posted a call for public comments on the substance of an informal working draft of the rule and its and possible implementation costs. In addition to receiving written comments on the draft, the department conducted a second stakeholder meeting on April 24, 2012, to discuss the draft and potential implementation costs, including compliance costs. Representatives from the Office of the Attorney General also attended this meeting.

The department received and considered stakeholder comments and, to the extent possible, integrated the comments into the proposed rules published for formal public comment in the September 28, 2012, issue of the *Texas Register* (37 TexReg 7681).

The department conducted a public hearing to consider adoption of the proposed rules on October 18, 2012, at 9:30 a.m. in Room 100 of the William P. Hobby Jr. State Office Building, 333 Guadalupe Street, Austin, Texas. Representatives from the Office of the Attorney General attended the hearing. The department considered oral comments

presented at the hearing. The period to submit written comments on the proposal ended October 29, 2012.

In response to written comments on the published proposal and oral comments made at the hearing, the department has changed some of the proposed language in the text of the rule as adopted. The department also has changed some of the proposed language for clarification purposes, and has made other nonsubstantive changes to conform with the agency's style guidelines. These changes do not materially alter issues presented in the proposal, introduce new subject matter, or affect persons other than those previously on notice.

Division 1. General Provisions.

Section 13.401 states that the purpose of Subchapter E is to implement Insurance Code Chapter 848 and other Texas insurance laws that apply to HCCs. It also provides that the subchapter's provisions are severable and do not limit the commissioner's exercise of statutory authority.

Section 13.402 defines the words and terms used in the new subchapter, providing for the uniform application of the subchapter. In response to comment, the department has changed the definition of "clinical director" in §13.402 to add the requirement that such persons must be licensed "in good standing in Texas," for consistency with the provision in §13.473(b) relating to the HCC's clinical director and for clarification of the appropriate licensure requirement. In response to comment, the department has changed the definition of "common service" in §13.402(3) to clarify that it is an identical or substantially similar health care service provided to patients by two or more independent HCC

participants. For further clarification, the department has added a new §13.402(18) to define the term "patient" as an individual who receives a health care service and renumbered the subsequent definitions. In response to comment, the department has changed the definition of "pro-competitive benefit" in §13.402(22) to clarify that it is a benefit "that ultimately accrues to the benefit of the HCC's patients."

Section 13.403 describes the location and method to file original or renewal HCC applications. It identifies and adopts by reference forms that must be used to facilitate review and requires completion of the forms in accord with each form's instructions and data content requirements.

The commissioner adopts by reference the following forms:

(1) Original/Renewal Application for Certificate of Authority to do the Business of a Health Care Collaborative (HCC) in the State of Texas

(2) Health Care Collaborative Officers and Directors Page

(3) Biographical Affidavit

(4) Request to Convert to Renewal of Certificate of Authority to do the Business of a Health Care Collaborative (HCC) in the State of Texas

(5) Financial Authorization and Release Form

(6) Health Care Collaborative Payor Information Form, and

(7) Health Care Collaborative (HCC) Acquisition Form.

Forms (1) and (4) – (7) have a June 2012 revision date. Forms (2) and (3) contain an update to the Agency Counsel Office e-mail address effective after the proposal but before the adoption of the sections, and have a March 2013 revision date. Section

13.403(c) has been changed to reflect revision dates for the seven forms.

Section 13.404 restricts the use of the terms "health care collaborative" or "HCC" by an applicant both before and after issuance of a certificate of authority to ensure that members of the public interacting with the developing or established HCC are informed about its operating status.

Division 2. Application for Certificate of Authority.

Section 13.411 sets amounts for non-refundable application fees for original and renewal applications at $10,000 and $5,000, respectively. It also provides that each HCC must pay an annual assessment to the department, as required by Insurance Code §848.152 and described in §13.421(c). The annual assessment is necessary to make up any shortfall between the expenses incurred by the department and the attorney general, and the funds collected through application fees, renewal fees, and examination expenses. The section also provides notice that the application is public information, except as provided by Insurance Code §848.005(b).

Section 13.412 addresses procedures governing revisions during the review of an HCC application. This section also requires that each revision to the basic organizational documents, bylaws, or officers' and employees' bonds include a certification by the HCC's corporate secretary or president that the revision is true, accurate, and complete.

Section 13.412 also specifies that the department will conduct examinations and notify the applicant of any necessary revisions to the application, and that the department can withdraw the application on behalf of the applicant if the applicant does not make the necessary changes. The section provides that if the time required by the applicant to

make the corrections will exceed the time limit provided in Insurance Code §848.056(c), the applicant must: (1) request a specific amount of additional time, which may not exceed 90 days; and (2) include sufficient detail for the commissioner to determine if cause exists to grant the extension. The applicant may request additional time. The commissioner may grant or deny a request under Insurance Code §848.056.

Section 13.413 sets forth the application contents for an HCC certificate of authority.

To facilitate the department's review, §13.413(a) requires that the application include items in the order listed in the section; and §13.413(b) requires that nonelectronic filings include two additional copies of the application.

Section 13.413(c) requires the applicant to submit to the department a complete application for a certificate of authority that includes an HCC representative's attestation that the HCC's collection methodology for confidential information satisfies rule requirements for any confidential information included in the filing. Subsection (c) includes nine categories of HCC general organizational, operational, and governance information filing requirements.

Section 13.413(d) sets forth financial information filing requirements, including the form and any proposed payment methodology of any contract between the applicant and any payor that addresses the applicant arranging for medical and health care services for the payor in exchange for payments in cash or in kind as provided in Insurance Code Chapter 848. In response to comment, the inclusion of the proposed payment methodology in §13.413(d)(3) represents a clarifying change to more clearly state the filing requirement for implementation of Insurance Code §848.103(c).

Section 13.413(e) sets forth provider and service area information filing requirements.

Section 13.413(f) identifies quality assurance (QA) and quality improvement (QI) information that an applicant must submit. It requires that the completed application includes a detailed description of policies and processes contained in the QA and QI program required by §13.482.

Section 13.413(g) requires disclosure information as specified about any accreditation the HCC has attained from a nationally recognized accrediting body. In response to comment, the department has changed the subsection to add the Accreditation Association for Ambulatory Health Care (AAAHC) to the referenced accrediting bodies to recognize the association's status as a nationally recognized accrediting body.

Section 13.413(h) sets forth information submission requirements for antitrust analysis.

Section 13.413(i) requires additional antitrust analysis information to be provided by an HCC applicant that does not fall within the limited filing exemption set forth in §13.414.

In response to comment the adoption includes a change to §13.413(i)(6) that reduces the look-back period for certain information from 36 to 24 months, consistent with the position that a 24-month period is sufficient to determine whether additional information is necessary. It also includes a change, in response to comment, that transfers §13.413(i)(7) as published to §13.461(c) as new paragraph (25) of the items the commissioner may require if deemed reasonably necessary to complete the review

required by Insurance Code Chapter 848. The paragraph relates to the HCC applicant submitting participants' contribution margins or fixed-or-variable costs for health services in the service area as part of the information provided in the application process. The change reflects that the burden of producing the information is sufficient to merit changing the nature of the requirement to one that is imposed by request under §13.461, and the remaining paragraphs in §13.413(i) are renumbered accordingly.

Section 13.414 establishes a limited exemption from certain information filing requirements and provides for certain exceptions.

Section 13.414(a) provides a general-purpose statement. The department has changed the subsection, in response to comment, to correct a grammatical error.

Section 13.414(b) states that an applicant is not required to provide the information specified in §13.413(i) if, for each primary service area (PSA) in which two or more participants provide common services, the applicant's market share is 35 percent or less; and no contract exists between the HCC and any participating hospital that restricts either party from contracting with other HCCs, networks, hospitals, physicians, physician groups, health care providers, or private payors.

Section 13.414(c) states that an HCC that contracts with a physician or health care provider in a rural county does not have to provide the information specified in §13.413(i) if there is no contract with a physician or health care provider that restricts that physician or health care provider from contracting or dealing with other HCCs, networks, physicians, or health care providers; and inclusion of the physician or health care provider is the sole reason that the HCC's share of any common service exceeds 35 percent.

Section 13.414(d) states an HCC that includes a rural hospital does not have to provide the information specified in §13.413(i) if no contract with the hospital restricts the hospital from contracting with other HCCs, networks, physicians, or health care providers; and inclusion of the rural hospital is the sole reason the HCC's share of any common service exceeds 35 percent.

Section 13.414(e) provides, by categories, the formula for calculating market share.

Section 13.414(f) permits an alternative method of calculating market share on a satisfactory demonstration that the calculation based on the HCC's PSA for a health care specialty provides a more accurate measure of competition relating to the participant in the context of the HCC than the calculation based on the participant's PSA.

Section 13.414(g) provides notice that the commissioner has discretion to require an applicant to provide any or all of the information specified in §13.413(i), §13.461, or both, when the commissioner deems the information is reasonably necessary to conduct the review required by Insurance Code Chapter 848.

Section 13.415 identifies documents that must be available for examinations and specifies 18 types of documents that an HCC must provide to the department on request, make available for the department to review at the HCC's office located in Texas, and maintain for at least five years. In response to comment, the adoption includes a clarifying change in §13.415(a)(2)–(4), (12), (13), (16), and (17) to replace the term "renewal applications" with the term "certified HCCs" to clarify that the document submission requirements apply to all certified HCCs, not just HCCs applying for renewal. The department has also changed §13.415(a)(2), in response to comment, to clarify that the

requirement to submit and make available documents related to QI encompasses documents in support of the requirements under §13.482. In response to comment the adoption also includes a change to §13.415(b) to clarify that documents listed in the section must be maintained for at least five years from the anniversary date of the applicable document's creation.

Section 13.416 addresses the review of an original or renewal application.

Section 13.416(a) provides that Insurance Code §§848.056 – 848.060 and §848.153 govern the processing of the application.

Section 13.416(b) explains when examinations will be performed.

Section 13.416(c) provides that application review will include the evaluation of pro-competitive benefits and the anticompetitive effects of market power increase in accord with established antitrust principles.

Section 13.416(d) sets forth by example six categories of restrictions that the commissioner has discretion to impose on an HCC applicant's certificate of authority if determined necessary to preserve competition.

Section 13.417 provides for withdrawal of an application by an applicant, or by the department on behalf of an applicant if the department determines that the applicant has failed to respond to department requests for additional information on an incomplete application in a timely manner.

Division 3. Examinations; Regulatory Requirements for an HCC after Issuance of Certificate of Authority; and Advertising and Sales Material.

Section 13.421 addresses examinations and fees for examination expenses.

Section 13.421(a) provides that the department may conduct financial, quality of care, market conduct, or antitrust examinations individually or in consolidation, during an original or renewal application review, or any other time as needed to oversee the HCC's activity.

Section 13.421(b) states the authority of the commissioner under Insurance Code §848.152(d) to set and collect fees in an amount sufficient to pay reasonable expenses of the department, the attorney general, and their contractors in administering Insurance Code Chapter 848. It also sets forth the specific fee components associated with examination of an HCC.

Section 13.421(c) outlines specific details for imposition of an annual assessment by the department and sets forth a timetable to phase in full implementation of HCC revenue reporting requirements, as well as the assessment basis and time frame for assessment of and payment by all certified HCCs.

Section 13.421(d) provides that an HCC, following the department's notification of a pending examination but prior to the department issuing a draft examination report, may request conversion to a renewal review. The subsequent renewal date for the HCC will be 12 months following the approval date of the application to renew.

Section 13.422 requires an authorized HCC to file certain information with the commissioner, either for approval prior to effectuation or for information only, and to report a material change in the size, composition, or control of the HCC after certification.

Section 13.422(c) addresses the specific filings that an HCC must make.

Section 13.422(c)(1) provides that the department will not accept a filing for review

until it is complete.

Section 13.422(c)(2) specifies those categories of filings that require approval before implementation or action. In response to comment, the adoption includes a clarifying change to §13.422(c)(2), adding new subparagraph (I) regarding proposed new or revised contract terms addressing payment methodology, for consistency with Insurance Code §848.103.

Section 13.422(c)(3) provides that an HCC must make certain filings for information about deletions or modification to specified categories of previously approved or filed operations or documents within 30 days after a change is effective. In response to comment, the adoption includes a clarifying change to §13.422(c)(3)(D), which specifies proposed new or revised payment methodologies as an item not filed for information only. The change is also necessary for consistency with Insurance Code §848.103.

Section 13.422(c)(4) addresses the approval time frame and process for approving, withdrawing approval for, and rejecting forms.

Section 13.422(c)(5) specifies the filing review procedures that apply to filings under the section. The adoption includes a clarifying change to §13.422(c)(5)(B) to correct an erroneous publication reference.

Section 13.423 addresses service area change applications. It requires the HCC to file an application for approval before expanding or reducing an existing service area or adding a new service area. It also sets forth categories of items that, if changed by a service area expansion or reduction, must be submitted to the department for approval or information, as appropriate.

Section 13.423(c) and (d) requires that the application be complete before review will begin, and states that an application is complete when all information reasonably necessary for a final determination by the department, including information demonstrating the HCC's compliance with the subchapter's QA, QI, and credentialing requirements, has been filed with the department.

Section 13.423(e) sets forth circumstances under which the department may require the HCC to file an application for renewal before the date required by Insurance Code §848.060(a).

Section 13.424 requires that an authorized HCC must file with the commissioner an application to renew its certificate no later than 180 days before its certificate anniversary date. It also sets forth items for inclusion in the filing.

Section 13.424(c) states that the HCC is not required to resubmit previously filed documents that are not amended, modified, revised, canceled, terminated, replaced, or otherwise changed since issuance of the HCC's most recent certificate of authority. Instead, the HCC must file a transmittal form identifying those documents along with an authorized HCC representative's attestation that the identified documents are unchanged.

Section 13.424(d) extends the scope of §13.424(c) to documents filed and either approved or accepted under §13.422 after issuance of the certificate of authority.

Section 13.424(e) states that file review will begin only when the filing is complete, and sets forth content specifications for notices the department will issue to advise an HCC about necessary additional submissions to complete the filing.

Section 13.424(f) provides that a completed renewal application review will be in

accord with Insurance Code §848.060.

Section 13.425 addresses necessary requirements and prohibitions associated with an HCC's compensation arrangements.

Section 13.425(a) restates the requirement that an HCC comply with Insurance Code §848.053, concerning a compensation advisory committee and data sharing.

Section 13.425(b) requires an HCC to establish and enforce procedures to maintain the confidentiality of charge, fee, and payment data; and information between its participants and any individual or entity outside the HCC, including information for transmittal to the department.

Section 13.425(c) prohibits a participant from using confidential charge, fee, and payment data collected by the HCC in any negotiation to which the HCC is not a party.

Section 13.426 addresses confidentiality requirements, including establishing and administering internal controls to safeguard and ensure against sharing confidential information with or among participants. The provisions mandate collection, custodial, retrieval, and transmittal procedures to ensure that confidential information is not shared either with entities and individuals outside the HCC or between or among participants.

Section 13.429 requires HCCs to comply with Insurance Code Chapters 541 and 542 and department rules adopted under those chapters, as applicable, in the same manner as insurance companies or HMOs.

Division 4. Financial Requirements.

Section 13.431 addresses reserves and working capital requirements. It requires an HCC to have and maintain

(1) working capital that is composed of current assets and that meets the requirements of the subsection concerning unencumbered net equity and asset-liability ratio as applicable, and

(2) reserves sufficient to operate and maintain the HCC and to arrange for services and expenses it incurs, and to compute financial reserves in accordance with Generally Accepted Accounting Principles in an amount not less than 100 percent of incurred but not paid claims of nonparticipating physicians and providers.

Section 13.431(c) specifies reserve requirements that apply to any certified HMO or insurer that forms an HCC under Insurance Code §848.001 or contracts with an HCC under Insurance Code §848.103. The reserve must be

(1) equivalent in value to three months of prepaid funding or capitation payments

(2) phased in over a period no more than 36 months

(3) maintained separately from and in addition to all other reserves and liabilities of the HMO or insurer

(4) unencumbered and dedicated to assure its availability for its intended purpose, and

(5) reported separately from all other reserves and liabilities of the HMO or insurer.

The adoption includes a change to §13.431(c) to clarify that it applies to an HMO or insurer certified by the department that forms an HCC under Insurance Code Chapter 848.

Section 13.431(d) limits current assets to U.S. currency, certificates of deposit with fixed terms of one year or less, money market accounts, accounts receivable from government payors, and other accounts receivable net of all allowances and no more than

90 days old for purposes of meeting the section's minimum working capital requirements.

Section 13.431(e) excludes investments in capital assets, mortgages, notes, and loan-backed securities from the calculation of reserves and net equity in determining satisfaction of the section's minimum requirements.

Section 13.432 prohibits a director, member of a committee, officer, or representative of an HCC who is charged with the duty of handling or investing its funds from intentionally

(1) depositing or investing those funds other than in the corporate name of the HCC or in the name of a nominee of the HCC, or

(2) taking or receiving for his or her own use any fee, brokerage, or commission for, or on account of, a loan made by or on behalf of the HCC, except for reasonable interest on amounts that the individual has loaned to the HCC.

Division 5. HCC Contract Arrangements.

Section 13.441 addresses general provisions concerning HCC contracts.

Section 13.441(a) provides that an HCC's contracts with physicians and health care providers must not impede application of provisions in the Insurance Code and Title 28 TAC that regulate HMOs and preferred provider benefit plans, and that impose requirements concerning relations with physicians or health care providers.

Section 13.441(b) prohibits an HCC from using a financial incentive or making a payment to a physician or health care provider if the incentive or payment acts directly or indirectly as an inducement to limit medically necessary services.

Section 13.441(c) prohibits an HCC with a dominant provider, as defined in the

subsection, in the PSA in which the dominant provider furnishes services, from requiring a private payor to contract exclusively with the HCC or otherwise restricting a private payor's ability to contract or deal with other HCCs, networks, physicians, or health care providers. The adopted section includes a change to §13.441(c) to more clearly reflect that the intended scope of its prohibition is the PSA in which the dominant provider furnishes services.

Division 6. Change of Control by Acquisition of or Merger with HCC.

Section 13.451 defines "control" and "voting security."

Section 13.452 addresses determination of control for this division of the subchapter, with provisions for rebutting the presumption of control and commissioner determination of control.

Section 13.453 addresses filing requirements that apply in connection with a change of control of the HCC by

(1) specifying prohibitions that apply concerning the acquisition of ownership interest in or control of a certified HCC unless the individual or entity acquiring the interest or control has filed specified documents with the department

(2) listing the documents that the individual or entity acquiring the ownership interest or control must file under oath or affirmation, and

(3) clarifying the application of the section's requirements concerning each partner of a partnership, member of a syndicate or group, and individual or entity who controls the partner or member subject to the filing requirements of the section.

Section 13.454 provides the grounds for commissioner disapproval of a proposed

acquisition of control, and the time frame within which either the commissioner's disapproval action is to take place or approval of the change of control is effective.

Section 13.455 provides that for a change of control of an HCC resulting in an increase to market share for any PSA, as provided in §13.414, the department may require that the HCC file an application for renewal before the date required by Insurance Code §848.060(a). Further, an HCC may submit an application for renewal of the certificate of authority in connection with a filing under this division.

Division 7. Administrative Procedures.

Section 13.461 provides that the commissioner may require additional information from an HCC or any participant necessary to make any determination required by Insurance Code Chapter 848, this subchapter, and applicable insurance laws and regulations, including any or all additional information item types set forth in the section. The section does not require the HCC to create the listed items unless they are required by the department to be provided; but once any of the items is created, the HCC or participant must maintain the items for at least five years. In response to comment, the adopted section transfers §13.413(i)(7) as published to §13.461(c) as new paragraph (25). The paragraph relates to the HCC applicant submitting participants' contribution margins or fixed-or-variable costs for health services in the service area in the application process. The transfer reflects that the burden of producing the information is sufficient to merit changing the nature of the requirement to one that is imposed by request under §13.461.

Division 8. Other Requirements.

Section 13.471 requires an HCC to notify all affected payors in writing of a material

change in the payment arrangements for physicians or health care providers, or both, within 30 days of any change in payment arrangement type. The notification must include descriptions of both the payment arrangement that has been changed and the new payment arrangement. This notice is distinct from notice requirements in Insurance Code §843.321 and §1301.136, which require notice not later than the 90th day before an insurer or HMO effects changes to coding guidelines or fee schedules that will result in a change of payments to a physician or provider.

Section 13.472 identifies contracts with other specified providers and requires the HCC to submit to the department a monitoring plan to ensure the implementation of all delegated functions in compliance with all department regulatory requirements. The section also requires the HCC to conduct an on-site or desk audit of the delegated entity, delegated network, or delegated third party at least annually to verify continuing compliance with department regulatory requirements. It also requires the HCC to take prompt action to correct any failure by the delegated entity, delegated network, or delegated third party to comply with the department's regulatory requirements applicable to delegated functions.

Section 13.473 addresses the general organization of an HCC.

Section 13.473(a) provides that the governing body of an HCC must be ultimately responsible for the development, approval, implementation, and enforcement of essential policies and procedures related to the HCC's operations. In response to comment, the adoption includes a clarifying change to §13.473(a) to reflect that the HCC's governing body must comply with Insurance Code §848.052.

Section 13.473(b) specifies requirements that apply to the HCC's clinical director.

Section 13.473(c) permits the HCC to establish one or more service areas within Texas, specified by counties and ZIP codes, or portions of counties, with cost center accounting for each service area to facilitate reporting on divisional operations in financial reporting. Section 13.473(c) also states the requirements for network adequacy for any of the service areas that the HCC establishes in Texas.

Section 13.473(d) requires that the HCC protect against acts of fraud or dishonesty by its officers and employees in one of three ways:

(1) maintaining in force in its own name a fidelity bond on its officers and employees in an amount of at least $100,000 or another amount prescribed by the commissioner

(2) maintaining in force in its own name insurance coverage in a form and amount acceptable to the commissioner, or

(3) depositing with the comptroller readily marketable liquid securities acceptable to the commissioner.

Section 13.474 sets forth essential requirements for an HMO's or insurer's delegation of functions to HCCs. The section states that delegation of HMO or insurer functions to an HCC is governed by Insurance Code Chapter 1272 and 28 TAC Chapter 11, Subchapter AA. It further provides that if this subchapter conflicts with Chapter 1272 or 28 TAC Chapter 11, Subchapter AA, this subchapter will govern. The section also requires specific disclosures in provider listings, insurance policies, and certificates distributed to insureds or enrollees if there is a delegation agreement between the HCC

and an HMO or insurer. In response to comment, the adoption includes a change to §13.474(d) to clarify that an HCC must require the HMO or insurer to disclose, in all provider listings distributed to insureds or enrollees, those providers participating in the HCC within the HMO's or insurer's approved service area.

Division 9. Quality and Cost of Health Care Services.

Section 13.481 provides essential details for the QI structure for HCCs. It requires the HCC to develop and maintain an ongoing QI program to objectively and systematically monitor and evaluate the quality and appropriateness of the health care services it arranges for or offers. It provides that the governing body ultimately is responsible for the QI program and sets forth QI duties of the governing board. It requires the board to appoint a QI committee (QIC) that must evaluate the overall effectiveness of the QI program, and to use multidisciplinary teams when indicated to accomplish the HCC's QI program goals. It permits the QIC to delegate QI activities to other appointed committees, that will prepare and submit written reports of any QI findings and recommendations.

Section 13.482 requires an HCC to establish, implement, and administer a continuous QA and QI program that includes defined policies and processes to achieve the basic legislative objectives for HCCs. The new section sets forth specific program components. These components include promoting use of evidence-based medicine and best practices, securing patient engagement, promoting coordination of care across a continuum of care, and measuring and reporting on quality of health care services and impact on cost. The adoption includes a change to §13.482(b)(1)(C) in response to comment to clarify the endorsed nature of the National Quality Forum standards

referenced in the subparagraph.

Section 13.483 addresses credentialing and requires an HCC to implement a documented process for selecting and retaining contracted participants. It provides that the process must comply with standards promulgated by the National Committee for Quality Assurance, URAC, the Joint Commission on Accreditation of Hospital Organizations (JCAHO), or the AAAHC, as appropriate and applicable. In response to comment, the department changed the section to include the AAAHC to clarify the association's status as a nationally recognized accreditation entity.

Division 10. Complaint Systems; Rights of Physicians; Limitations on Participation.

Section 13.491 requires each HCC to implement and maintain a complaint system that complies with Insurance Code §848.107 to provide reasonable procedures for resolving an oral or written complaint concerning the HCC or health care services arranged by or offered through the HCC. The section defines "complaint," requires a process for notice and appeal of a complaint initiated by or on behalf of a patient who sought or received health care services by a participant, and affirms the commissioner's authority to examine a complaint system for compliance with §848.107 and the subchapter.

Section 13.492 sets forth requirements for acknowledging, responding to, and investigating complaints, and issuing a complaint resolution letter. It also provides for issuing a decision letter in cases where a patient complaint is appealed. The complaint resolution and decision letters must include specific reasons for the resolution or decision, and must disclose that the complainant may file a complaint with the department if the

complainant is dissatisfied with the resolution, the appeal, or the HCC's complaint process. The section also requires maintenance of a complaint log that captures and categorizes each complaint. The HCC must maintain the log for each complaint and documentation on each complaint, complaint proceeding, and action taken until the third anniversary after the date the complaint was received.

Section 13.493 addresses rights of physicians and provides that before a complaint against a physician is resolved, or before an HCC involuntarily terminates a physician, the HCC must provide the physician with the opportunity to dispute the complaint or termination. The section requires that the dispute process include providing the physician with written notice of the complaint or the basis of termination, an opportunity for hearing and presentation of information at the hearing, and a written decision from the HCC that specifies reasons for the decision.

Section 13.494 permits an HCC to limit a physician or physician group from participating in the HCC only if the limitation is based on an established development plan approved by the HCC's board of directors, a copy of which must be provided to the physician or physician group. The section also prohibits the HCC from taking a retaliatory or adverse action against a physician or health care provider that files a complaint with a regulatory authority regarding an HCC's action.

3. HOW THE SECTIONS WILL FUNCTION.

Division 1. General Provisions.

Division 1 consists of §§13.401 – 13.404, addresses general provisions of the rule.

Section 13.401 sets forth the purpose of Subchapter E, provides that the subchapter's provisions are severable, and states that the subchapter does not limit the commissioner's exercise of statutory authority.

Section 13.402 defines terms for uniform application throughout the subchapter.

Section 13.403 describes the location and method to file original or renewal HCC applications.

Section 13.404 restricts the use of the terms "health care collaborative" and "HCC" by an applicant both before and after issuance of a certificate of authority.

Division 2. Application for Certificate of Authority.

Division 2 consists of §§13.411 – 13.417 and addresses the application process for an HCC certificate of authority.

Section 13.411 provides for payment of a nonrefundable application fee, provides for annual assessments to cover any shortfall between incurred expenses by the department and attorney general and the funds collected through the application and examination process, and advises that the application is public information except as provided by Insurance Code §848.005(b).

Section 13.412 addresses procedural details for revisions during review, including requests for additional time to make necessary revisions, and also provides for corporate officer certification for revisions to basic organizational documents, bylaws, or officers' and employees' bond.

Section 13.413 addresses necessary contents of the application and arrangement of those contents. The section includes specific requirements for submission of several

categories of HCC information, including organizational, financial, provider and service area, QA and QI, accreditation, and antitrust analysis at varying levels.

Section 13.414 establishes a limited exemption from certain information filing requirements, provides for certain exceptions, provides by categories the formula for calculating market share and alternative calculation methods, and provides notice of commissioner discretion to require additional information if necessary to meet the review requirements of Insurance Code Chapter 848.

Section 13.415 addresses document availability for examination purposes and specifies 18 types of documents that an HCC must provide on department request, make available for review at its Texas office location, and maintain for at least five years.

Section 13.416 addresses review of an original or renewal application, including the timing of examinations, notice of evaluation of pro-competitive benefits and anticompetitive effects of market power increase in accord with established antitrust principles, and categories of restrictions the commissioner may impose on a certificate holder if determined to be necessary to preserve competition.

Section 13.417 provides for withdrawal of an application by the applicant or by the department under specified circumstances.

Division 3. Examinations; Regulatory Requirements for an HCC after Issuance of Certificate of Authority; and Advertising and Sales Material.

Division 3 consists of seven sections and addresses examinations and regulatory requirements that apply after issuance of an HCC's certificate of authority.

Section 13.421 addresses examinations and fees for examination expenses for

financial, quality of care, market conduct, or antitrust examinations performed individually or in consolidation. It states the authority of the commissioner to set and collect fees sufficient to pay reasonable expenses of the department, the attorney general, and their contractors. It also specifies HCC examination fee components, outlines specific details, and sets forth the implementation time frame for imposition of an annual fee assessment. The section provides that an HCC, on department notification of a pending examination, may request conversion to a renewal review if specified conditions are met.

Section 13.422 addresses post-certification HCC filing requirements. It specifies information that must be filed with the commissioner, either for approval prior to effectuation or for information, and that a filing submitted for review must be complete to be accepted for review. It also specifically requires the HCC to report a material change in size, composition, or control of the HCC to the commissioner.

Section 13.423 addresses service area change applications. It requires an application be approved before expansion or reduction of an existing service area or adding a new service area. It sets forth categories of items that must be submitted if affected by a service area change. It further requires that an application be complete before review begins and provides criteria for achieving application completion. The section also sets forth circumstances under which the department may require the HCC to file an application for renewal before the date provided in Insurance Code §848.060(a).

Section 13.424 addresses certificate of authority renewal requirements. It sets forth the time frame for filing, the items required to be included with the filing, the criteria for a complete application, and the scope and extent of review for a renewal application.

Section 13.425 addresses compensation arrangements. It restates the Insurance Code §848.053 requirements concerning an HCC's compensation advisory committee and data sharing; requires that the HCC have and enforce procedures to maintain confidentiality of charge, fee, and payment data, and information between participants and individuals or entities outside the HCC; and prohibits a participant from using HCC-collected confidential charge, fee, and payment data in any negotiation to which the HCC is not a party.

Section 13.426 addresses confidentiality requirements, including establishing and administering internal controls to safeguard and ensure against sharing confidential information with or among participants. The provisions mandate collection, custodial, retrieval, and transmittal procedures to ensure that confidential information is not shared either with entities and individuals outside the HCC or between or among participants.

Section 13.429 requires HCCs to comply with Insurance Code Chapters 541 and 542 and department rules adopted pursuant to those chapters, as applicable, in the same manner as insurance companies and HMOs.

Division 4. Financial Requirements.

Division 4 consists of §13.431 and §13.432.

Section 13.431 addresses reserves and working capital requirements. It specifies the working capital requirements and standards that apply to an HCC based on its composition and certification experience. It sets forth a minimum reserve standard and the methodology for its computation. It also specifies reserve requirements that apply to an HMO or insurer certified by the department that forms an HCC or enters into a contract

with an HCC. It defines what qualifies as a current asset for the purpose of meeting the section's minimum working capital requirements and specifies that accounts receivable must be reported net of all allowances. It also excludes specified investments from the calculation of reserves and net equity in determining satisfaction of the section's minimum requirements.

Section 13.432 addresses the fiduciary responsibility of a director, member of a committee, officer, or representative of an HCC who handles or invests HCC funds.

Division 5. HCC Contract Arrangements.

Division 5 consists of §13.441, which generally addresses HCC contracts. It prohibits

(1) an HCC's contracts with physicians and health care providers from impeding application of provisions in the Insurance Code and Title 28 TAC that regulate HMOs and preferred provider benefit plans

(2) an HCC from using a financial incentive or making a payment to a physician or health care provider if the incentive or payment acts directly or indirectly as an inducement to limit medically necessary services, and

(3) an HCC with a dominant provider as defined in the subsection, in the PSA in which the dominant provider furnishes services, from requiring a private payor to contract exclusively with the HCC or otherwise restricting a private payor's ability to contract or deal with other HCCs, networks, physicians, or health care providers.

Division 6. Change of Control by Acquisition of or Merger with HCC.

Division 6 consists of §§13.451 – 13.455.

Section 13.451 defines "control" and "voting security."

Section 13.452 addresses determination of control and rebutting the presumption of control for Division 6 purposes.

Section 13.453 addresses filing requirements that apply in connection with a change of control of the HCC, including

(1) specifying the prohibitions applicable to the acquisition of ownership interest in or control of a certified HCC

(2) specifying the documents that the individual or entity acquiring the ownership interest or control must file under oath or affirmation, and

(3) clarifying the application of the section's requirements concerning each partner of a partnership, member of a syndicate or group, and individual or entity who controls the partner or member subject to the section's filing requirements.

Section 13.454 specifies grounds for commissioner disapproval of a proposed acquisition of control and the timetable for commissioner action.

Section 13.455 addresses the department's discretion to require, and the HCC's discretion to submit, an application for renewal before the date required by Insurance Code §848.060(a) for any change of control of an HCC resulting in an increase to market share for any PSA as provided in §13.414.

Division 7. Administrative Procedures.

Division 7 consists of §13.461 and permits the commissioner to require additional information from an HCC or any participant necessary to make any determination required by Insurance Code Chapter 848; 28 TAC Chapter 13, Subchapter E; and applicable

insurance laws and regulations. Additional information includes any or all of the information item types set forth in the section. It does not require the creation of the items listed unless they are required to be provided. It mandates a document retention period of at least five years.

Division 8. Other Requirements.

Division 8 consists of §§13.471 – 13.474.

Section 13.471 requires specified written notice from an HCC to all affected payors of a material change in the payment arrangement for physicians, health care providers, or both within 30 days of any change in payment arrangement type.

Section 13.472 identifies contracts with other specified providers and requires for those contracts that the HCC submit to the department a monitoring plan to ensure the implementation of all delegated functions in compliance with all department regulatory requirements. The section requires audits of delegated entities at least annually and also requires prompt corrective action for regulatory compliance failure, as necessary.

Section 13.473 addresses the general organization of an HCC and

(1) provides that the governing body of an HCC must be ultimately responsible for the development, approval, implementation, and enforcement of essential policies and procedures related to the HCC's operations

(2) specifies requirements that apply to the HCC's clinical director

(3) permits the HCC, subject to network adequacy requirements, to establish one or more service areas within Texas, specified by counties, ZIP codes, or portions of counties, with cost center accounting for each service area to facilitate the reporting of

divisional operations in financial reporting, and

(4) requires that the HCC protect against acts of fraud or dishonesty by its officers and employees, as specified.

Section 13.474 sets forth essential requirements for an HMO's or insurer's delegation of functions to HCCs, including that delegation of HMO or insurer functions to an HCC is governed by Insurance Code Chapter 1272 and 28 TAC Chapter 11, Subchapter AA. It also requires specified disclosures.

Division 9. Quality and Cost of Health Care Services.

Division 9 consists of §§13.481 – 13.483 and addresses both quality and cost of health care services in providing essential requirements for the QI structure for HCCs.

Section 13.481 and §13.482 require an HCC to have an ongoing QI program, and to establish and administer a specified continuous QA and QI program, respectively.

Section 13.483 requires an HCC to have a documented process for selection and retention of contracted participants.

Division 10. Complaint Systems; Rights of Physicians; Limitations on Participation.

Division 10 consists of §§13.491 – 13.494 and addresses complaint systems and physician rights.

Section 13.491 requires an HCC to have and maintain a complaint system with reasonable complaint resolution procedures that comply with Insurance Code §848.107.

Section 13.492 requires that the system include complaint acknowledgement, response, investigation, and issuance of a resolution letter. It also provides for an appeals

process, and maintenance of a complaint log that captures and categorizes each complaint.

Section 13.493 addresses rights of physicians and provides that before a complaint against a physician is resolved or a physician's association with an HCC is involuntarily terminated, the HCC must provide the physician with the opportunity to dispute the complaint or termination.

Section 13.494 permits an HCC to limit a physician or physician group from participating in an HCC only if the limitation is based on an HCC board-approved development plan, a copy of which must be provided to the physician or physician group. It prohibits an HCC from taking a retaliatory or adverse action against a physician or health care provider that files a complaint with a regulatory authority regarding an HCC's action.

4. SUMMARY OF COMMENTS AND AGENCY RESPONSE.

General Comments: Several commenters express appreciation for the state's efforts to develop new and innovative health care delivery systems and thank the department and attorney general staff for their work on the HCC rules. Several commenters express appreciation for the department's work to seek and consider stakeholder responses regarding the regulation of HCCs through an informal draft posting. Two of the commenters also state that the proposal now addresses several of the commenters' previous concerns.

Agency Response: The department appreciates the supportive comments.

Comment: §13.402 – "Hospital-based physician" or "facility-based physician." A commenter recommends that the department define "hospital-based physician" or "facility-based physician" in the absence of a statutory definition as follows: "An anesthesiologist, emergency room physician, neonatologist, pathologist, radiologist, or other physician specialty who furnishes substantially all of their professional services in a hospital-based or facility-based setting."

Agency Response: The department disagrees that the rule should include definitions for the terms "hospital-based physician" or "facility-based physician" because the rule uses neither term. Inclusion of the proposed definition for the terms would not result in increased uniformity because of the ambiguity in the proposed definition. As proposed, any class of physician specialty could potentially meet the definition, and the definition could create confusion about applicability to specialty physicians who furnish substantially all of their professional services on behalf of a hospital or facility at a remote location. The department, therefore, declines to make this change.

Comment: §13.402(2) – Definition of Clinical Director. Some commenters recommend that the department change the definition of "clinical director" in §13.402(2) to reflect the need for Texas-licensed physician leadership in the clinical oversight of the HCC because the proposed definition includes any appropriately licensed "health care professional." The commenters state that the term does not: require the clinical director to be a physician; limit the licensure status of the director to Texas; or require that the license be in good standing with the applicable licensing agency.

The commenters state that SB 7 expressly recognizes physicians as a critical component of HCCs by defining an HCC in Insurance Code §848.001(2)(C) as an entity that must always be composed of physicians, regardless of any additional provider or insurer composition. Also, the commenters state that Insurance Code §848.056(b)(4) requires the HCC to demonstrate in its application for a certificate of authority that it has a sufficient number of primary care physicians in the HCC's service area.

To address these issues, the commenters propose the following revised definition: "(2) Clinical director– A physician who is: (A) licensed and in good standing with the Texas Medical Board; (B) an individual who is a party to a contract with an HCC; and (C) responsible for clinical oversight of the utilization review program, the credentialing of professional staff and QI functions."

The commenters state their proposed revised definition conforms with Insurance Code Chapter 848. They state that it recognizes that a physician is the appropriate professional to be responsible for the utilization review program, the credentialing of professional staff, and the QI functions of the HCC. The commenters say only a physician has the requisite education, training, and experience necessary to credential the HCC's staff, which will necessarily include other physicians.

The commenters note that the suggested definition sets a higher standard than the federal regulations concerning accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP), but they assert that a higher state law standard does not preclude an HCC from participation in the MSSP. The commenters state that the legislative goal of improving the quality and efficiency of health care through HCCs can be

accomplished through a Texas-licensed physician clinical director without disadvantaging MSSP-participating HCCs.

Agency Response: The department agrees that it is appropriate for a Texas HCC's clinical director to be licensed in Texas because the clinical director will be actively involved in all quality management activities for provision of services in Texas. In addition, the director will be responsible for clinical oversight of the utilization review program and credentialing functions. For these reasons, §13.473(b) requires an HCC's clinical director to be licensed in Texas or otherwise authorized to practice in this state. The department also clarifies that the status of the requisite license or authorization must be one of good standing. To clarify both of these requirements, the department is changing §13.402(2)(A) to require that the clinical director be "appropriately licensed in good standing in Texas."

While the department agrees that the clinical director will appropriately be a physician in many cases, the department does not agree that this will be required in all cases. It is possible that a specialty HCC will form to provide select health care services and inclusion of a more restrictive physician-licensing requirement could be unnecessarily burdensome to this type of HCC. The department's definition does not prevent an HCC from employing a physician as its clinical director. The department suggests an HCC consider its participation in programs such as MSSP in making this type of oversight determination.

The department agrees that Insurance Code Chapter 848 requires that: (1) an HCC must consist of physicians, with or without other health care providers, insurers, or HMOs; and (2) an HCC's application for a certificate of authority must demonstrate that the HCC

contracts with a sufficient number of primary care physicians in the HCC's service area. But the department does not interpret these requirements to mean that an HCC's clinical director can only be a physician, or be a party to a contract with an HCC.

The department further disagrees that the clinical director's oversight of utilization review, credentialing, and QI functions require that the clinical director be a physician. As stated, a specialty HCC could form to provide select health care services, and inclusion of a more restrictive physician-licensing requirement could potentially be unnecessarily burdensome to this type of HCC. Further, an HCC is permitted to delegate credentialing and utilization review functions under Insurance Code §848.108, rendering the suggested limitation unnecessary. The department declines to require an HCC's clinical director to be a physician.

Comment: §13.402(21) – Definition of "pro-competitive benefit." A commenter states that the definition of "pro-competitive benefit" is inadequate and does not tie to the concept codified in Insurance Code Chapter 848 because the definition's examples describe "pro-quality" benefits. The commenter requests that the definition instead refer to systems or protocols that, if implemented, would benefit the competitiveness of the health care marketplace and give consumers, including employers and other purchasers of health care, more choice in how they access and pay for that care.

A second commenter states that the definition of pro-competitive benefit should link to the goals of quality and coordinated care outlined in Insurance Code Chapter 848 and clarify that the benefit is to the HCC's patients. The commenter states that the use of electronic health records, for example, is not itself a benefit for patients. Instead, the

commenter asserts that electronic health records are a tool that can result in benefits for patients (such as reduction of duplicative tests, fewer prescription errors, and remote patient access to medical records), and providers (such as improved efficiency in records maintenance and improved coding and billing).

When showing that pro-competitive benefits outweigh the risks of provider consolidation, the commenter asserts that HCCs should not be able to propose expanding electronic health records as a pro-competitive benefit, for example, and then measure the percentage of HCC providers using them. Instead, the commenter states that the HCCs should propose a reduction of duplicative tests as an example of the pro-competitive benefit, and measure improvement in that outcome.

The commenter recommends that the department revise the definition based on requirements in Insurance Code §848.057(a)(2)(A) as follows:

(21) Pro-competitive benefit – A benefit to patients obtained from clinical or financial integration by the establishment and operation of the HCC in the form of increased provider collaboration, improved quality-based health care outcomes, improved patient safety, improved patient engagement, improved coordination of services, reduced potentially preventable events, or incentives that reduce health care costs without jeopardizing patient quality of care.

Agency Response: The department does not agree that the published definition of "pro-competitive benefit" excludes systems or protocols that increase competitiveness and provide choice in how to access and pay for health care. The department also disagrees that the definition does not reflect the concept in Insurance Code Chapter 848.

Insurance Code §848.057(a)(6) provides that an applicant must, as a condition of certification as an HCC, satisfy the commissioner that "the pro-competitive benefits of the applicant's proposed health care collaborative are likely to substantially outweigh the anticompetitive effects of any increase in market power." In this regard, the department notes that an ACO, an organization analogous in many respects to an HCC, may form and provide services to Medicare beneficiaries under the MSSP, even if the ACO's formation will potentially lead to an increase in market power. The antitrust test in Insurance Code §848.057(a)(6) is consistent with that undertaken by the Federal Trade Commission (FTC) and Department of Justice (DOJ) in assessing whether an ACO satisfies federal antitrust concerns. See *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, 76 Fed. Reg. 67026, Oct. 28, 2011, (final Policy Statement), "A rule of reason analysis evaluates whether the collaboration is likely to have anticompetitive effects and, if so, whether the collaboration's potential pro-competitive efficiencies are likely to outweigh those effects."

The final Policy Statement clarifies those agencies' enforcement policy concerning collaborations among independent providers that wish to form an ACO in the Medicare Shared Savings Program. *Id.* at 67026. Specifically, the FTC and DOJ will apply a rule of reason analysis to joint price agreements among competitor health care providers that are financially or clinically integrated, if the agreements are "reasonably necessary to accomplish the pro-competitive benefits of the integration." *Id.* at 67027.

The federal agencies consider both the financial and clinical integration components in determining whether an agreement is reasonably necessary to accomplish the pro-

competitive benefits of the integration, citing as an example the possibility that the joint venture will create "an active and ongoing program to evaluate and modify practice patterns by the venture's providers, and to create a high degree of interdependence and cooperation...to control costs and ensure quality." *Id.*

The FTC and DOJ analysis considers the ACO eligibility requirements to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care for beneficiaries. The analysis concludes that these requirements are consistent indicators of the level of clinical integration that the federal agencies have identified as "reasonably likely to be bona fide arrangements intended to improve the quality and reduce the costs of providing medical and other health care services through their participants' joint efforts." *Id.* at 67027–67028.

It is the department's position that the definition of "pro-competitive benefit" in §13.402(22) is, in its inclusion of quality-related factors, consistent with the application of the term as used in the federal antitrust analytical model for an ACO, providing for increased consistency in the application of antitrust scrutiny between the analogous federal and state models.

The definition in §13.402(22) is also consistent with the requirements in Insurance Code Chapter 848, which specifically include quality-related eligibility criteria, such as promoting improvement in quality-based health care outcomes, patient safety, patient engagement, and coordination of services under §848.057(a)(2)(A)(ii), incorporating requirements for very specific categories of pro-competitive benefits as a matter of statute.

The department agrees that it is appropriate to clarify the implicit requirement that a pro-competitive benefit ultimately accrues to the HCC's patients. This agreement is based on

(i) the emphasis in antitrust analysis on QI for patients, as previously discussed, and

(ii) the express eligibility requirements in Insurance Code §848.057(a)(2)(A) that the HCC applicant satisfy the commissioner that the applicant is willing and able to ensure its services will be provided in a manner to

(a) increase collaboration among health care providers and integrate health care services

(b) promote improvement in quality-based health care outcomes, patient safety, patient engagement, and coordination of services, and

(c) reduce the occurrence of potentially preventable events.

The department is changing the definition to explicitly clarify this point.

Because of this change, the department is also adding a definition for the term "patient" at §13.402(18), defining the term as "an individual who receives a health care service."

Insurance Code §848.057(a)(2)(A) already includes the specific broad categories of patient benefits referenced in the second commenter's proposed definition. The department does not agree that those categories must also be restated in the definition of pro-competitive benefit, since the department will already receive related information as part of the basic application requirements. The department does agree that the eligibility

requirements in Insurance Code §848.057(a)(2)(A) are related to the types of pro-competitive benefits contemplated in Insurance Code Chapter 848 and in the department's rule, as explained previously in this response.

Regarding the commenter's concern about use of electronic health records as a pro-competitive benefit, the department clarifies that the quantifier usage described by the commenter would instead be part of the analysis provided with the application under §13.413(h)(6). The example of usage of electronic health records in the definition of "pro-competitive benefit" refers to usage to improve patient outcomes. The department's change to this definition emphasizing that the benefit must ultimately accrue to the patient population should serve to clarify this point, and no further changes to the definition are necessary.

Comment: §13.404(c) – Use of the Term "HCC," Trademarks, d/b/a. Some commenters note that §13.404 permits HCC applicants to use the terms "health care collaborative" and "HCC" provided that the developmental status of the proposed HCC is clearly communicated. The commenters support this provision as a means of permitting HCC organization, but suggest an additional new subsection to require disclosure to the public that an HCC is not an insurance or HMO product to prevent public confusion over the status and functions of certain HCCs. The commenters suggest new subsection (c) as follows: "(c) Unless an organization holds a certificate of authority as an HMO or is licensed as an insurer, an organizer of a HCC, an applicant for a certificate of authority under this chapter, and a HCC that is a certificate holder under this chapter must clearly communicate that the HCC is not providing an insurance or HMO product."

Agency Response: The department appreciates the supportive comment. However, because Insurance Code §848.003 already prohibits an HCC that is not an insurer or HMO to use words or initials that are descriptive of the insurance or HMO business in its name, contracts, or literature, the department disagrees that the commenter's suggested additional required disclosure is necessary. While an HCC's additional voluntary disclosure that its services are not an insurance or HMO product would help to demonstrate an HCC's intent to comply with §848.003, an additional required disclosure is not necessary. The department declines to make this requested change.

Comment: §13.411(d) and §13.421 – Filing Fee, Annual Assessments, Fee for Expenses. Some commenters note that §13.411(d) and §13.421 operate respectively to impose an annual assessment on HCCs to fully fund the expense of regulating HCCs under Insurance Code Chapter 848 and the proposed rules, with the annual assessment based on the total annual gross revenues reported by the HCCs and adjusted for the amount of any HCC application fees. For purposes of reporting gross revenues relevant to the assessment, the commenters state that §13.421 permits the HCC to reduce its gross revenues by amounts paid to individuals or entities unaffiliated with the HCC for: (i) drugs or biological supplies that, by law, require a prescription to be dispensed; and (ii) devices or medical supplies that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

The commenter supports the exclusion of the costs of drugs, biological supplies, and devices from the calculation of gross revenue as proposed in §13.421 and incorporated into §13.411(d) because this exclusion will help ensure that smaller disease-

or disorder-specific HCCs do not bear a disproportionate assessment due to the cost of basic supplies.

Agency Response: The department appreciates the supportive comment for the determination to permit the exclusion of these amounts from an HCC's gross revenues in calculating an HCC's annual assessment amount.

Comment: §13.413 and §13.482 – Reporting and publication of quality measures; QA and QI; uniform measures. *Accountability.* A commenter states that the rules lack sufficient accountability to ensure that HCCs deliver improved coordinated care to patients across various health care settings, a goal of SB 7. The commenter states that HCC formation allows health care providers to consolidate in ways that might otherwise be prevented by anti-trust law to facilitate this goal. However, the commenter states that provider consolidations often result in declining quality despite pledges of QIs. To ensure that HCCs deliver real value to consumers through less fractured health care delivery, the commenter asserts that HCCs must be accountable for delivering better coordinated, higher quality care focused on patient and enrollee needs. The commenter recommends that the department accomplish this by requiring HCCs to report on quality metrics.

Uniform measures. The commenter notes that HCCs may pick the measures that they report on under §13.413(h)(6)(C) and §13.482(b)(1), and recommends the department develop a core set of standard quality measures that all HCCs will report on at renewal to preclude HCCs from picking the measures on which they score well and avoiding those that show room for improvement. The commenter asserts that self-selection of measures misses the point of performance measures and will inhibit the

regulator's ability to ensure the public benefits from provider consolidation and integration through HCCs.

The commenter states that the department and the attorney general have sufficient authority to adopt a uniform set of quality measures for reporting under Insurance Code §848.151. The commenter asserts that standard quality performance measures would aid in the agencies' evaluation of an HCC's actual performance in delivering quality, coordinated care under Insurance Code §848.060(b)(2)(D) and (E). The commenter states that requiring HCCs to report on standard quality measures that support the goals in Insurance Code Chapter 848, and publicly displaying the results, is vital. The commenter noted that the required reporting would help achieve the following: oversight of pro-competitive benefits; monitoring HCC progress on promoting evidence-based medicine, patient engagement, coordination of care, and quality reporting; and ensuring that cost savings do not come from limiting medically necessary services, a trend that could show up in quality measure reporting.

Due to the complexity of setting uniform quality measures for HCCs that may take different forms for providers that do not always agree on quality measures, the commenter recommends several approaches.

The commenter suggests that the department

(1) Partner with the Department of State Health Services or an agency that has expertise in quality measures.

(2) Use a small set of measures that have been validated and broadly accepted within the provider community, such as National Quality Forum-endorsed standards.

(3) Choose measures from the specific domains that are goals in Insurance Code §848.057(a)(2).

(4) Use the 33 standard quality measures in the Medicare ACO regulation as a starting point because the measures align with the Physician Quality Reporting System and the Electronic Health Record Incentive Programs, will be familiar to providers, and might already be subject to reporting by some HCC participants.

(5) Use ACO Measures 1 - 7 from the Clinician and Group Consumer Assessment of Health Care Providers and Systems (CAHPS) that measure the patient and caregiver experience, and ACO Measure 8, the risk-adjusted 30-day hospital readmission rate, which measures coordination of care.

(6) Use another National Quality Forum-endorsed, readmission-based measure or other measures that are part of the Medicare ACO care coordination domain.

The commenter asks the department to establish the uniform measure requirements either as part of an HCC's renewal submission requirements or as part of §13.482, provided inclusion in §13.482 does not affect public reporting of quality measures.

The commenter also suggests that the department require an HCC to explain to the department and the attorney general why any standard measure does not apply to the HCC if the HCC is narrowly focused, replacing that measure with another in the same domain, such as patient experience or care coordination. Further, the commenter recommends that the department require HCCs to report on other quality measures that

the HCC determines to be appropriate that go beyond the scope of the core set of standard measures.

The commenter states support for the inclusion of a CAHPS survey as a uniform measure in support of consumer protection that all the HCCs will be submitting under §13.482(b).

Section 13.413(h)(6). The commenter also recommends requiring applicants under §13.413(h)(6) to identify the pro-competitive benefits that support the goals in Insurance Code Chapter 848, using a set of standard HCC quality measures to support the assessment of their pro-competitive benefits in addition to other relevant standards, as appropriate. For example, the commenter states that if the applicant anticipates that the HCC will improve the coordination of care, it should use the department-defined standard measures from the care coordination domain in its renewal application, along with other appropriate measures.

The commenter states that it supports the use of interim benchmarks in §13.413(h)(6)(C)(iii) when benefits will take more than one year to be achieved because the commenter understands that it will take time for some pro-competitive benefits to be achieved. The commenter also asserts that, consistent with Insurance Code Chapter 848, cost control measures should not jeopardize the quality of patient care. The commenter, recommends that if an HCC proposes a pro-competitive benefit under §13.413(h)(6)(D), it should similarly lay out the reference point, standards, and time frame that it will use to demonstrate that alternative payment methods either led to improvements in or did not result in diminished quality of care.

Transparency. The commenter also states that because transparency will be key to consumer protection and consumers' understanding of HCCs, CAHPS surveys and the quality measures that HCCs report on should be publicly posted and available. The commenter notes that the statute makes QIC activities confidential but asserts that the measures themselves don't improve quality, are not confidential, and are already reported by health plans, Medicaid plans, and HMOs. Further, the commenter asks the department to move the requirement for use of CAHPS and quality measures out of §13.482 if necessary to ensure publication.

Agency Response: *Accountability.* The department agrees that improved patient outcomes are a key focus for HCC design, operation, and regulation. This focus is evidenced by the certification requirements in Insurance Code §848.057(a), which provides that the applicant demonstrate that the HCC is able to ensure that the health care services it provides will promote improvement in quality-based health care outcomes, patient safety, patient engagement, and coordination of services.

The department asserts that new Subchapter E implements this by requiring in §13.482(a) that HCCs establish, implement, and administer a continuous QA and QI program with defined policies and processes to: (i) promote evidence-based medicine and best practices; (ii) secure patient engagement; (iii) promote coordination of care across a continuum of care; and (iv) measure and report the quality of health care services and impact on cost. Further, the HCC is required as part of its application under §13.413(f) to include a detailed description of these QI processes.

As a result of a different comment, the department has changed §13.415(a)(2) to clarify that specified documents supporting an HCC's QI program must be provided to the department on request and made available for review at the HCC's office in Texas.

Given this focus on quality of health care services and QI, the department disagrees that the rule lacks accountability for achieving the QI goals of Insurance Code Chapter 848.

Uniform measures. As previously explained in this response, §13.482 implements the improved patient outcome requirements of Insurance Code §848.057(a) by requiring an HCC to establish, implement, and administer a continuous QA and QI program with defined policies to promote evidence-based medicine and best practices, secure patient engagement, promote coordination of care, and measure and report the quality of health care services and the impact on cost. An HCC must also include a detailed description of its QI program processes as part of the application process under §13.413(f) and provide specified documents supporting its QI program to the department on request in accord with adopted §13.415(a), as clarified by the department in response to a different comment.

The department purposefully established these requirements in a manner that permits some flexibility in an HCC's selection of measures under §13.482(a) so that an HCC may tailor its measures in a manner appropriate to its services.

The department disagrees that it is necessary to require HCCs to target, assess, and report on standard measures in a more specific manner at this initial phase of regulation, either to address the patient outcomes of Insurance Code §848.057(a), or to ensure that there is a public benefit from provider consolidation. Sections 13.413(f),

13.415(a), and 13.482 implement the patient outcome requirements of §848.057(a) and provide for periodic department oversight of an HCC's QA and QI program in a manner that permits flexibility in an HCC's selection of measures. The department's position is that these requirements will provide sufficient information for the department and the attorney general to determine whether an HCC meets the requirements in Insurance Code §848.057 in a manner consistent with the requirements of Insurance Code §848.060(b)(2)(D) and (E). These two paragraphs incorporate requirements for an HCC's application to include evaluations of the quality and cost of health care services provided by the HCC and of the HCC's processes to promote evidence-based medicine, patient engagement, and coordination of health care services provided by the HCC, respectively.

For these, the department declines to adopt uniform measures. Should the department determine that the adoption of uniform standards is appropriate in the future, the department agrees that it would be appropriate to consider the implementation options suggested by the commenter.

The department further disagrees that HCCs will likely choose only measures at which they already excel because HCCs are required as part of the application process under §13.413(h)(6) to provide detailed information about how the applicant will achieve or extend pro-competitive benefits that the applicant expects from the HCC's formation. This information must include a pre-implementation starting point regarding the pro-competitive benefit to be achieved. Under Insurance Code §848.060(a), the HCC must file a renewal application at least 180 days prior to the anniversary of the date on which its certificate of authority was issued or most recently renewed. This process gives the department an

opportunity to periodically review an HCC's application information, and assess the HCC's pro-competitive achievements.

The measures reporting requirements in §13.482 implement patient outcome requirements in Insurance Code §848.057(a) that are necessary for both certification and, by incorporation of Insurance Code §848.060(c), renewal; and they ensure that patient outcomes will be continuously addressed by the HCC. Insurance Code §848.057(a)(6) requires that the pro-competitive benefits of the applicant's proposed HCC must be likely to substantially outweigh the anticompetitive effects of any increase in market power. The department's position is that an HCC is likely to choose a measure in which there is room for demonstrated improvement or expansion in support of its application. The department expects that HCCs might select pro-competitive benefits from among its QA and QI measures as part of its ongoing certification and renewal requirements. That selection would permit an HCC to efficiently address the certification and renewal requirements of Insurance Code §848.057(a) and §13.482(a), while simultaneously addressing the requirements to identify pro-competitive benefits to comply with Insurance Code §848.057(a)(6).

CAHPS. The department appreciates the comment in support of the inclusion of CAHPS surveys.

Section 13.413(h)(6). As previously explained, the department disagrees that it is necessary to adopt uniform and standard quality measures in §13.482(a), so there are no uniform standards to incorporate by rule into the identification of pro-competitive benefits under §13.413(h)(6), as the commenter recommends. But the department agrees that the

QI elements reflected in §13.482(a) would be appropriate for use in identification of pro-competitive benefits under §13.413(h)(6).

Because the department is not adopting uniform measures and has already addressed the relationship of the pro-competitive benefit referenced in §13.413(h)(6) to the QI requirements referenced in §13.482, the department disagrees that incorporating uniform measures under §13.482 into the identification and assessment of pro-competitive benefit requirements in §13.413(h)(6) is necessary or appropriate. Section 13.413(h)(6) provides sufficient identification and assessment requirements concerning the pro-competitive benefits the applicant anticipates will result from establishing the HCC, so the department declines to make this change.

The department appreciates the statement of support for the requirements concerning interim benchmarks in §13.413(h)(6). The department clarifies that §13.413(h)(6)(C) requires an applicant to submit information about all pro-competitive benefits that the HCC anticipates it will achieve through its formation, including those that derive from financial integration. The department disagrees that it is necessary to change §13.413(h)(6)(D) to require HCCs to submit this information and declines to make this change.

Transparency. The department agrees that transparency is important but disagrees that it is necessary at this time to require public posting of CAHPS surveys and quality measures because stakeholders have not had sufficient notice of, and opportunity to comment on, a public posting requirement; and it is not clear that the quality measures information is public information.

Insurance Code §848.005 specifies that an application, filing, or report required under Chapter 848 is public information subject to disclosure under Government Code Chapter 552. Section 848.005 also includes exceptions to this public information requirement. These exceptions include: (i) information relating to trade secrets submitted to the department or attorney general; (ii) information relating to the diagnosis, treatment, or health of a patient who receives health care services from an HCC under a contract for services; and (iii) information relating to QI or peer review activities of an HCC.

It is possible that an HCC's quality measures results could fall into one of these excepted categories or another provision of law that specifically provides for the confidentiality of information held by a governmental body, and stakeholders have not had an opportunity to comment on the issue. The department declines to add a public posting requirement at this time.

The department notes that Government Code Chapter 552 specifies the process for obtaining open records and for an attorney general decision as to whether requested information falls within an exception from public disclosure. This process remains available to stakeholders interested in obtaining and reviewing information concerning an HCC's quality measures results.

Because the potential exception from public disclosure of CAHPS and other survey measures is not solely dependent on the placement of the requirement to submit this information within the rule, the department disagrees that the provision needs to be moved and declines to make this change.

Comment: §13.413(c)(9) – Contents of Application. A commenter states that §13.413(c)(9) is too broad and covers too many disparate subjects without specifying what the applicant should submit to comply with this subsection. The commenter asks that the department separate the paragraph into distinct provisions for greater clarity.

Agency Response: The department disagrees that §13.413(c)(9) is too broad and requires further clarity. The requirements in §13.413(c)(9) are similar to those in 28 TAC §11.204(23) concerning an HMO application, which applicants successfully implement on a routine basis. The department declines to make this change.

However, in response to the comment, the department clarifies that the focus of §13.413(c)(9) is to describe how the specified components of the HCC incorporate meeting the needs of patients and participants, and the requirements of regulatory and contracting entities. The department does not prescribe how the HCC must meet this description requirement, permitting flexibility for the HCC in addressing the requirement, provided that each element of the requirements in §13.413(c)(9) is addressed. The department also does not specify the logistics of how an HCC will establish processes sufficient to meet the patient, participant, regulatory, and contracting entity needs described in the paragraph, instead allowing flexibility in business decisions and design to address how each HCC will meet these needs. Where particular organizational requirements do exist, the department has clearly identified the requirement. See, for example, §13.481, addressing QI structure requirements.

Comment: §13.413(d)(3) – Applicant contracts with payors. A commenter states that Insurance Code §848.103(c) and (d) address its primary concern by prohibiting an HCC

from accepting compensation on a capitation or prepaid basis from any entity other than an insurer or HMO and by requiring the department to review an HCC's proposed payment methodologies with government or private entities to ensure compliance with that requirement. The commenter states that the department may have addressed this issue in §13.413(d)(3) by requiring the original application to include the form of any contract between any payor and the HCC that addresses the applicant arranging for medical or health care services for the payor in exchange for payments in cash or in kind.

However, the commenter suggests that the department revise this language to parallel the statutory language because the proposed requirement is to file the template contract terms and does not directly address the compensation methodology. The commenter suggests the following revised provision: "...the form and proposed payment methodology of any contract between the applicant and a governmental or private entity related to the provision of medical or health care services." The commenter also notes that the department requires these contracts to be filed for informational purposes subsequent to licensure, per §13.422(3)(D).

A second commenter asks whether there are any minimum standards or required provisions for the applicant contracts with payors that an HCC applicant must submit under §13.413(d)(3).

Agency Response: The department agrees that the intent in §13.413(d)(3) is, in part, to address the review requirement specified in Insurance Code §848.103(c). The department further agrees that additional clarification will prevent confusion as to the scope of the requirement. The department revises §13.413 (d)(3) to read as follows: "...(3) the form,

including any proposed payment methodology, of any contract between the applicant and any payor that addresses the applicant arranging for medical and health care services for the payor in exchange for payments in cash or in kind as provided in Insurance Code Chapter 848."

The department also agrees that the requirement for the department to review proposed payment methodologies in Insurance Code §848.103(c) requires review of such methodologies before execution. Therefore, the department changes §13.422(c)(2)(I) to require an HCC to submit for approval any new or revised proposed payment methodology for use in any contract between the HCC and a payor that relates to the applicant HCC arranging for medical or health care services for the payor in exchange for payments in cash or in kind.

The department has made a conforming change to §13.422(c)(3)(D) to clarify that these proposed new or revised payment methodologies are not within the scope of the provision as subject to filing for information.

The department clarifies that §13.474 addresses requirements for HMO or insurer delegation of functions to HCCs, including contract requirements. This is not an exhaustive identification of requirements, and other standards or requirements may apply, depending on the type of payor with which an HCC contracts and the plans covered by the contract. For example, Insurance Code §1301.0625 addresses contract requirements that apply to a contract between an HCC and an insurer that issues a preferred provider benefit plan. A payor and an HCC are responsible for ensuring that their contracts comply with the standards and requirements applicable to specific contracts.

Comment: §13.413(e) – Provider and service area information. A commenter requests that the department revise §13.413(d) to require that an HCC application include the submission of an access plan if the HCC does not meet the rule's provider access standards in every ZIP code within its proposed service area, as well as a description of what the expected patterns of care will be for those provider services not offered by participants of the HCC applicant. The commenter states that HMOs are required to submit similar information to the department.

The commenter also requests that the department add a new provision to §13.413(e) to require the submission of the form of each provider contract template between the HCC and a physician and other health care provider that plans to provide health care services through the HCC.

Agency Response: The department clarifies that in most cases an HCC will not constitute the entirety of the payor's network. An insurer or HMO will remain responsible to provide access to physicians and health care providers. The department disagrees that the requested change is appropriate or necessary.

The department also clarifies that §13.413(e)(5)(B) already requires the HCC to submit the form used in any contract between the applicant and any delegated entity, delegated network, or delegated third party as described in Insurance Code Chapter 1272; the form used in any contract used with other physicians or health care providers; and the form used in any subcontract between those individuals or entities and any physician or health care provider to provide health care services. Because this information is already

required under this existing provision, the additional provision requested by the commenter is not necessary.

Comment: §13.413(g) – Disclosure of accreditation, and **§13.483** – Credentialing. A commenter requests that the department change §13.413(g) to specifically list the AAAHC among the examples of nationally recognized accrediting bodies whose accreditation information an HCC applicant must disclose if it has attained the accreditation. The commenter also requests that the department change §13.483 to state that an HCC's credentialing process must comply with the privileging and credentialing standards promulgated by the AAAHC in addition to the list of credentialing organizations included in the proposed section.

The commenter states that §13.413(g) and §13.482 do not include the AAAHC despite previous recognition by the department, state, and other state and federal jurisdictions of its accreditation and credentialing standards. The commenter supports its request by asserting that the AAAHC has extensive experience related to QI in ambulatory health care and accreditation of ambulatory health care providers, with an accreditation program recognized by regulators, third-party payors, and commercial insurance carriers, as well as health plan and HMO accreditation.

The commenter further notes that the AAAHC standards, including credentialing standards, are published annually, developed professionally, and designed to be dynamic.

Agency Response: The department agrees that the AAAHC has a long history of nationally recognized provider and health plan accreditation and credentialing, including recognition in Texas. See, for example, Insurance Code Chapter 847, recognizing AAAHC

as a nationally recognized accreditation organization for purposes of determining a health benefit plan issuer's presumed compliance with certain requirements. The department agrees that inclusion of the AAAHC among the examples of nationally recognized accrediting bodies whose accreditation information an HCC applicant must disclose if it has attained the accreditation is appropriate. The department has changed §13.413(g) accordingly.

For the same reason, and because the department has specifically recognized the quality of the AAAHC credentialing program in relation to preferred provider benefit plan credentialing requirements in §3.3706(c), the department also agrees that the AAAHC's credentialing standards are an appropriate option for inclusion in §13.483. The department has changed §13.483 to state, "The credentialing process must comply with the standards promulgated by the National Committee for Quality Assurance, URAC, the Joint Commission on Accreditation of Hospital Organizations, or the Accreditation Association for Ambulatory Health Care, as appropriate, to the extent that those standards are applicable and do not conflict with other laws of this state." This change provides an additional and appropriate option to HCCs that are choosing among nationally recognized credentialing standards.

Comment: §13.413(h) – Antitrust analysis information required of all applicants, and **§13.414(b)–(d)** – Limited exemption from certain information filing requirements. Some commenters state general support for §13.413(h), and the detailed list of information that each HCC application must contain to enable the department to perform the antitrust analysis required under SB 7. The commenters note that much of this information is

comparable to information necessary to conduct an antitrust analysis under MSSP, and should facilitate participation by HCCs in the MSSP as well as the commercial markets in Texas.

The commenters assert that it is imperative that the list of information contained in proposed §13.413(h) promote the application of the state action doctrine for antitrust immunity contemplated by the Texas Legislature in SB 7, Article 2, §2.01(c). The commenters state that the legislative intent of granting antitrust immunity to HCCs may only be fulfilled through compliance with the two prongs of the state action doctrine, which requires the challenged restraint to be clearly articulated and affirmatively expressed as state policy, and "actively supervised by the State itself." *California Retail Liquor Dealers Association v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980).

Market share threshold. Some commenters state support for the requirement in §13.413(h)(4)(A) for an HCC to provide data used in determining market share because the data will enable the department to substantiate the market share analysis provided by HCC applicants. But the commenters recommend that the department change §13.413(h)(4)(B) to require the HCC to highlight each common service area in each PSA in which the market share exceeds 30, rather than 35, percent.

The commenters note that the department has set the threshold for a more rigorous antitrust analysis at market shares exceeding 35 percent and question this deviation from the 30 percent threshold established for the basic ACO safety zones articulated in the FTC and DOJ *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.*

To support legislative intent to grant HCCs certified by the department an exemption from antitrust enforcement under the state action doctrine, the commenters state that HCCs should undergo more scrutiny than that contemplated by the federal guidance, particularly since ACOs in the MSSP have to meet detailed clinical integration requirements that are not required under SB 7 for HCCs. The commenters argue that the market share threshold for the department's analysis should be the same or lower than the 30 percent threshold established at the federal level.

The commenters also recommend that the department correspondingly lower the threshold for the limited filing exemption in §13.414(b)(1), (c), and (d) to 30 percent to further the legislative intent to invoke the state action doctrine's antitrust immunity for HCCs. The commenters assert that the state must apply significant oversight for HCCs to avail themselves of a potential state action doctrine immunity defense.

One commenter adds that in the major metropolitan areas of Texas, with thousands of physicians practicing in each market, it is highly unlikely that an HCC will form in which the participants' common services make up 35 percent or more of the market share. The commenter requests that the department lower the threshold to 15 to 20 percent, which the commenter asserts constitutes a significant portion of a given market that has potential anti-competitive effects, including on pricing.

Disclosure of market share studies. Also, to increase state oversight and substantiate the market share information provided under proposed §13.413(h), some commenters recommend that the department amend §13.413(h) to require all HCC applicants, and not only those with a market share exceeding 35 percent, to supply

documentation of market studies and forecasts, and studies of patient origin and flow. The commenters oppose the market share-based limitation on disclosure of the studies.

Policies and procedures for noninducement of limitations on medically necessary services. Some commenters state support for §13.413(h)(7), which provides that the application must include "a description of the policies and procedures the HCC will establish and administer to ensure that none of its financial incentives will result in any limitation on medically necessary services." The commenters state that this requirement is important to ensure that quality of care is not sacrificed to cost containment.

The commenters assert that HCCs should not be permitted to incentivize physicians or other health care providers to limit medically necessary services because

(1) Patient care must be paramount in the framework established by the department for HCCs.

(2) Physicians have a general ethical obligation to act in the patient's best interest without regard to financial conflicts that should preclude an HCC from acting counter to the physicians' ethical obligations or impinging on physicians' independent medical judgment.

(3) An HCC's intrusion into the patient-physician relationship would foster conduct that may negatively impact patient care.

(4) Section13.413(h)(7) is aligned with Insurance Code §843.314 and §1301.068, which prohibit HMOs and insurers from paying or providing financial inducements to physicians or other health care providers to limit medically necessary services, so that adoption of the language in proposed §13.413(h)(7) will facilitate compliance with these laws by HCCs that include HMO or insurer participants.

Agency Response: The department appreciates the supportive comments.

Section 13.413(h)(7). Regarding the §13.413(h)(7) requirement addressing medically necessary services, the department agrees it is an essential component. Insurance Code §848.057(a)(2)(B) states the ongoing HCC process requirement to help ensure that no HCC health care cost containment process has a negative impact on the quality of patient care provided through the HCC. The policies and procedures referenced in §13.413(h)(7) must be established and administered to safeguard against financial process elements that would impact quality through limitation on medically necessary services. This provision is crucial to maintain the legislatively stated dynamic between quality of medically sufficient patient care and appropriate health care cost containment.

Market share threshold. The department disagrees that a lower threshold percentage for exemption is necessary or that the 35 percent threshold is too lenient. This is because antitrust review under Insurance Code Chapter 848 is mandatory, frequent, and subject to restrictions by the commissioner where additional protections are appropriate; and because the commissioner retains authority to require disclosure of any or all of the information specified in §13.413(i) or §13.461, or both, when the information is reasonably necessary for the department to conduct its review.

Insurance Code §848.057 and §848.059 require the commissioner and attorney general to determine that an HCC applicant satisfies the requirements for approval of a certificate of authority, including that the pro-competitive benefits of the applicant's proposed HCC are likely to substantially outweigh the anticompetitive effects of any increase in market power.

Under Insurance Code §848.060(c), the application for renewal that an HCC must submit not later than the 180th day after a certificate of authority is most recently issued or renewed is subject to a review by both the commissioner and the attorney general as if the application for renewal were a new application.

Further, Insurance Code §848.060(e) requires an HCC to report to the department a material change in the size or composition of the collaborative and authorizes the department to require the HCC to file its application for renewal even earlier than 180 days from issuance or renewal of the HCC certificate of authority.

Thus, under Insurance Code §§848.057, 848.059, and 848.060, antitrust review of an HCC by both the department and the attorney general is both mandatory and frequent, demonstrating significant active supervision of the HCC in a manner consistent with SB 7, Article 2, §2.01, concerning the state action doctrine.

Further demonstrating active supervision by the department, §13.416(d) clarifies that the commissioner may impose restrictions on an applicant's certificate of authority as necessary to preserve competition.

Finally, while §13.414(b)(1), (c), and (d) establish a preliminary limited filing exemption, §13.414(g) makes clear that the section does not limit the authority of the commissioner to require provision of any or all of the information under §13.413(i) or §13.461, or both, when the information is reasonably necessary for the department to conduct its review. The limited filing exemption in the section does not negate that authority, and the level of the threshold at which the limited filing exemption attaches does not preclude the department from obtaining any of the additional market power information

that it determines to be necessary to its review. The department will review substantial market power information for all applicants in a manner consistent with active state supervision.

The department also notes that any benefit that would be obtained by routinely requiring all HCCs to submit more extensive market information would not likely be worth the additional burden, given that the department already has expansive authority under Insurance Code Chapter 848 and, as clarified in this rule, can request and obtain the additional market information on a case-by-case basis.

The department declines to lower the limited exemption threshold.

Market study disclosures. With respect to the recommendation to require all applicants to provide the information specified in §13.413(i)(3)(A)–(C), the department disagrees that it is necessary to expand the requirement. As previously explained, the department retains the authority to obtain the HCC's information about market studies and forecasts, studies of patient origin and flow, and market share studies following review of an initial application. The department is already requesting substantial information under §13.413(h), and this information should provide sufficient screening data for the department to determine whether a particular application warrants requesting and reviewing additional information. This approach will also prevent creating an undue burden in producing the information for all applicants, even those for whom additional review would otherwise be unnecessary.

The department, therefore, declines to expand this requirement.

Comment: §13.413(i) – Market power and market power information. A commenter states concern with the antitrust review process and the amount of information required for submission with an application if an HMO's market share exceeds 35 percent. The commenter asserts that the amount of information required by §13.413(i) is extensive and will be very expensive to assemble and produce. The commenter agrees that a broad range of business and financial information is needed to conduct the antitrust review but asserts that the documents required by §13.413(i) substantially exceed what the FTC and DOJ have required in the policy statement regarding ACOs.

The commenter recommends that any business documents or other information requested be more limited and that the time frames specified in §13.413(i)(3), (6), and (9) be limited to the previous 12 months. In addition, the commenter states concerns about §13.413(i)(7) and the required documentation of each participant's contribution margins or fixed and variable costs. For HCCs with a significant number of participating providers, the commenter states that developing this documentation will be complicated and costly and may have limited benefit to the antitrust review of a proposed collaborative. The commenter recommends that the department delete §13.413(i)(7).

Agency Response: The department acknowledges that, as supported by the department's cost note portion of the proposal, there will be costs associated with the HCC formation and application process. This cost may be higher for larger HCCs with more participants. The department has mitigated this cost by requiring that only HCCs with a market share that exceeds 35 percent submit the documents described in §13.413(i). The department has consulted extensively with the Office of the Attorney General concerning

antitrust analysis and has determined that the requirements in §13.413(i) are appropriate for antitrust analysis. The requirements support application of the state action doctrine to an HCC's formation that might otherwise violate antitrust law. To obtain immunity through the state action doctrine, a restraint must be clearly articulated and affirmatively expressed as state policy and be actively supervised by the state. *California Retail Liquor Dealers Association v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980). The submission requirements in §13.413(i) directly support the active supervision requirement of the state action doctrine. The department declines to make the recommended changes to §13.413 except as follows:

With respect to reducing the time frames for which document submission requirements apply in §13.413(i)(3), (6), and (9), the department disagrees that 12 months is a sufficient time frame for adequate consideration of the effects of an HCC's formation on the market. Review of business planning information for a 24-month period, as required under §13.413(i)(3), will permit the department and attorney general to assess the market impact of HCC formation on business planning by providing a pre-formation baseline. With respect to §13.413(i)(9), adopted as §13.413(i)(8), review of memoranda relating to potential and realized cost savings and efficiencies for any participant through a joint venture, internal cost-cutting, or associated transaction for a 24-month period will likewise permit the department and attorney general to assess both pre-formation and formation stage market impact. The department agrees that information for a 24-month period is sufficient for purposes of §13.413(i)(6) as a screen to determine whether additional information is necessary and has changed the paragraph accordingly.

With respect to deleting the submission requirement in §13.413(i)(7), the department disagrees that the information concerning contribution margins and quantified costs is of limited benefit because the information will aid in the assessment of both profits and costs to participants of the HCC. However, the department agrees that the burden of producing the information is sufficient to merit changing the nature of the requirement to one that is imposed by request under §13.461. Accordingly, the department has changed §13.413(i) by deleting paragraph (7) and renumbering the remaining paragraphs to conform to the change. The department has also changed §13.461 by adding the requirement as new subsection (c)(25).

Comment: 13.414(a) – Limited exemption from filing requirements. A commenter states that §13.414(a) is missing the word "or" between "original" and "renewal application."

Agency Response: The department agrees and has revised §13.414(a) to clarify that the subsection addresses the filing of an original *or* renewal application.

Comment: §13.402 – Definition of common service, and **§13.414(e)(2)** – Market share calculation. A commenter states that §13.414(e)(2) provides that the market share for outpatient services at a facility is calculated by dividing the number of physicians or other health care providers participating in the HCC within the service area by the total number of physicians or health care providers within the service area that provide a common service. The commenter states that the provision addresses the market share calculations for physicians and other health care professionals that provide outpatient services in a health care facility but does not provide a basis for calculating the market share for outpatient hospital services. Further, the commenter states that the term "common

service" is not well defined and it may be difficult to determine how to make the calculation for physician and other health care professional services.

To clarify the calculation of market share for outpatient services provided by physicians and other health care providers, the commenter recommends that the department change §13.414(e)(2) to refer to a common service provided within a medical specialty, pointing out that the FTC and DOJ policy statement provides that each medical specialty is identified by its Medicare Specialty Code, as defined by the Centers for Medicare and Medicaid Services (CMS). The commenter also recommends that the department add a new provision to §13.414(e) to require the market share for outpatient hospital services be calculated in the manner specified by the FTC and DOJ policy statement that bases the calculation on outpatient categories, as defined by CMS.

Agency Response: The department agrees that a clarifying revision to the definition of "common service" in §13.402(3) will result in a more informed application of §13.414(e)(2), for purposes of calculating an HCC's market share under §13.414.

The intent of the rule is that the term "common service" should be defined in terms of the health care service provided, not who is providing the service. The department has revised the definition of "common service" in §13.402(3) to include reference to "health care" in the introductory wording and to emphasize the nature of the health care service as a predominant factor in the definition as follows: "Common service—An identical or substantially similar health care service provided to patients by two or more independent HCC participants."

This clarification highlights the intent of the rule that a common service is defined in terms of what is provided, and it recognizes the potential overlap between a common service and who is providing it. This recognition is consistent with the recognition reflected in the joint final Policy Statement of the FTC and DOJ on antitrust enforcement policy regarding ACOs participating in the MSSP. The October 20, 2011, joint final Policy Statement includes an appendix explaining how to calculate the PSA shares of common services discussed in the Policy Statement. For example, an appendix footnote explains that primary care services, though categorized by differing specialty codes, are considered a single service for purposes of the statement because they represent substantially similar services.

This clarifying revision to §13.402(3) addresses the portion of the comment recommending the addition of the reference "within a medical specialty" at the end of §13.414(e)(2), and that inclusion of the recommended reference is, therefore, unnecessary.

Finally, consistent with its response to comment on §13.414(e)(3) of the rule, the department declines to make the change recommended for an additional paragraph in §13.414 to address calculation of market share for outpatient hospital services on the basis of outpatient categories as defined by CMS.

Comment: §13.414(e)(3) – Market share calculation. A commenter states that §13.414(e)(3) provides that the market share for inpatient hospital services be based on staffed beds by medical specialty for each common service area. The commenter states that the terms "medical specialty" and "common service area" are not defined, but points

out that the use of the phrase "major diagnostic category for inpatient services at a hospital" in §13.413(h)(2)(B) suggests that a hospital's market share would be determined based on the number of staffed beds in each of the 25 major diagnostic categories.

The commenter states that §13.414(e)(3) also provides that the determination of hospital market share be based on information reported by hospitals to the Texas Department of State Health Services (TDSHS). The commenter agrees that using major diagnostic categories makes sense for inpatient hospital services, and is generally consistent with how market share is calculated for inpatient services under the FTC and DOJ joint final Policy Statement. But the commenter notes that the final Policy Statement uses the number of discharges in a particular diagnostic category rather than the number of beds to make the calculation.

The commenter asserts that the primary source of hospital data, including information on the types of services provided by hospitals, is the Annual Survey of Hospitals, which collects information on the number of hospital-staffed beds but does not report information by major diagnostic categories. The commenter asserts that because hospitals report staffed beds by broad categories of services, such as general medical-surgical care, pediatric medical-surgical care, and obstetrics, rather than by diagnostic categories, it will not be possible to calculate the market share for inpatient hospital services based on the data reported to TDSHS on the hospital annual survey.

For these reasons, the commenter recommends that the department change §13.414(e)(3) to allow the calculation of inpatient hospital services to be based on the number of discharges for each of the applicable major diagnostic categories. While this

calculation is more complicated, the commenter states that it would be consistent with the approach taken by the federal antitrust agencies, and that there is a state data source for this information because most Texas hospitals are required to submit discharge data to the TDSHS through its Texas Health Care Collection, Division of Health Statistics.

Agency Response: The department appreciates the comment and its focus on alternative data types for calculation of market share under §13.414(e)(3). For the reasons set forth below, however, the department declines to make a change to the paragraph.

Section 13.414(e)(3) relies on a depository of publicly available and verifiable data that is sufficient to permit the department and the attorney general to determine whether market share for a submitting entity exceeds 35 percent. The section also relies on the number of staffed beds as a measure. The department's position is that §13.414(e)(3) provides a fundamental and meaningful basis on which to conduct an initial market share analysis. Historically, federal antitrust enforcers and the attorney general have utilized the same data specified in §13.414(e)(3) to perform necessary analysis in the hospital merger context.

In addition, §13.414(e)(3) reflects consideration and balancing between requiring submission of potentially more precise data with the additional expense associated with submission of more complicated, less accessible data for purposes of the §13.414(e)(3) calculation. The department emphasizes that the calculation of market share serves as only the initial step in determining whether the proposed HCC gives rise to antitrust concerns. Once the initial market share is calculated, the antitrust review process provides for a detailed appraisal of the potential anti-competitive effects of the proposed HCC, if

necessary. If an HCC applicant believes that the market share calculation is not a proper measure of the transaction's anticompetitive effects, it will have an opportunity during the antitrust review process to bring this to the attention of the department or the attorney general.

For these reasons, the department makes no change to §13.414(e)(3).

Comment: §13.415(a)(3) – Documents to be available for quality of care and financial examination. A commenter notes that §13.415(a)(3) describes the utilization management documents that an HCC must make available for the department's review, and asks if the provision implies that an HCC composed of physicians, ancillary service providers, and hospitals will have staff employed by the HCC performing utilization management services for all services rendered by HCC participants without the HCC holding a utilization review agent's license. The commenter states that exemption from URA licensing requirements would conflict with the URA Act and regulations. The commenter states that it is unable to find an exemption from URA Act compliance within Chapter 848 of the Insurance Code.

The commenter asserts that, other than like providers being able to provide utilization review with respect to services of similarly licensed providers, it would be unlawful for an HCC made up of both physicians and other provider types to perform utilization review without a URA's license or without delegating this function to a licensed URA.

Agency Response: The department clarifies that §13.415(a)(3) does not address certificate of registration requirements for a URA under Insurance Code Chapter 4201, concerning URAs. Insurance Code §848.108(c)(1)(G) authorizes an HCC to enter into a

delegation agreement with an entity licensed under Chapter 841, 842, or 883 if the delegation agreement assigns to the entity responsibility for a function regulated by Chapter 4201. Based on this statutory requirement, it is appropriate for an HCC to have and make available for department review utilization management documents as described in §13.415(a)(3). Actual performance of utilization review is subject to the licensing requirements under Insurance Code Chapter 4201.

Comment: §13.415 – Documents to be available for quality of care and financial examinations. Some commenters state their support for §13.415 and the extensive list of documents and information that an HCC must make available for review on request, as well as for the alignment of the disclosures for quality of care and financial examinations. The commenters contend that §13.415 appropriately ensures that the department has broad access to the information necessary to perform an adequate review of the HCC.

The commenters state specific support for §13.415(a)(4), which requires the HCC to maintain and provide complaints and appeals logs on department request, provided the department retains the detailed categories in §13.492(e) in the rule. The commenters assert that the department must have the ability to track and monitor the different types of complaints and appeals that an HCC receives.

A commenter states specific support for §13.415(a)(6), which requires the HCC to supply the department with the network configuration information necessary for the department to discern the HCC's capability to provide the health care services it has promised to deliver.

The commenters also state support for §13.415(a)(7)–(9), which require the HCC to provide to the department executed contracts during the qualifying examination, contending that making this information available to the department will provide the department with a basis to review whether an operating HCC must obtain a certificate as an insurer.

The commenters also note that §13.415(b) includes a five-year document retention requirement. The commenters state support for the retention policy and suggest that the department clarify the requirement by specifying that the documents listed in the section must be maintained for at least five years from the anniversary date the documents were created.

Agency Response: The department appreciates the supportive comments. The department agrees that the recommendation concerning §13.415(b) adds clarification to the document retention requirement and has changed §13.415(b) to clarify that the documents must be maintained for at least five years from the anniversary date of the applicable document's creation.

Comment: §13.415 – Documents to be available for quality of care and financial examination, and **§13.424** – Certificate of authority renewal requirements. A commenter states that the title of §13.415 does not reference renewal applications, which are addressed in §13.424, but states that §13.415(a)(2)–(4), (12), (16), and (17) reference information that must be submitted with renewal applications that are not found in §13.413, concerning content of the application, or §13.424.

The commenter recommends that the department clarify which documents must be available at the HCC's office or provided to TDI on request during examinations, and which documents an HCC must submit as part of a complete renewal application. The commenter further suggests that the document requirements for the renewal application be listed in §13.413 or §13.424 and included in Form 492, Original/Renewal Application for Certificate of Authority.

The commenter recommends that the department change §13.415 to require HCCs to make the quality measure data, documentation of data validation, and supporting documents available during examinations in order to hold HCCs accountable for improving quality of care and better coordinating care by measuring and reporting on a core set of quality measures defined by the department. The commenter asserts that this data is essential to the department in order to review and evaluate at renewal the HCC's quality of care, promotion of evidence-based medicine, promotion of patient engagement, and coordination of care as is required under Insurance Code §848.060(b)(2)(D) and (E).

The commenter states that the department should add a requirement to submit these measures for evaluation at renewal and recommends that either §13.415 or §13.482 could establish the standard set of HCC quality measures by referencing the Medicare ACO regulation or a subset of it, or the core set of measures. The commenter also states that §13.415 should specifically require HCCs to have for examinations and submit on renewal the results of the CAHPS survey and other quality measures required under §13.482(b)(1).

The commenter also recommends the use of a standard patient experience of care survey like CAHPS, as opposed to a patient "satisfaction survey," referenced in §13.415(a)(16).

Agency Response: *Available documents versus submissions with an application.* The department clarifies that the references to renewal applications in §13.415 do not constitute additional application submission requirements for a renewal application. Instead, the references specify those documents that a certified HCC must provide to the department on request and have available for review in the HCC's office, but that an uncertified applicant would not yet have available, such as program evaluations.

Based on the comment, the department agrees that this language may cause confusion. The department has changed the sections to delete references to renewal applications and substitute references to certified HCCs in §13.415(a)(2)–(4), (12), (13), (16), and (17). Because this change should eliminate confusion concerning documents that must be available on request and for review, as opposed to documents that are required elements of an application, no additional changes are necessary.

Documents supporting quality measures data. The department clarifies that §13.415(a)(2) requires an HCC to provide to the department on request and make available for review at the HCC's office the quality measures data, documentation of data validation, and supporting documents referenced by the commenter. Because the comment indicates that the proposed text in §13.415(a)(2) may cause confusion as to the scope of the provision and what is encompassed by the term "program evaluations," the

department is changing §13.415(a)(2) to clarify this point. Adopted §13.415(a)(2) reads as follows:

"(2) quality improvement: program description and work plan as required by §13.481 of this title (relating to Quality Improvement Structure for HCCs); and, to support requirements under §13.482 of this title (relating to Quality Assurance and Quality Improvement) for certified HCCs, program evaluations and meeting minutes for committees and subcommittees."

Uniform standards for quality measures. Because the department is not adopting uniform standards for quality measures in this rule for the reasons previously explained, the department has determined that it is not necessary to make additional changes to §13.415 or §13.482 to reflect such a requirement.

Patient care surveys. The department disagrees that only standard surveys such as CAHPS are appropriate measures of patient experience of care. Section 13.415(a)(16) reflects the department's decision to permit additional flexibility in how an HCC may capture this information. This flexibility may be particularly appropriate in the case of specialized HCCs. The department notes that under §13.482, an HCC must establish, implement, and administer a QA and QI program that includes appropriate evaluation tools applicable to the services provided by the HCC, including CAHPS surveys. As such, an HCC must also use CAHPS survey information and make it available under §13.415(a)(16). No additional change to the section is necessary.

Comment: Division 3. Some commenters state support for the framework established in Division 3 with regard to examinations and other regulatory requirements imposed on

HCCs after issuance of a certificate of authority. The commenters state that the division's requirements make clear that the department has undertaken its role as regulator of the new HCC entities with the diligence necessary to protect patients, protect participating physicians and providers, and ensure that HCCs are able to fulfill the obligations they undertake. The commenters also state that the provisions in Division 3 offer proof of ongoing state oversight, which is critical to protect against undue federal scrutiny with regard to antitrust concerns.

Agency Response: The department appreciates the supportive comment.

Comment: §13.411 – Filing fee, and **§13.421(c)** – Fee for expenses. A commenter states that §13.421(c) requires an HCC to pay an annual assessment based on the expenses incurred by the department to administer the regulatory requirements under the law. The commenter agrees that the department must recover its costs associated with the regulatory process, but states that the amount of the assessment each year is uncertain and could be a significant amount if only a few organizations are certified as HCCs. The commenter recommends that the department change §13.421(c) to limit the responsibility of organizations to pay annual assessments to an amount such as $5,000 per year.

A second commenter states appreciation for the department's decision to apply assessment obligations in 2014 to allow time for a larger number of HCCs to share in the costs. However, the commenter states concern regarding the potential assessment amount. The commenter agrees with the approach of increasing the filing fee associated with licensure under §13.411 because the department could spend time and resources reviewing applications that fail to ultimately obtain HCC certification. The commenter

states that a higher application fee would more fairly share the costs of administrative oversight.

Agency Response: The department disagrees with the recommendation to set a cap on assessment amounts in §13.421. Insurance Code §848.152(d) specifically requires the commissioner to set fees and assessments under this section in an amount sufficient to pay the reasonable expenses of the department and attorney general in administering Chapter 848, including the direct and indirect expenses incurred in examining and reviewing HCCs. The department has mitigated potential assessment expenses by using a $10,000 nonrefundable filing fee for an original application. The department agrees that assessment amounts could be more significant if there are few HCC applicants, but asserts that this is the necessary result under Insurance Code §848.152(d).

The department agrees that a higher initial application filing fee is appropriate because it is true that an application could require the expenditure of significant money and resources without resulting in certification. The department's opinion is that the initial $10,000 fee for an original application and the subsequent $5,000 fee for a renewal application are appropriate based on the department's experience in reviewing other complex applications. For these reasons, the department makes no changes to §13.411 or §13.421.

Comment: §13.422 – Filing requirements that apply after issuance of a certificate of authority. Some commenters state that §13.422 sets forth the list of documents that the department will require the HCC to file with the commissioner after certification.

In regard to filings that require approval, the commenters state that §13.422(c) mandates approval of dividends issued by the HCC that reach a certain threshold, presumably to provide a regulatory mechanism that, in part, serves to protect the financial stability of an HCC. The commenters assert that in the insurance market, many Texas carriers do not own the trademarks or service marks they use. The commenter explains that, as a result, the Texas subsidiary pays a fee to the carrier's holding company for the use of that intellectual property. The commenter asserts that this expense for the use of intellectual property serves as a method to transfer funds to a parent without triggering a dividend that the department must approve.

The commenter suggests that the department regulate this method of transferring funds in the HCC rules by amending the proposed rules to provide that any agreements to pay for the use of intellectual property, such as trademarks or service marks, be subject to the same thresholds and approvals as dividends.

Agency Response: The department disagrees with the commenter's recommended change because the rule already requires an HCC to provide sufficient information concerning contracts between an HCC and an affiliate for the department to monitor for solvency purposes.

Section 13.413(c)(7) requires, as part of the application, the submission of separate organizational charts or lists that meet certain requirements. The charts must clearly identify the contractual relationships involved in the applicant's health care delivery system and between the applicant and any affiliates, and a list of contracts to provide services between the applicant and affiliates. The information must clearly identify any relationship

between the HCC and any affiliate or other organization if a common individual or entity directly or indirectly controls 10 percent or more of both the HCC and the affiliate or other organization. Further, §13.422(c)(2)(H) specifies as a required filing for approval any original or renewal service contracts and management agreements, the terms of which must comply with Insurance Code §823.101 as if the HCC were an insurer.

For these reasons, and based on the department's experience in administering comparable provisions, the department disagrees that the recommended change is necessary and declines to change the rule.

Comment: §13.423 – Service area change applications. A commenter states support for §13.423, which requires that a proposed expansion or addition of a service area will require an HCC to file certain documents and obtain affirmative approval by the department before the expansion or addition may occur. The commenter also states support for the level of detail and content of the application to expand or add a service area, stating that including these requirements will ensure that the HCC maintains its ability to adequately arrange for or provide health care services in the applicable service areas, as well as to assess the proposal for antitrust implications.

Agency Response: The department appreciates the supportive comment.

Comment: §13.429 – HCCs subject to the Insurance Code Chapters 541, 542, and 547 and related rules. Some commenters state their support for §13.429, which provides that HCCs must comply with certain chapters of the Insurance Code. Although this is a requirement of SB 7, the commenters support the rule's emphasizing that the law and

rules will apply, to ensure that HCCs are cognizant of the numerous laws affecting their formation and operation beyond Insurance Code Chapter 848.

Agency Response: The department appreciates the supportive comments.

Comment: §13.431 and 13.432 – Financial Requirements. Some commenters state that Division 4 contains the basic financial requirements for HCCs and state strong agreement that working capital and reserves are necessary to protect patients and providers from the adverse consequences of an HCC's insolvency. A commenter states concern that insolvencies may occur despite the requirements in Division 4 absent additional changes. With those changes, the commenter asserts that provisions set forth in Division 4, in conjunction with the annual review requirements, are reasonable.

The commenters state that §13.431(a) establishes a ratio of current assets to current liabilities of 1.25:1 and working capital requirements based on the composition of an HCC, so that there is one set of requirements for HCCs consisting of physicians and one or more facilities and another set of requirements for all other HCCs. The commenter states support for these strong solvency requirements to protect the public and the physicians who participate in HCCs. To monitor compliance with this standard, the commenter suggests that the department consider either modifying §13.424(b) to allow for audited financial statements to accompany renewal applications as necessary or taking some additional step to ensure that current assets and liabilities are correctly stated, such as requiring audited statements.

The commenters also state support for §13.431(b), noting that reserve requirements are prudent to ensure that providers who are not part of the HCC do not face financial losses due to risk voluntarily taken by the HCC.

The commenters state support for the §13.431(c) requirement that HMOs and insurers hold reserves when they enter into pre-payment or capitation payment arrangements that transfer some of their risk to the HCC. The commenters state support for the concept that HMOs and insurers are required to ensure that those reserves remain available to pay for services of the HCC and other providers who provide services on behalf of the HCC, and also for the requirement that the reserves should not be encumbered or limited in ways that could prevent their availability for that purpose.

Another commenter states that §13.431(c) contains a new reserve obligation on HMOs or insurers that contract with HCCs that may be duplicative of existing financial reserve obligations for HMOs and insurers. An additional commenter requests that the department delete the requirement in §13.431(c) because the commenter asserts that HMO and insurance company reserve requirements are already substantial. The commenter instead asks that the department revise §13.431(c) to state that the dedicated reserves due to an HCC risk contract be maintained within existing and current reserves but not in addition to such reserves.

Regarding §13.431(d), some commenters state that the subsection clarifies the rule's working capital requirements by listing the HCC's current assets that are permitted to count towards the working capital requirements. Commenters state support for the

requirement that reported accounts receivable always be reduced to net of all allowances as a means to ensure the HCC is solvent and able to meet obligations.

Commenters also state support for the fiduciary responsibility requirements proposed in §13.432 on directors, members of committees, officers, and representatives of HCCs who are charged with the duty of handling or investing the HCC's funds because the provisions should help to prevent private enrichment at the expense of HCC solvency.

Agency Response: The department appreciates the statements of support. The department also notes that an HCC's financial statements must comply with Insurance Code §848.060(b)(2)(A), which requires certification by an independent certified public accountant. Based on the department's experience in addressing solvency protection issues in the past, the department's position is that solvency requirements in §13.431 are strong enough without the need for additional and expensive audit requirements. The department declines to make this change.

The department disagrees that the HCC reserve requirements are duplicative. The reserve requirements mandate contingency reserving in lieu of regular reserving to provide for stronger solvency protection than is available under regular reserving. This stronger protection is appropriate based on the department's experience in addressing solvency failures in the past and provides a basis for transition of health care consumers to new providers.

Comment: §13.441(a) – HCC contract arrangements. A commenter states that §13.441(a) provides that an HCC's contracts with providers may not "impede" application

of provisions of Insurance Code Chapters 843 and 1301 and asks for clarification of what the section means and why it is required.

A second commenter also states concern with §13.441(a) because it requires that an HCC's contracts with participating providers must meet the requirements imposed on HMOs and preferred provider organizations concerning relations with physicians or other health care providers. The commenter asserts that Insurance Code Chapter 848 creates a number of requirements that an HCC must comply with in its relationships with participating physicians and other health care providers but does not require an HCC to meet the referenced provisions in Insurance Code Chapters 843 and 1301. The commenter also states that Insurance Code §848.004(b) provides that an HCC must comply with specific chapters of the Insurance Code but does not include Insurance Code Chapter 843 or 1301, except to the extent that an HCC is accepting prepaid or insurance risk and would be subject to regulation as an HMO or insurance company. The commenter states that if the Texas Legislature had intended for HCCs to be subject to certain provisions of Chapter 843 or 1301, those chapters would have been listed in Insurance Code §848.004(b). The commenter asserts that the department lacks the statutory authority to impose these requirements on HCCs and asks that the department delete §13.441(a).

Agency Response: The department clarifies that §13.441(a) underscores the relationship between requirements in Insurance Code Chapters 843 and 1301, and HCC contracts with physicians and health care providers. The requirements of those chapters apply to a plan regulated under the chapters regardless of whether the HMO or insurer provides access to

services under a contract with an HCC. This is consistent with Insurance Code §843.344 and §1301.109, which specify applicability of provisions of those chapters to entities with whom HMOs and insurers contract.

The department disagrees that it lacks statutory authority to require an HCC to comply with Insurance Code §843.344 and §1301.109 due to the lack of specific reference to those sections in Insurance Code §848.004(b). This is because the plain language of the sections makes the additional inclusion of the sections in Insurance Code §848.004(b) unnecessary. However, the department does clarify that §13.441(a) applies only to services provided under a contract between an HCC and an HMO or insurer making services available under a plan regulated under Insurance Code Chapter 843 or 1301.

The department declines to delete §13.441(a).

Comment: §13.441(c) – HCC contract arrangements. Some commenters state that §13.441(c) prohibits an HCC with a dominant provider from: (i) requiring a private payor to contract exclusively with the HCC; or (ii) otherwise restricting a private payor's ability to contract or deal with other HCCs, networks, physicians, or health care providers. The commenters also note that in defining a "dominant provider," the section provides that if an HCC participant's market share exceeds 50 percent in a PSA on any service that no other HCC participant provides to patients in that PSA, the participant furnishing the service is a dominant provider.

The commenters note that this requirement is similar to that regarding dominant participants under the FTC or DOJ's *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.*

Several commenters assert that the 50 percent threshold in §13.441(c) for determining a dominant provider is high, and some commenters assert that the subsection should not be construed to permit those providers below the threshold to require exclusive contracts with a private payor or otherwise affect contracts or deals with other networks.

The commenters state that per the FTC and DOJ Policy Statement, the availability of the PSA safety zone for ACOs in the MSSP differs in some cases, depending on whether an ACO participant is exclusive or nonexclusive to the ACO. Commenters add that any hospital or ambulatory surgical center participating in an ACO must be nonexclusive to fall within the federal ACO safety zone, regardless of its PSA share. The commenters state that the federal safety zone for physicians, regardless of the physician's status as a hospital employee, does not differ based on whether the physicians are exclusive or nonexclusive to the ACO unless the physician falls within the rural exception or dominant participant limitation described in the Policy Statement.

The commenters note that recent FTC and DOJ action, as well as that of the attorney general, has stopped efforts by hospital systems in Houston and Wichita Falls from adversely affecting contracting by insurers with other systems in their market area. The commenters also state that in *Jefferson Parish Hospital Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984), the standard for a health care antitrust monopoly was set at one-third, which the commenter asserts to be supportable and rational. The commenters also state that research indicates that employers who are more profitable pay higher insurance premiums even when there are as many as ten major carriers in a market, and that this exercise of market power is most pronounced in markets with six or fewer carriers.

One commenter asks that the department add a new provision to §13.441(c) to restrict an HCC with a dominant provider from contracting with, or otherwise allowing to join the HCC, any further participants who practice in the same practice area, including general, specialty, or subspecialty areas, as the dominant provider.

Agency Response: The department agrees that §13.441(c) does not authorize an HCC that does not have a dominant provider in a PSA to require a private payor to contract exclusively with the HCC or otherwise restrict the private payor's ability to contract with or deal with other HCCs, networks, physicians, or health care providers. The department disagrees that the 50 percent threshold in §13.441(c) for determining when a provider is dominant is too high or that a new provision automatically prohibiting an HCC with a dominant provider from contracting with or obtaining the participant services of additional physicians or health care providers in the same practice area is necessary. Section 13.416(d) makes clear that the commissioner may impose restrictions on an applicant's certificate of authority as necessary to preserve competition. This permits the department to tailor its approach to antitrust implications that are unique to a particular service area or practice area in a way that is most likely to maximize the pro-competitive effects of the HCC and outweigh the anticompetitive effects of any increase in market power. The department declines to change the dominant provider threshold in §13.441(c) or to add a new automatic prohibition on an HCC with a dominant provider.

Comment: Division 6 – HCC contract arrangements, and **§13.455** – Change of control with increased market share. Some commenters state that Division 6 contains requirements for obtaining commissioner approval of a proposed acquisition of control of

an HCC and state support for those provisions that are similar to the current requirements for holding companies under Insurance Code Chapter 823.

The commenters assert that §13.455 refers to an increase in an HCC's "market share" as a potential triggering event for the HCC to file an application for renewal, and they state support for this requirement. The commenters note the use of the "market share" terminology in this section refers to §13.414, which describes the markets for physician services, outpatient services, and inpatient services. The commenters state that three additional market share definitions may aid the department's regulatory efforts: (i) the market for physician services, referred to in Insurance Code §848.057(a)(5); (ii) the HCC's geographic market, referred to in Insurance Code §848.057(a)(5)(B); and (iii) the HCC's "market power," referred to in Insurance Code §848.057(a)(6).

Agency Response: The department appreciates the supportive comments and agrees that Insurance Code §848.057, including each of the provisions cited by the commenters, establishes the threshold eligibility requirements for approval of an HCC's application for approval of a certificate of authority. Further, the department notes that these requirements are incorporated into any renewal application pursuant to Insurance Code §848.060(c).

The department's position is that the market share calculation methodology in §13.414(e) considers each of the aspects of market share emphasized by the commenters. This is because the calculation considers participant market shares in the aggregate within participant PSAs by class of service. Further, §13.414(f) provides for

calculation of market share through reference to the HCC's PSA for a health care specialty if calculation on that basis provides the more accurate measure of competition.

Comment: §13.461 – Commissioner's authority to require additional information. Some commenters state support for the statement in §13.461 of the commissioner's authority to require additional information from the HCC or any participant in the HCC as reasonably necessary to make a determination required by Insurance Code Chapter 848, the attendant rules, and other insurance laws and regulations applicable to HCCs.

The commenters also state their support for the list of additional information that the commissioner may require under §13.461(b). The commenters state opposition to the §13.461(c)(9) statement that the commissioner may require the HCC or any participant in the HCC to provide "questionnaires submitted by participants to applicable professional associations in connection with annual surveys of association members, and to any other association, accreditation agency, or government agency, in connection with any annual or other periodic survey of such participant."

The commenters seek clarification regarding the relevance of professional association annual surveys for HCC regulation purposes, and an appropriate narrowing of this provision to exclude all surveys that are not directly related to the department's determination of the HCC's compliance with applicable laws and regulations.

Further, the commenters state opposition to §13.461(c)(9) due to the burden this requirement places on HCCs and HCC participants when read in conjunction with the requirement in §13.461 that the submitted questionnaires be retained by the HCC or HCC participant for a minimum of five years. The commenters note that it is not a common

practice for physicians or other health care providers to retain questionnaires submitted to professional associations for any length of time. Thus, the commenters assert that the retention requirement imposes a significant new administrative burden on HCC participants with little discernible benefit to the department's HCC review. Additionally, the commenters assert that many questionnaires are now submitted electronically and retention of the surveys in conformity with the rule may be impractical, if not impossible, under some circumstances.

The commenters also state that §13.461(c)(9) will unnecessarily chill participation in professional surveys without any compelling corresponding benefit to the department's review of HCCs.

Agency Response: The department appreciates the supportive comments. Concerning §13.461(c)(9), the department disagrees that the requirement to produce the participant questionnaires is overly burdensome, unlikely to benefit the department's HCC review, or likely to produce a chilling effect on survey participation. Section 13.461(b) provides that an HCC or HCC participant is not required to create the items in subsection (c) unless and except as required by the commissioner. The department clarifies that submitting responses to an electronic survey for which the participant does not and will not have electronic or physical possession of a document containing all survey responses will not trigger the maintenance requirement. The retention requirement applies only after the HCC creates a document. Section 13.461(c) exemplifies the information that the commissioner could determine to be reasonably necessary to make any determination required by law.

These types of questionnaires are beneficial to the department's oversight of HCCs because they might provide information to substantiate or contradict known information concerning QA, QI, contract, and marketing activities that is relevant to the physician market, the geographic market, and the HCC and participant market share. The information could affect the commissioner's and the attorney general's determination of whether the pro-competitive benefits of the applicant's proposed HCC are likely to substantially outweigh the anticompetitive effects of any increase in market power. The department also has no reason to believe that a participant will be unwilling to provide survey information or responses to associations, accreditation agencies, or government agencies if the participant knows that the department might request the information, and the commenter has provided no support for this proposition.

The department declines to change §13.461(c)(9).

Comment: §13.472(1) – Requirements for certain delegation contracts. Some commenters state that under §13.472, an HCC that contracts with a delegated entity must submit a monitoring plan, conduct an on-site or desk audit of the delegate, and take prompt action to correct any failure by the delegate. The commenters suggest that the department, as part of the submission of a monitoring plan, mandate the HCC provide the name of the delegate, the delegate's primary business address, and contact information of a person at the delegated entity who is responsible for communicating with the department, should the need arise.

Agency Response: The department disagrees that it is necessary to add these contact information requirements to §13.472 based on the department's experience concerning

similar monitoring plans. In the department's experience, there have not been difficulties to the department's oversight and regulation of monitoring plan requirements due to a lack of contact information in the monitoring plan, so this requirement does not appear to be necessary at this time. The department, therefore, declines to make this change.

Comment: §13.473 – Organization of an HCC. Some commenters state that §13.473 describes the essential governing, operating, contracting, and other requirements that govern an HCC's eligibility to receive a certificate of authority from the department and suggests moving the section nearer to §13.413, concerning the required contents of the application, due to the fundamental nature of these criteria as prerequisites for certification.

The commenters also recommend that the governing body composition, referenced in Insurance Code Chapter 848, be expressed in the regulatory language itself. The commenters assert that the composition of the governing board is a key protection of Insurance Code Chapter 848. The commenters state that an HCC comprised solely of physicians may have a physician-only governing body, while a "mixed" provider HCC must have a governing body with 50 percent of its members selected by physicians participating in the HCC, with an additional physician selected by nonphysician participants.

Another commenter agrees, stating that anesthesiologists supported the Legislature's inclusion of requirements in Insurance Code §848.052 for material physician participation in the governance of all HCCs and asserting that hospital-based anesthesiologists have a unique perspective on how health care organizations led by hospitals and for-profit health care organizations function.

The commenter further states that the active participation of hospital-based physicians will be critical to the success of HCCs and hospital-based physicians should have a voice in the management of these organizations. The commenter, therefore, recommends that the department include a requirement in §13.473 that at least one of the physician members of an HCC's governing board be a hospital-based physician, as set out in Insurance Code §848.052(d-1).

Agency Response: The department appreciates the supportive comments and clarifies that an HCC's board membership under Insurance Code §848.052 consists of an odd number of members so that there is no "50 percent" of the board. Insurance Code §848.052 requires that if the participants in an HCC are both physicians and other health care providers, the board of directors must consist of: (i) an even number of members who are individual physicians, selected by physicians who participate in the HCC; (ii) a number of members equal to the number of members under Subdivision (1) who represent health care providers, one of whom is an individual physician, selected by health care providers who participate in the HCC; and (iii) one individual member with business expertise, selected by unanimous vote of the members described by Subdivisions (1) and (2).

The department disagrees that §13.473 needs to be moved to emphasize the crucial nature of HCC organization requirements. The department has structured Chapter 13, Subchapter E, so that Division 2 includes the sections most pertinent to the actual application for a certificate of authority, including §13.413. This arrangement does not denote any lesser importance for the requirements located in any other division, including

§13.473. The department considers all of the requirements of the subchapter to be important to the compliant operation of an HCC both during and after the HCC's formation. The department declines to move the contents of §13.473.

The department's position is that the plain language of Insurance Code §848.052 is sufficient to administer requirements concerning the composition of an HCC's governing board. However, to facilitate compliance with the new statutory requirements and based on this comment, the department is changing §13.473(a) to clarify that the governing body must comply with the requirements described in Insurance Code §848.052 instead of simply referring to the governing body described in that section. This language should suffice to remind an applicant that the statute includes specific requirements concerning the governing board without the need to restate those statutory requirements.

Comment: §13.473(a) – Organization of an HCC. A commenter states support for §13.473(a) and the requirement that the governing body has the ultimate responsibility for developing, approving, implementing, and enforcing administrative, operational, personnel, and patient care policies and procedures related to the operation of an HCC. The commenter expresses concern that applicants may attempt to limit the authority of the HCC governing board through "reserved powers." The commenter states that joint ventures are not an unusual undertaking in the health care marketplace. Per the commenter, it is not unusual for a hospital partner to reserve certain powers to itself over capital investment and important financial matters in the joint venture or partnership documents. The commenter asserts that §13.473(a) ensures that the governing board

must be empowered to make decisions that certain hospital partners attempt to reserve to their board.

Agency Response: The department appreciates the supportive comment. Insurance Code §848.052(a) specifies that an HCC must be governed by a board of directors, and Insurance Code §848.052(i) prohibits an HCC's organizational documents from conflicting with the requirements of Insurance Code Chapter 848. Section 13.473(a) clarifies the department's interpretation of Chapter 848's governance requirements. An HCC's organizational documents may not conflict with these requirements, including through the use of reserved powers.

Comment: §13.473(b) – Organization of an HCC. Some commenters state support for §13.473(b), stating that an HCC's clinical director must be a physician licensed and residing in Texas, be available to resolve complaints, demonstrate active involvement in quality management, and be subject to credentialing.

Agency Response: The department appreciates the supportive comments concerning the clinical director requirements in §13.473(b). However, the department clarifies that §13.473(b) does not require that the clinical director be a physician, and the department is not changing this requirement for the reasons explained previously in the comment and response section of this adoption order.

Comment: §13.473(c) – Organization of an HCC. A commenter states concern with §13.473(c), which establishes network adequacy requirements for HCCs. While an HCC should have a sufficient number of participating providers to meet the medical needs of patients who will receive services under contracts the HCC has entered into with public or

private payors, the commenter asserts that the range of services provided by an HCC may vary significantly, and the network adequacy standards should be consistent with the scope of services provided by a particular HCC. For example, the commenter asserts that §13.473(c)(1)(E) would require an HCC to provide emergency care on a 24-hour, seven-days a week basis even if the HCC did not include a hospital and none of the participating providers offered emergency services. The commenter states that many of the other requirements imposed by this provision may not be appropriate for a particular HCC and recommends that the department modify §13.473(c) to state the network adequacy requirements in more general terms or clarify that the different requirements be made conditional or as applicable to an HCC.

Agency Response: The department clarifies that the requirements in §13.473(c) apply on an "as applicable" basis. Section 13.473(c)(1) requires the HCC to provide a delivery network that meets the requirements of the paragraph "as applicable to the services that the HCC has contracted or will contract to provide." It is the department's position that the subsection already tailors the requirements to accommodate a specialty HCC.

Using the requirement in §13.473(c)(1)(E) as an example, the department would consider whether the type of service offered by the HCC is consistent with the need for an HCC to ensure that it has an adequate number of participants available and accessible to patients 24 hours a day, seven days a week in considering an HCC's compliance with the provision. For instance, if the HCC will provide diabetes care, depending on the scope of the HCC, it may or may not need a hospital and emergency services. If the HCC will provide physical therapy, there is little need for a hospital or emergency services. If the

HCC will provide primary care services or cardiac services, it will need a hospital and all associated services.

However, to enhance rule clarity, the department has made a change to §13.473(c)(1) to emphasize that an HCC is required to demonstrate is its ability to provide continuity, accessibility, availability, and quality of services that it has contracted or will contract to provide within its service area, including items in subparagraphs (A) through (I), as applicable.

Comment: §13.474(d) – Requirements for HMO or insurer delegation of functions to HCCs. A commenter notes that §13.474(d) requires a delegation agreement between an HMO or insurer and an HCC to mandate that the HMO or insurer disclose in all provider listings distributed to insureds or enrollees those providers participating in the HCC. The commenter requests that the department revise this subsection to reflect that these listings are only mandated with respect to providers whose practices and office locations are within the HMO's or insurer's approved service area, as applicable; and providers who have open panels and are accepting new patients.

Agency Response: The department agrees that it is reasonable to restrict the provider listing requirement in §13.474(d) to those providers whose practices and office locations are within the HMO's or insurer's approved service area, as applicable. The department has, therefore, changed §13.474(d) to incorporate this limitation on the requirement. Adopted §13.474(d) provides that a delegation agreement between an HMO or insurer and an HCC must mandate that the HMO or insurer disclose in all provider listings distributed

to insureds or enrollees those providers participating in the HCC within the HMO's or insurer's approved service area.

With respect to limiting the listing requirement to providers who have open panels and are accepting new patients, it is the department's position that existing provider listing requirements already address provider listing content requirements for specific plans, and additional requirements in §13.474(d) are unnecessary. See, for example, Insurance Code §843.2015 and §1301.1591 concerning information that an HMO and an insurer offering a preferred provider benefit plan must list concerning physicians and providers if the HMO or insurer maintains an internet website. The department, therefore, declines to make this requested change.

Comment: §13.481 – QI Structure for HCCs. Some commenters state support for the §13.481(b) requirement that the governing body is ultimately responsible for the QI program and agree that it is appropriate for the governing body to have ultimate responsibility for the HCC's QI program due to the strong physician composition of the HCC's governing body mandated by Insurance Code §848.052. The commenters assert that the physician members of the governing body possess the necessary education, training, and experience to approve the QI program and plan and to assess the QI program's performance. For the same reason, the commenters support the governing body's appointment of the QI committee in §13.481(b)(1).

However, the commenters also state support for the express inclusion of the physician clinical director on the QI committee, asserting that to be actively involved in

quality management activities as required by §13.473, the clinical director must be part of this QI committee.

The commenters also state support for the requirement in §13.481(b)(1) that clarifies that the health care provider members of the committee must be individual health care providers in lieu of corporate entities, and the department position that "individual health care providers" are necessary members of the QI committee only where applicable, so that a physician-only HCC would not be required to name a nonphysician member to the committee.

The commenters recommend that the department strengthen §13.481(c)(1) by requiring that the QIC subcommittee include practicing physicians because, as currently drafted, the subcommittees are permitted, but not required, to include practicing physicians, individual health care providers, and patients from the service area. Additionally, the commenters recommend that the department modify §13.841(c)(1) to acknowledge that some HCCs may be composed solely of physicians, as permitted by Insurance Code §848.001(2)(C)(i).

The commenters assert that these changes would ensure that practicing physicians are always a part of the QI improvement process, even if those activities are delegated by the QI committee. Given the clinical nature of QI activities, the commenters assert that it is imperative that physicians have active involvement in and oversight over all QI activities.

Agency Response: The department appreciates the supportive comments and agrees that inclusion of the clinical director in the QIC under §13.481(b)(1) is consistent with the requirement for the clinical director to be actively involved in quality management activities

under §13.473. However, the department clarifies that §13.473(b) does not require that the clinical director be a physician, and the department declines to change this requirement for the reasons explained previously in the comment and response section of this adoption order.

The department also agrees that nonphysician participation in an HCC's QIC would not be required for a physician-only HCC. However, the department disagrees that §13.481(c)(1) should be changed to require the inclusion of practicing physicians and, as applicable, individual health care providers on QI subcommittees. Subcommittees generally focus on discrete functions that may be less appropriate for mandatory direct physician participation. For example, a subcommittee could address customer service issues. The department's position is that the oversight of the QIC, as required under §13.481(c)(1)(B), in conjunction with collaboration with other committees as required under §13.481(c)(1)(B), sufficiently addresses physician participation. The department, therefore, declines to make this change.

Comment: Division 9 – Quality and cost of health care services. A commenter states that future physician participation in HCCs has been enhanced by the Legislature's decision to include in Insurance Code §848.053(d) a requirement that an HCC's compensation advisory committee and board of directors may not use or consider a government payor's payment rates in setting charges or fees for health care services provided by a physician or health care provider who participates in an HCC, except in certain limited circumstances. The commenter recommends that the department include this statutory language in Division 9.

Agency Response: The department's position is that the plain language of Insurance Code §848.053(d) is sufficient to administer and enforce the requirement. Because the department finds restatement of the requirement to be unnecessary, the department declines to change the rule as requested.

Comment: §13.482(a) – Definition of "Evidence-Based Medicine." Some commenters state that §13.482(a) requires the HCC to establish, implement, and administer a continuous QA and QI program that includes defined policies and processes to be used to promote evidence-based medicine and best practices, but note that the department does not define "evidence-based medicine" in the rules.

To clarify the rule, the commenters recommend that the department include the following definition of "evidence-based medicine" in §13.402: "Evidence-based medicine means the use of current best quality medical evidence formulated from credible clinical studies, including peer-reviewed medical literature, and treatment and practice guidelines in making decisions about the care of individual patients."

Agency Response: The department disagrees that it is necessary to define "evidence-based medicine" to provide guidance concerning the department's expectations. In administering comparable requirements concerning evidence-based medicine, the department's experience is that the term is commonly understood in general terms in the health care market. Further, it is the department's intent to leave some flexibility in the use of the term to accommodate the possibility that a specialty HCC would have difficulty in meeting more rigidly defined requirements concerning evidence-based medicine, and defining the term in more specific terms in the manner recommended by the commenter

would not be consistent with that intent. The department, therefore, declines to change the section to define the term.

Comment: §13.482(a) – QI structure for HCCs. A commenter states that §13.482(a) does not mention patient safety or the reduction of potentially preventable events as components of the mandatory QA and QI program, although those components reflect goals that are incorporated into Insurance Code Chapter 848. The commenter recommends that the department expressly incorporate patient safety and the reduction of potentially preventable events into §13.482(a).

Agency Response: The department's position is that the broad requirement for an HCC to establish, implement, and administer a continuous QA and QI program that includes defined policies and processes to promote evidence-based medicine and best practices already encompasses policies and processes to address patient safety and reduce potentially preventable events.

Further, the department's position is that this requirement implements and is in addition to specific statutory requirements. Insurance Code §848.057(a)(2)(A)(ii) and (iii) requires an applicant to satisfy the commissioner that it is willing and able to ensure health care service provision in a manner that promotes patient safety and reduces the occurrence of potentially preventable events. Also, Insurance Code §848.106 requires the HCC to establish QI policies using standards relating to the development, implementation, monitoring, and evaluation of evidence-based best practices and other processes to improve the quality and control the cost of health care services provided by participating physicians and health care providers, including practices or processes to reduce the

occurrence of potentially preventable events. For this reason, the department disagrees that a change to §13.482 is necessary and declines to make the change.

Comment: §13.482(b) – QA and QI. A commenter states that §13.482(b)(1)(B) and (C) references Agency for Healthcare Research and Quality (AHRQ) standards, and National Quality Forum (NQF) standards, respectively, among the practice evaluation tools that a QA and QI program must include as appropriate. However, the commenter states that NQF endorses quality measures, but AHRQ does not. The commenter also says that AHRQ has a database of quality measures, but they are not "AHRQ standards." The commenter, therefore, questions the meaning of the requirement in §13.482(b)(1)(B) and recommends that the department change §13.482(b)(1)(C) to "National Quality Forum endorsed standards."

Agency Response: The department clarifies that §13.482(b)(1)(B) references all of the measures within the AHRQ database of measures, including but not limited to the measures created by AHRQ. The department agrees that it is more accurate to state that National Quality Forum endorses measures and is, therefore, changing §13.482(b)(1)(C) to reference "National Quality Forum-endorsed standards."

Comment: §13.482(c)(1) – QA and QI. A commenter states support for the requirement in §13.482(c)(1) that HCCs have a process in place to evaluate the health needs of their enrolled populations. However, the commenter suggests the department require that the evaluation occur at least annually, include considerations of diversity in the HCC's patient population, and be used by the HCC to create a plan to address the needs of its population. The commenter further states that one way to help ensure network adequacy

is to require the HCC to demonstrate how they will update their network in response to the findings of the needs assessment.

Agency Response: The department appreciates the supportive comment, but the department disagrees that it is necessary to incorporate annual evaluation requirements for diversity considerations into §13.482(c)(1) because §13.481(b) and (c) already address requirements for the QI committee to approve an annual QI plan and evaluate the overall effectiveness of the QI program. The department's position is that additional discrete evaluation and plan requirements are unnecessary. For this reason, the department declines to make the suggested change.

Comment: §13.482(c)(2) – (4) – QA and QI. A commenter states support for the requirements in §13.482(c)(2)–(4) that HCCs have processes and written standards in place to help providers communicate clinical information understandably and promote patient engagement, but asks the department to require HCCs to provide a detailed explanation of how its providers will communicate clinical knowledge and evidence-based medicine to enrollees in a way that is understandable and engages the patient in treatment decisions. Examples include requiring the HCC to demonstrate how it will ensure information is conveyed at the appropriate literacy level and in the beneficiary's primary language, what specific decision aids providers will use, and how the HCC will identify and incorporate patient values and preferences. The commenter suggests that the HCC can accomplish this by providing examples of the materials that the HCC will use as part of its application.

The commenter asks that the department monitor HCCs in this area at renewal and during quality-of-care exams to ensure that the HCC is following the processes set out in the application. Among other things, the commenter notes that CAHPS measures how enrollees feel providers communicate and their experience with shared decision making, so the commenter states that monitoring CAHPS results at renewal will help the department to monitor and improve patient engagement.

The commenter suggests the department amend §13.482(c) to read:

"(c) The patient engagement process should include:

(1) evaluating the health needs of its enrolled population, including considerations of diversity in its patient population, and a plan to address the needs of its patient population;

(2) communicating clinical knowledge and evidence-based medicine to patients and patient representatives clearly and understandably;

(3) promoting patient engagement, through shared-decision making and independent care plans that take into account the patients unique needs, preferences, values, and priorities;

(4) establishing written standards for patient communications; and

(5) establishing a process for patients to access their medical records."

The commenter asserts that without this measurement the department, the attorney general, and the public cannot ascertain that: (i) quality care is delivered; (ii) quality improves overtime; (iii) HCCs are facilitating coordinated care and not just provider consolidation; and (iv) HCCs are not sacrificing quality as a means to contain costs.

Agency Response: The department's position is that the detailed explanations and materials requested for inclusion in §13.482(c) are already sufficiently addressed in the adopted rule text in a way that provides flexibility for the HCC to demonstrate how it will meet the requirement. Section 13.413(f) requires an application to include a detailed description of the policies and processes contained in the QA and QI program required by §13.482; and adopted §13.415(a)(2) requires the HCC to provide to the department on request and make available for review the HCC's program description and work plan as required by §13.481, as well as program evaluations in support of requirements under §13.482 for certified HCCs.

The department notes that some of the suggestions for change, such as requiring an HCC to provide information on its use of decision aids to help engage patients in treatment standards, could have the effect of imposing uniform standards in a manner that is inconsistent with the department's intent to provide for HCC flexibility to establish, implement, and administer defined policies and processes to secure patient engagement. The additional flexibility is especially appropriate given the possibility that a specialty HCC will form that might otherwise have difficulty meeting the more rigid requirements concerning the patient engagement process. For these reasons, the department declines to make the suggested change.

Comment: §13.482 – Processes for measuring and reporting quality of health care services and impact on cost. Some commenters state that prior informal draft rules would have required that each HCC's processes for measuring and reporting quality of health care services and impact on cost include "standards that are consistent with those

promulgated by the Texas Institute of Health Care Quality and Efficiency established under Health and Safety Code Chapter 1002."

The commenters state support for the department's decision not to retain this requirement and opposition to inclusion of language that would require HCCs to follow institute recommendations, based on the lack of a requirement in SB 7 for HCCs to comply with any of the standards recommended by the institute. The commenters also state that Health and Safety Code §1002.101(3) and §1002.151 only require the institute to make recommendations rather than establish standards.

Agency Response: The department appreciates the supportive comment.

Comment: §13.493 – Rights of Physicians. Some commenters note that §13.493 closely tracks Insurance Code §848.110 in stating the rights of physicians before a complaint against a physician under Insurance Code §848.107 is resolved or before the involuntary termination of a physician's association with an HCC. The commenters recommend that the department amend §13.493 to expressly include the right for a physician to appeal an adverse determination so that the section will comport with more stringent standards applicable to participants who may form an HCC, such as hospitals who are accredited by the JCAHO.

The commenters state that JCAHO Standard MS.10.01.01 requires accredited hospitals to have a fair hearing and appeal process to address adverse decisions regarding denial, reduction, suspension, or revocation of privileges that may relate to quality of care, treatment, or service issues; and JCAHO's Element of Performance No. 5 for MS.10.01.01 specifies that a compliant policy developed by the organized medical staff

for a fair hearing and an appeal process has the following characteristic: "with the governing body, has a mechanism to appeal adverse decisions as provided in the medical staff bylaws."

The commenter asserts that the JCAHO due process standard, which includes the right to an appeal, is the framework on which most medical staff bylaws are modeled and is one with which most facilities are familiar. Absent a compelling reason, the commenter asserts that the department should not deviate from the JCAHO standard.

Further, the commenter asserts that the stated rationale for MS.10.01.01 generally applies to HCCs, as well as hospitals accredited by the JCAHO, by stating that "the purpose of a fair hearing and appeal is to assure full consideration and reconsideration of quality and safety issues, and ... allow practitioners an opportunity to defend themselves."

The commenter asserts that under SB 7, the Texas Legislature envisioned HCCs as entities that would enhance the quality of health care provided to Texas residents; thus, any strengthening of the due process requirements under §13.494 would achieve that goal by providing "full consideration and reconsideration of quality and safety issues" consistent with the stated rationale of the JCAHO standard. The commenter asserts that Texas patients need assurance that their physicians have the freedom to act in their best interest without the fear of termination through a process that lacks full consideration and reconsideration of the relevant issues.

Agency Response: The department disagrees that it is necessary to make this change because the department has already addressed requirements for the selection and retention of participants in §13.483. Adopted §13.483 requires an HCC to implement a

documented process for the selection and retention of contracted participants. The section requires the credentialing process to comply with the standards promulgated by the National Committee for Quality Assurance, URAC, the JCAHO, or the AAAHC, as appropriate, to the extent that those standards are applicable and do not conflict with other laws of this state. Because these standards address the physician right of appeal, no change to §13.493 is necessary, and the department declines to make the change.

5. NAMES OF THOSE COMMENTING FOR AND AGAINST THE SECTIONS.

For, with recommended changes: Texas Chapter of the American College of Cardiology; Texas Medical Association; Texas Orthopaedic Association; Texas Radiological Society; Texas Society of Anesthesiologists; Texas Society for Gastroenterology and Endoscopy; Texas Society of Pathologists; and Texas Urological Society.

Neither for nor against, with recommended changes: Accreditation Association for Ambulatory Health Care; Center for Public Policy Priorities; Superior Health Plan, Inc.; Texas Association of Health Plans; and Texas Hospital Association.

6. STATUTORY AUTHORITY. The new sections are adopted under Insurance Code §§848.054(b), 848.056(d), 848.108(c)(2), 848.108(d), 848.151, 848.152(d), and 36.001.

Section 848.054(b) requires the commissioner to adopt rules governing the application for a certificate of authority to organize and operate an HCC.

Section 848.056(d) authorizes the commissioner by rule to extend the date by which an application is due and to require the disclosure of any additional information necessary to implement and administer Chapter 848, including information necessary to antitrust review and oversight.

Section 848.108(c)(2) authorizes the commissioner to specify by rule functions in addition to those referenced in §848.108(c)(1) under which an HCC may assign responsibility to a delegated entity by agreement.

Section 848.108(d) authorizes the commissioner by rule to set maintenance requirements for reserves and capital in an amount and form in addition to amounts required under Chapter 1272 as are necessary for the liabilities and risks assumed by the HCC.

Section 848.151 authorizes the commissioner and the attorney general to adopt reasonable rules as necessary and proper to implement the requirements of Chapter 848.

Section 848.152(d) requires the commissioner to set fees and assessments in an amount sufficient to pay the reasonable expenses of the department and attorney general in administering Chapter 848, including the direct and indirect expenses incurred by the department and attorney general in examining and reviewing HCCs.

Section 36.001 provides that the commissioner of insurance may adopt any rules necessary and appropriate to implement the powers and duties of the department under the Insurance Code and other laws of this state.

7. TEXT.

DIVISION 1. GENERAL PROVISIONS

§13.401. Purpose. This subchapter implements Insurance Code Chapter 848 and other insurance laws of this state that apply to health care collaboratives to provide the framework to support the use of innovative health care collaborative payment and delivery systems in this state.

(1) Severability. If a court of competent jurisdiction holds that any provision of this subchapter or its application to any person or circumstance is invalid for any reason, the invalidity does not affect other provisions or applications of this subchapter that can be given effect without the invalid provision or application, and to this end the provisions of this subchapter are severable.

(2) Effect of rules. The sections in this subchapter govern the performance of appropriate statutory and regulatory functions and do not limit the exercise of statutory authority by the commissioner of insurance.

§13.402. Definitions. The following words and terms, when used in this subchapter, have the following meanings unless the context clearly indicates otherwise.

(1) Affiliate--As defined in Insurance Code §848.001(1).

(2) Clinical director--Health professional who is:

(A) appropriately licensed in good standing in Texas;

(B) an employee of, or party to a contract with, an HCC; and

(C) responsible for clinical oversight of the utilization review program, the credentialing of professional staff, and quality improvement functions.

(3) Common service--An identical or substantially similar health care service provided to patients by two or more independent HCC participants.

(4) Confidential information--Information that relates to bidding, pricing, trade secrets, business planning documents, financial position and related operational results, profit and loss statements, contracts, salaries, employee benefits, or other competitively sensitive information.

(5) Credentialing--The periodic process of collecting, assessing, and validating qualifications and other relevant information pertaining to a physician or health care provider to determine eligibility to deliver health care services.

(6) Entity--An artificial person, including a partnership, association, organization, trust, or corporation; the term does not include a securities broker performing no more than the usual and customary broker's function.

(7) Facility--

(A) an ambulatory surgical center licensed under Health and Safety Code Chapter 243;

(B) a birthing center licensed under Health and Safety Code Chapter 244; or

(C) a hospital licensed under Health and Safety Code Chapter 241 or 577.

(8) Financial statement--An HCC's annual statement of financial position and operating results, including a balance sheet, receipts, and disbursements, certified by an independent certified public accountant and prepared in accord with Generally Accepted

Accounting Principles.

(9) Health care collaborative or HCC--As defined in Insurance Code §848.001(2).

(10) Health care provider--As defined in Insurance Code §848.001(4).

(11) Health care services--As defined in Insurance Code §848.001(3).

(12) Health maintenance organization or HMO--As defined in Insurance Code §848.001(5).

(13) Hospital--As defined in Insurance Code §848.001(6).

(14) Individual--A natural person.

(15) Individual health care provider--A health care provider who is a natural person.

(16) Network--A health care delivery system in which an HCC provides or arranges to provide health care services directly or through contracts and subcontracts with governmental entities or private individuals or entities.

(17) Participant--Each physician or health care provider that has agreed to participate in the HCC.

(18) Patient--An individual who receives a health care service.

(19) Physician--As defined in Insurance Code §848.001(8).

(20) Primary service area or PSA--For each common service and each participant, the area defined by the smallest number of postal ZIP codes from which the participant draws at least 75 percent of its patients for that service.

(21) Private payor--Any of the following:

(A) an insurer that writes health insurance policies;

(B) an HMO, to the extent that it pays physicians or health care providers for health care services under an HMO evidence of coverage or under a negotiated-rate contract with the physician or health care provider; or

(C) any other entity, including an insurer or third-party administrator for self-insured private or governmental employers, that provides, or offers to provide, health care services to a patient pursuant to a negotiated-rate contract that the entity negotiated with physicians or health care providers.

(22) Pro-competitive benefit--A benefit obtained from clinical or financial integration by the establishment and operation of the HCC that ultimately accrues to the benefit of the HCC's patients. A pro-competitive benefit may include use of electronic medical records, implementation of quality control procedures, utilization review, clinical protocols, coordination of care, and financial incentives to reduce costs or increase quality.

(23) Quality improvement or QI--A system to continuously examine, monitor, and revise processes and systems that support and improve administrative and clinical functions.

(24) Rural hospital--A hospital:

(A) that is paid under the Medicare hospital inpatient prospective payment system and is either located more than 35 miles from other like hospitals or is located in a rural area, and meets the criteria for sole community hospital status as specified by 42 CFR §412.92; or

(B) located in a rural area and that has been certified as a Medicare critical access hospital based on the criteria set forth in 42 CFR Part 485, Subpart F.

(25) Service area--A geographic area within which health care services are available and accessible to an HCC's patients who live, reside, or work within that geographic area and that complies with §13.473 of this title (relating to Organization of an HCC).

(26) Utilization review--As defined in Insurance Code §4201.002.

§13.403. Filing and Required Forms; How to Obtain Forms.

(a) All HCC filings for original or renewal application as required by this subchapter must be made to Company Licensing & Registration, Mail Code 305-2C, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104, and copies of all HCC forms are available through that address. All forms also are available on the department website at www.tdi.texas.gov.

(b) All HCC forms for an original or renewal application filing may be submitted electronically in a format permitted by the department.

(c) Paragraphs (1)–(7) of this subsection identify the forms specified for use with the rules adopted under this subchapter. Forms identified in paragraphs (1) and (4)–(7) have a June 2012 revision date. Forms identified in paragraphs (2) and (3) have a March 2013 revision date. Each HCC or other individual or entity must use the form(s) as required by this title in accord with the form's instructions and content requirements and as appropriate to particular activities. The commissioner adopts by reference the following

forms:

(1) Original/Renewal Application for Certificate of Authority to do the Business of a Health Care Collaborative (HCC) in the State of Texas;

(2) Health Care Collaborative Officers and Directors Page;

(3) Biographical Affidavit;

(4) Request to Convert to Renewal of Certificate of Authority to do the Business of a Health Care Collaborative (HCC) in the State of Texas;

(5) Financial Authorization and Release Form;

(6) Health Care Collaborative Payor Information Form; and

(7) Health Care Collaborative (HCC) Acquisition Form.

§13.404. Use of the Term "HCC;" Service Mark; Trademarks; d/b/a.

(a) While planning or developing an HCC, an organization may use the terms "health care collaborative" or "HCC" as a part of the proposed HCC's name provided the developmental status of the proposed HCC is clearly communicated in all dealings with employers, individuals, prospective contract holders, news media, and other individuals or entities.

(b) After the certificate of authority is issued, the HCC must include the name as it appears on the certificate of authority on all advertising and forms distributed to the public.

DIVISION 2. APPLICATION FOR CERTIFICATE OF AUTHORITY

§13.411. Filing Fee; Annual Assessments; Open Records.

(a) The application filing fee required by Insurance Code §848.152 must accompany the application required to be filed by Insurance Code §848.056 or §848.060.

(b) The fee for filing the original application for certificate of authority is $10,000 and is nonrefundable.

(c) The fee for filing the annual renewal application for certificate of authority is $5,000 and is nonrefundable.

(d) In addition to the filing fee addressed in this section, each HCC must pay to the department annually an assessment as set forth in §13.421(c)(1) – (6) of this title (relating to Examination; Fee for Expenses).

(e) Except as provided by Insurance Code §848.005(b), the application is public information subject to disclosure under the Government Code Chapter 552.

§13.412. Revisions During Review Process.

(a) Revisions during the review of the application must be addressed to: Company Licensing & Registration, Mail Code 305-2C, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104.

(b) Each revision to the basic organizational document, bylaws, or officers' and employees' bond must be accompanied by a certification of the corporate secretary or corporate president of the applicant that the revision submitted is true, accurate, and complete.

(c) The department will conduct examinations in connection with each application and notify the applicant of the need for revisions necessary to meet the requirements of

Insurance Code Chapter 848, this subchapter, and applicable insurance laws and regulations of this state. If the applicant does not make the necessary revisions, the department may withdraw the application on behalf of the applicant. If the time required for the revisions will exceed the time limit provided in Insurance Code §848.056(c), the applicant must request additional time within which to make the revisions. The applicant must specifically state the length of time requested, which may not exceed 90 days. The request for any extension must describe the need for the additional time in writing in sufficient detail for the commissioner to determine if good cause for the extension exists. The applicant may request additional extensions. The commissioner has discretion to grant or deny the request for an extension of time under Insurance Code §848.056.

§13.413. Contents of the Application.

(a) Order of contents. The application must include the items in the order listed in this section.

(b) Original and copies. An applicant filing a nonelectronic application must submit two additional copies of the application along with the original application.

(c) General contents. An application must include:

(1) a declaration executed under oath or affirmation by an officer or other authorized representative of the HCC certifying that the collection of any confidential information for purposes of satisfying filing requirements of this subchapter was made in accord with the confidentiality requirements of §13.426 of this title (relating to Confidentiality);

(2) a completed application for certificate of authority;

(3) the basic organizational documents and any amendments to them, complete with the original incorporation certificate with charter number and seal indicating certification by the secretary of state, if applicable;

(4) the bylaws, rules, or any similar documents regulating the conduct of the internal affairs of the applicant, certified by an officer or other authorized representative of the applicant HCC;

(5) a plan of operation for the HCC, including an overview, history, types of health care service offered, and operations provisions that include pro-competitive strategies of the HCC;

(6) information about officers, directors, and staff:

(A) a completed officers and directors page; and

(B) biographical data forms for all individuals who are to be responsible for the day-to-day conduct of the affairs of the applicant;

(7) separate organizational charts or lists, as described in subparagraphs (A) - (C) of this paragraph:

(A) charts clearly identifying the contractual relationships involved in the applicant's health care delivery system and between the applicant and any affiliates, and a list of contracts to provide services between the applicant and the affiliates;

(B) a chart showing the internal organizational structure of the applicant's management and administrative staff; and

(C) for the purposes of this paragraph, the information provided must

clearly identify any relationship between the HCC and any affiliate or other organization if a common individual or entity directly or indirectly controls 10 percent or more of both the HCC and the affiliate or other organization;

(8) notice of the physical address in Texas of all books and records described in §13.415 of this title (relating to Documents to be Available for Quality of Care and Financial Examinations); and

(9) a description of the information systems, management structure, and personnel that demonstrates the applicant's capacity to meet the needs of patients and participants and to meet the requirements of regulatory and contracting entities.

(d) Financial information. An application must include financial and financially-related information consisting of the following:

(1) projected financial statements, including a balance sheet, income statement, and cash flow statement. Additionally:

(A) the projected data must be provided for two consecutive annual reporting periods;

(B) the financial statements must include the identity and credentials of the individual making the projections; and

(C) the projected data must reflect compliance with §13.431 of this title (relating to Reserves and Working Capital Requirements);

(2) a balance sheet reflecting actual assets and liabilities, and net assets sufficient to comply with §13.431 of this title;

(3) the form, including any proposed payment methodology, of any contract

between the applicant and any payor that addresses the applicant arranging for medical and health care services for the payor in exchange for payments in cash or in kind as provided in Insurance Code Chapter 848;

(4) if applicable, insurance or other protection, or both, against insolvency and:

(A) any reinsurance agreement and any other agreement described in Insurance Code §848.102 covering the cost of a potential significant event or catastrophe; and

(B) any other arrangements offering protection against insolvency;

(5) proof of the applicant's maintenance of a fidelity bond or similar officer and employee antifraud protection as provided in §13.473(d) of this title (relating to Organization of an HCC); and

(6) authorization for disclosure to the commissioner of the financial records of the applicant and affiliates to confirm assets.

(e) Provider and service area information. An application must include:

(1) a description and a map of the service area, with key and scale, that identifies the county or counties, or portions of the county or counties, to be served. If the original map is in color, all copies also must be in color;

(2) network configuration information, including maps demonstrating the location and distribution of the participants by physician type and provider type within the proposed service area by county, counties, or ZIP code(s); lists of participants in Excel-compatible format, including business address, county, license type and specialization,

hospital admission privileges, and an indication of whether they are accepting new patients;

(3) the identity of any integrated practice group or independent practice association to which any participant belongs, including the group's name, business address, type of legal organization, and approximate number of members;

(4) for each participating facility:

(A) the facility's name and business address;

(B) a description of the services provided by the facility; and

(C) a statement as to whether the facility's agreement with the HCC allows the facility to contract or affiliate with other HCCs;

(5) the form of any contract or monitoring plan between the applicant and:

(A) any individual listed on the officers and directors page;

(B) any delegated entity, delegated network, or delegated third party as described in Insurance Code Chapter 1272; or any other physician or health care provider, plus the form of any subcontract between those individuals or entities and any physician or health care provider to provide health care services. All contracts must include a hold-harmless provision that complies with Insurance Code §843.361 and §1301.060, as applicable, for the protection of patients covered by health benefit plans;

(C) any exclusive agent or agency; or

(D) any individual or entity who will perform management, marketing, administrative, data processing, or claims processing services; and

(6) a written description of the types of compensation arrangements, such as

compensation based on fee-for-service arrangements, risk-sharing arrangements, prepaid funding arrangements, or capitated risk arrangements, made or to be made with physicians and health care providers in exchange for the provision of, or the arrangement to provide, health care services to patients, including any financial incentives for physicians and health care providers.

(f) Quality assurance and quality improvement information. An application must include a detailed description of the policies and processes contained in the quality assurance and quality improvement program required by §13.482 of this title (relating to Quality Assurance and Quality Improvement).

(g) Accreditation disclosure. If an HCC has attained accreditation from a nationally recognized accrediting body such as the National Committee for Quality Assurance, URAC, or the Accreditation Association for Ambulatory Health Care, the HCC must disclose:

(1) the name of the accrediting body;

(2) the date accreditation was granted;

(3) the accreditation level;

(4) current accreditation status; and

(5) a copy of the accreditation report.

(h) Antitrust analysis information required of all applicants. An application must include:

(1) for each participant in the HCC, disclosure of any known past or pending investigation, or administrative or judicial proceeding, in which it is alleged that the

participant has engaged in any form of price-fixing or other antitrust violation, or health care fraud or abuse, including any governmental or private investigations, lawsuits, and any judgments, fines, or penalties relating to those allegations;

(2) identification of each common service provided by participants, grouped by:

(A) specific Medicare specialty code for each specialty of any participating physician or health care provider;

(B) specific major diagnostic category for inpatient services at a hospital; and

(C) specific outpatient category as established by the Centers for Medicare and Medicaid Services for outpatient services at a facility;

(3) identification of the PSA for each common service for each participant;

(4) the HCC's calculated market share for each common service in each PSA in which two or more participants serve patients for that service, utilizing the identification procedures and calculation steps set forth in §13.414 of this title (relating to Limited Exemption from Certain Information Filing Requirements); and

(A) identifying the market participants and providing the data used in determining the market share; and

(B) highlighting each common service area in each PSA in which the market share exceeds 35 percent;

(5) identification of all physicians, physician group practices, or other entities the HCC applicant considers to be or have been competitors of the HCC or its participants

in its proposed service area;

(6) for each pro-competitive benefit that the applicant anticipates will result from the establishment of the HCC:

(A) a description of the pro-competitive benefit;

(B) an explanation as to why the establishment of the HCC will help achieve the pro-competitive benefit or will help extend the pro-competitive benefit to new patient populations or service areas; and

(C) a description of how the HCC will assess whether the pro-competitive benefit has been achieved, including:

(i) the reference point to be used in determining the status prior to implementation of the pro-competitive benefit;

(ii) the standard to be used by the HCC in tracking progress toward achieving the pro-competitive benefit; and

(iii) the period of time to be used in assessing whether the pro-competitive benefit has been achieved. If the period is longer than one year, the applicant must set forth interim benchmarks that will allow the commissioner to assess whether the HCC is making progress toward achieving the pro-competitive benefit; and

(D) for any pro-competitive benefit that the HCC expects to achieve as the result of financial integration, a description of the alternative payment methods the HCC anticipates using to create the financial, pro-competitive benefit;

(7) a description of the policies and procedures the HCC will establish and administer to ensure that none of its financial incentives will result in any limitation on

medically necessary services; and

(8) a description of the confidentiality policies and procedures established and enforced by the HCC applicant as required by §13.426 of this title to protect the confidential information of a participant in the HCC from disclosure to other participants in the HCC. The description must include the types and specifications of safeguards and address confidential information collected in the process of preparing or submitting the HCC application.

(i) Market and market power information. HCC applicants ineligible for the limited information filing exemption. An HCC application for an applicant that does not qualify for the limited information filing exemption set forth in §13.414 of this title must also include additional information. For each PSA that does not fall within the limited filing exemption, for each participant in the PSA, the application must include:

(1) for each participant, the name of each private payor that individually accounts for five percent or more of the participant's business in the past year, measured by:

(A) revenue;

(B) billed charges, if revenue data is unavailable; or

(C) patient visits, if billed charges data is unavailable;

(2) for each participant referenced in paragraph (1) of this subsection, a completed Health Care Collaborative Payor Information Form;

(3) all business planning documents created within the previous 24 months relating to the HCC applicant's or its participants' plans relating to any health care

service in each service area, including:

(A) market studies and forecasts;

(B) studies of patient origin and flow;

(C) market share studies;

(D) budgets;

(E) investment banker and other consultant reports;

(F) expansion or retrenchment plans;

(G) research and development documents; and

(H) presentations to management committees, executive committees, and boards of directors;

(4) the name of each individual responsible for negotiating contracts on behalf of participants with payors over the last five years, the name of the participant on whose behalf the individual negotiated, the period of time during which the individual was responsible for those negotiations, and, if known, the individual's current address and phone number;

(5) documents reflecting the applicant's price lists, pricing plans, pricing policies, pricing forecasts, pricing strategies, pricing analyses, and pricing decisions relating to any medical or health care service in the service area;

(6) for each individual or entity that has provided or stopped providing any competing health care service in the service area within the previous 24 months, the following items:

(A) name and address of the individual or entity;

(B) beginning date, or beginning and ending date, of the individual's or entity's provision of the health care service in the service area; and

(C) whether the individual or entity built a new facility, converted assets previously used for another purpose, or began using facilities that already were being used for the same purpose;

(7) if the applicant believes that approval of the application is necessary for the future financial viability of one or more of the participants, for that participant, documents referencing its future viability, gross or net margins, ability to obtain financing for capital improvements, or other documents the applicant deems necessary for the evaluation of that participant's financial condition;

(8) all memoranda created within the previous 24 months relating to cost savings, economies, or other efficiencies that have been or could be achieved by any participant through a joint venture, internal cost-cutting, or any associated transaction, regardless of whether the applicant establishes and operates the proposed HCC;

(9) identification of every physician or health care provider in its proposed PSA that the applicant has communicated with concerning the possibility of contracting with the HCC within the previous 12 months; and

(10) for each participant, for the previous 12 months, all agendas, minutes, summaries, handouts, and presentations made to the participant's: board of directors; executive committee; strategic or business planning committees; physician or health care provider recruitment committee; and any committee responsible for approving contracts with facilities, clinics, or private payors.

§13.414. Limited Exemption from Certain Information Filing Requirements.

(a) This section specifies circumstances under which an applicant is not required to provide the information specified in §13.413(i) of this title (relating to Contents of the Application) in filing an original or renewal application for certificate of authority.

(b) An applicant is not required to provide the information specified in §13.413(i) of this title if:

(1) for each PSA in which two or more individual or group participants provide common services, the applicant's market share is 35 percent or less; and

(2) no contract between the HCC and any participating hospital restricts the HCC or hospital from contracting with other HCCs, networks, hospitals, physicians, physician groups, health care providers, or private payors.

(c) Notwithstanding the provisions of subsection (b) of this section, an HCC that has a contract with a physician or health care provider in a rural county as defined by the U.S. Census Bureau and that does not restrict that physician's or health care provider's ability to contract or deal with other HCCs, networks, physicians, or health care providers is not required to provide the information specified in §13.413(i) of this title, if the inclusion of the physician or health care provider alone causes the HCC's share of any common service to exceed 35 percent.

(d) Notwithstanding the provisions of subsection (b) of this section, an HCC that includes a rural hospital but does not restrict the hospital from contracting with other HCCs, networks, physicians, or health care providers is not required to provide the

information specified in §13.413(i) of this title, if the inclusion of the rural hospital alone causes the HCC's share of any common service to exceed 35 percent.

(e) For purposes of this section, an HCC's market share is determined by aggregating the market shares of its participants, calculated as follows:

(1) for physicians or individual health care providers within a particular health care specialty, by dividing the number of physicians or individual health care providers in the specialty within the HCC by the total number of physicians or health care providers providing each of the common services within that health care specialty within a participating physician's or health care provider's PSA;

(2) for outpatient services at a facility, by dividing the number of physicians or health care providers participating in the HCC within each PSA by the total number of physicians or health care providers within each PSA that provide each common service;

(3) for hospital inpatient services, by dividing the number of staffed hospital beds by particular medical specialty within the hospital or group of hospitals as reported to the Texas Department of State Health Services, for each common service area, by the total number of staffed hospital beds by medical specialty within each participating hospital's PSA; and

(4) if an HCC's participants can be classified as falling within more than one of the categories set forth in paragraphs (1) – (3) of this subsection, calculations must be made for all of the categories within which the participants in the HCC provide services.

(f) Notwithstanding the definition of PSA in §13.402 of this title (relating to Definitions), a participant may calculate market share through reference to the HCC's PSA

for a health care specialty rather than the participant's PSA if the participant demonstrates to the commissioner's satisfaction that analysis of competition within the HCC's PSA provides a more accurate measure of competition relating to the participant in the context of the HCC than the analysis of competition within the participant's PSA.

(g) Notwithstanding this section, on receipt of the original or renewal application, the commissioner has discretion to require an applicant to provide any or all of the information specified in §13.413(i) of this title or §13.461 of this title (relating to Commissioner's Authority to Require Additional Information), or both, when the commissioner deems the information reasonably necessary to conduct the review required under Insurance Code Chapter 848.

§13.415. Documents to be Available for Quality of Care and Financial Examinations.

(a) The following documents must be provided to the department on request and available for review at the HCC's office located within Texas:

(1) administrative: policy and procedure manuals, including procedures relating to confidentiality; patient materials; organizational charts; and key personnel information, such as resumes and job descriptions;

(2) quality improvement: program description and work plan as required by §13.481 of this title (relating to Quality Improvement Structure for HCCs); and, to support requirements under §13.482 of this title (relating to Quality Assurance and Quality Improvement) for certified HCCs, program evaluations and meeting minutes for committees and subcommittees;

(3) utilization management: program description; policies and procedures; criteria used to determine medical necessity; templates of adverse determination letters and adverse determination logs for all levels of appeal, or, for certified HCCs, examples of those letters and logs; and, for certified HCCs, utilization management files;

(4) complaints and appeals: policies and procedures; and templates of letters, complaint logs, and appeal logs, or, for certified HCCs, examples of those letters and logs, including documentation and details of actions taken;

(5) health information systems: policies and procedures for accessing patient health records and a plan to provide for confidentiality of those records in accord with applicable law;

(6) network configuration information: as outlined in and required by §13.413(e)(2) of this title (relating to Contents of the Application), demonstrating adequacy of the physician and health care provider network;

(7) executed agreements, including:

(A) contracts with payors;

(B) management services agreements;

(C) administrative services agreements; and

(D) delegation agreements;

(8) executed participant contracts: copy of the first page, including the form number, and signature page of individual and group contracts;

(9) executed subcontracts: copy of the first page, including the form number, and signature page of all contracts with subcontracting physicians and providers;

(10) physician and health care provider manuals: current physician manual and current health care provider manual, which must be provided to each contracting physician and health care provider, respectively, and which must contain details of the requirements by which the physicians and health care providers will be governed;

(11) credentialing documentation: credentialing policies, procedures, and files that demonstrate compliance with §13.483 of this title (relating to Credentialing);

(12) reporting system: the statistical reporting system developed and maintained by the HCC that allows for compiling, developing, evaluating, and reporting statistics relating to the cost of operation, the pattern of utilization of services, and the accessibility and availability of services; and, for certified HCCs, reports generated by the system concerning those components;

(13) claims systems: policies and procedures that demonstrate the capacity to pay claims timely, if applicable, and to comply with all applicable statutes and rules; and, for certified HCCs, as applicable, evidence of timely claims payments and reports that substantiate compliance with all applicable statutes and rules regarding claims payment to physicians, health care providers, and patients;

(14) financial records: including statements; ledgers; checkbooks; inventory records; evidence of expenditures, investments, and debts; and related bank confirmations necessary to ascertain funding;

(15) compliance or accreditation: records regarding compliance with applicable statutes and rules or accreditation standards, including audits or examination reports by other entities, such as governmental authorities or accrediting agencies;

(16) satisfaction surveys: for certified HCCs only, patient, physician, and provider satisfaction surveys; and patient disenrollment and termination logs;

(17) reports: for certified HCCs only, any reports submitted by the HCC to a governmental entity; and

(18) other documents and information: any records requested pursuant to Insurance Code §848.153.

(b) The documents listed in this section must be maintained for at least five years from the anniversary date of the applicable document's creation.

§13.416. Review of Original or Renewal Application; Commissioner Discretion.

(a) An original application or renewal application will be processed pursuant to Insurance Code §§848.056 – 848.060 and §848.153.

(b) The department will conduct an examination as specified in §13.421(a) of this title (relating to Examination; Fee for Expenses) in conjunction with each application. If a hearing is held in connection with an application, then the examination(s) will occur prior to the date of the hearing.

(c) Application review will include a determination of compliance with Insurance Code §848.057. The review of pro-competitive benefits of the proposed or existing HCC in relation to anticompetitive effects of market power increase will be in accord with established antitrust principles of market power analysis.

(d) The commissioner has sole discretion to impose restrictions on an HCC applicant's certificate of authority that are deemed necessary to preserve competition. Examples of these restrictions include the following:

(1) prohibiting the HCC applicant from including "anti-steering," "guaranteed inclusion," "product participation," "price parity," or similar contractual clauses or provisions in its contracts with a private payor;

(2) prohibiting the HCC applicant from tying sales, explicitly or implicitly through pricing policies, of the HCC's services to a private payor's purchase of other services from physicians or health care providers outside of the HCC (and vice versa), including providers affiliated with HCC participants;

(3) prohibiting contracting with HCC participants on a basis that prevents or discourages them from contracting outside the HCC, either individually or through other HCCs or provider networks;

(4) prohibiting restrictions on a private payor's ability to provide its health plan enrollees with cost, quality, efficiency, and performance information used by the HCC to aid enrollees in evaluating and selecting physicians and health care providers in the health plan;

(5) prohibiting sharing with or among the HCC's participants any competitively sensitive pricing or other data that could be used to set prices or other terms for services that the participants provide outside the HCC; and

(6) restricting the HCC's certificate of authority to certain geographic areas or health care services.

§13.417. Withdrawal of an Application.

(a) On written notice to the department, an applicant may request withdrawal of an application from consideration by the department.

(b) The department may in its discretion withdraw an application on behalf of the applicant if the department determines that the applicant has failed to respond in a timely manner to requests made by the department for additional information or if the application is incomplete.

DIVISION 3. EXAMINATIONS; REGULATORY REQUIREMENTS FOR AN HCC AFTER ISSUANCE OF CERTIFICATE OF AUTHORITY; AND ADVERTISING AND SALES MATERIAL

§13.421. Examination; Fee for Expenses.

(a) The department has authority to conduct examinations of HCCs under Insurance Code §848.153. The department will conduct examinations in conjunction with an application and as needed to oversee the HCC's activity. The scope of the examination may vary based on the scope of an applicant's or HCC's activities and may include desk review. Any examination may include the review of one or more of the following components:

(1) financial condition;

(2) quality of health care services;

(3) compliance with laws affecting the conduct of business; or

(4) effect on market competition.

(b) The commissioner has authority under Insurance Code §848.152(d) to set and collect fees in an amount sufficient to pay the reasonable expenses of the department and attorney general in administering Insurance Code Chapter 848, including direct and indirect expenses incurred by the department, the attorney general, and their contractors in examining and reviewing HCCs. The department will maintain active oversight of individuals performing examination functions to assure that the examination fee reflects expenses that are reasonable and necessary. The examination fee will include the actual salary, fees, and expenses of the examiners directly attributable to the examination as follows:

(1) any actual salary amount included in an examination fee for an examiner who is a department employee will be the part of the annual salary attributable to each hour an examiner examines the HCC;

(2) any expenses included in an examination fee for an examiner who is a department employee will be actual expenses incurred by an examiner and attributable to the examination, including the actual cost of:

(A) transportation;

(B) lodging;

(C) meals;

(D) subsistence expenses;

(E) parking fees; and

(F) department overhead expense; and

(3) any amount included as an examination fee or expense by an examiner

who is not a department employee will be determined according to the terms of the contract between the examiner and the department.

(c) An HCC must pay to the department annually an assessment as set forth in paragraphs (1) – (6) of this subsection.

(1) On or before January 31 of each year, each certified HCC must submit to the department a statement of its gross revenues for the previous calendar year.

(2) On or before January 31, 2014, and annually thereafter, the department will calculate the cost by fiscal year to administer Insurance Code Chapter 848 and this subchapter, including direct and indirect expenses incurred by the department and the attorney general attributable to carrying out their responsibilities under Chapter 848, but excluding examination expenses billed directly to an HCC.

(3) On or before April 1, 2014, and annually thereafter, the department will assess all certified HCCs on a pro rata basis for the expenses determined pursuant to paragraph (2) of this subsection, based on the total annual gross revenues reported by the HCCs. The assessment amount for each HCC will be adjusted by the amount of any application fees received from the HCC.

(4) For purposes of reporting gross revenues relevant to this subsection, an HCC may choose to reduce its gross revenues in a clearly disclosed manner by amounts paid to individuals or entities unaffiliated with the HCC for the following items:

(A) drugs or biological supplies that, by law, require a prescription to be dispensed; and

(B) devices or medical supplies that, by law, require premarket

approval by or premarket notification to the Food and Drug Administration.

(5) On receipt of an assessment pursuant to paragraph (3) of this subsection, the HCC must pay the assessment amount before the later of 30 days following receipt of the assessment or May 1.

(6) The department may issue additional assessments as necessary to fully fund the expense of regulation under Insurance Code Chapter 848 and this subchapter.

(d) When an HCC has been notified by the department of a pending examination under this section, it may request that it instead submit a renewal application and that the examination be converted into a renewal review.

(1) To initiate the request, the HCC must file the Request to Convert to Renewal of Certificate of Authority to Do the Business of a Health Care Collaborative (HCC) in the State of Texas form.

(2) The HCC must submit the request prior to the issuance of any draft examination report.

(3) If the department approves the request, the HCC must file an application for renewal within 30 days of the approval to convert to renewal review. The application filing must comply with §13.424 of this title (relating to Certificate of Authority Renewal Requirements).

(4) The subsequent renewal date for the HCC will be 12 months following the approval date of the application to renew.

§13.422. Filing Requirements That Apply After Issuance of Certificate of Authority.

(a) After the issuance of a certificate of authority, each HCC must file certain information with the commissioner, either for approval prior to effectuation or for information only, as provided in this section.

(b) In accord with Insurance Code §848.060(e), an HCC must report to the department a material change in the size, composition, or control of the HCC.

(c) An HCC must make the filings outlined in paragraphs (2) and (3) of this subsection and in §13.423 of this title (relating to Service Area Change Applications). These requirements include filing changes necessitated by federal or state law or regulations.

(1) Complete filings required. The department will not accept a filing for review until the filing is complete.

(2) Filings requiring approval. After the issuance of a certificate of authority, an HCC must file for approval with the commissioner a written request to implement or modify the following operations or documents and receive the commissioner's approval prior to effectuating those modifications:

(A) a description and a map of the service area, with key and scale, that identifies the county, counties, or portions of counties to be served;

(B) any material change in size, composition, or control of the HCC;

(C) proposed dividends for any calendar year that if declared and paid will, individually and in the aggregate, have a distribution value equal to or exceeding the greater of:

(i) 10 percent of the HCC's net asset value for the prior year; or

(ii) 10 percent of the HCC's net income for the prior year;

(D) any new or revised loan agreements evidencing loans made by the HCC to any affiliated individual or entity or to any physician or health care provider, whether providing services currently, previously, or potentially in the future; and any guarantees of any affiliated individual's or entity's or of any physician's or health care provider's obligations to any third party;

(E) a copy of any proposed material amendment to basic organizational documents; however, if the approved amendment must be filed with the secretary of state, an original or a certified copy of the document with the original file mark of the secretary of state must be filed with the commissioner;

(F) a copy of any material amendments to bylaws of the HCC, with a notarized certification bearing the original or electronic signature of the corporate secretary of the HCC that it is a true, accurate, and complete copy of the original;

(G) any name, or assumed name, on a form, as specified in §13.404 of this title (relating to Use of the Term "HCC;" Service Mark; Trademarks; d/b/a);

(H) original or renewal service contracts and management agreements, the terms of which must comply with Insurance Code §823.101 as if the HCC were an insurer; and

(I) any proposed new or revised payment methodology for use in any contract between the HCC and any payor that addresses the applicant arranging for medical and health care services for the payor in exchange for payments in cash or in kind as provided in Insurance Code Chapter 848.

(3) Filings for information. Material filed under this paragraph is not to be considered approved, but may be subject to review for compliance with Texas law and consistency with other HCC documents. On or before 30 days after the effective date of a change, an HCC must file with the commissioner, for information only, deletions and modifications to the following previously approved or filed operations and documents:

(A) the list of officers and directors, a biographical data sheet for each individual listed on the officers and directors page, and biographical affidavit forms in §13.413(c)(6)(A) and (B) of this title (relating to Contents of the Application);

(B) any change in the physical address of the books and records described in §13.415 of this title (relating to Documents to be Available for Quality of Care and Financial Examinations);

(C) any new trademark or service mark or any changes to an existing trademark or service mark;

(D) a copy of the form of any new contract or subcontracts or any substantive changes to previously filed copies of forms of all contracts described in §13.413(d)(3) and (e)(5) of this title, not including management agreements or proposed new or revised payment methodologies filed for approval, with amended contract forms accompanied by an additional copy of the contract form that reflects the revisions made;

(E) notice of the cancellation of any management contracts described in §13.413(e)(5)(D) of this title;

(F) any insurance contracts or amendments to those contracts, guarantees, or other protection against insolvency, including the stop-loss or reinsurance

agreements, if changing the insurer or description of coverage, as described in §13.413(d)(4)(A) of this title;

(G) any change in the affiliate chart as described in §13.413(c)(7) of this title;

(H) modifications to any types of compensation arrangements, such as compensation based on fee-for-service arrangements, risk-sharing arrangements, prepaid funding arrangements, or capitated risk arrangements, made or to be made with physicians and health care providers in exchange for the provision of, or the arrangement to provide, health care services to patients, including any financial incentives for physicians and providers. The HCC must maintain the confidentiality of these compensation arrangements;

(I) any material change in network configuration; and

(J) a description of the quality assurance and quality improvement program, as set forth in §13.481 and §13.482 of this title (relating to Quality Improvement Structure for HCCs and Quality Assurance and Quality Improvement, respectively).

(4) Approval period. Any modification for which commissioner's approval is required is considered approved unless disapproved within 60 days from the date the filing is determined by the department to be complete. The commissioner may postpone the action for a period not to exceed 60 days, as necessary for proper consideration. The commissioner will notify the HCC by letter of any postponement. The commissioner, after notice and opportunity for hearing, may withdraw approval of a filing made under

paragraph (2) of this subsection or reject any informational filing made under paragraph (3) of this subsection.

(5) Filing review procedure. Within 20 days from the department's receipt of an initial filing for commissioner's approval under this section, the department will determine whether the filing is complete or incomplete for purposes of acceptance for review and, if found to be incomplete, the department will issue a written notice in paper or electronic form to the HCC of its incomplete filing.

(A) Incomplete filing. The written notice of an incomplete filing will state that the filing is not complete and has not been accepted for review. In addition, the notice will specify the information, documentation, and corrections necessary to make the filing complete for purposes of this section. If a filing is resubmitted in whole or in part and is still incomplete, an additional written notice will be issued. The notice will specify the corrections or information necessary for completeness and state that the 60-day period for official action will not begin until the date the department determines the filing to be complete. If a filing is not resubmitted within 30 days of the date of the written notice of incompleteness, the department will consider the filing withdrawn and will close it.

(B) Processing of complete filing. The department will in writing approve or disapprove a complete filing within the period of time set forth in paragraph (4) of this subsection, beginning on the date the filing is determined to be complete. The HCC may waive in writing the deemed approval time line set forth in paragraph (4) of this subsection.

(C) Conversion to renewal review. If the filing by the HCC under this subsection is sufficiently material, the department may require the HCC to file an application for renewal before the date required by Insurance Code §848.060(a).

§13.423. Service Area Change Applications.

(a) An HCC must file an application for approval with the department before the HCC may expand or reduce an existing service area or add a new service area.

(b) If any of the following items are changed by a proposed service area expansion or reduction, the new item or any amendments to an existing item must be submitted for approval or filed for information, as specified in §13.422 of this title (relating to Filing Requirements That Apply After Issuance of Certificate of Authority):

(1) a description and a map with key and scale, showing both the currently approved service area and the proposed new service area as required by §13.413(e)(1) of this title (relating to Contents of the Application);

(2) a form of any new contracts or amendment of any existing contracts in the new area, as described in §13.413(e)(5) of this title;

(3) network configuration information, as required by §13.413(e)(2) of this title;

(4) a brief narrative description of the administrative arrangements and organizational charts as described in §13.413(c)(7) of this title and any other information the HCC considers to be pertinent;

(5) biographical data sheets for any new management staff assigned to the

new area;

(6) copies of leases, loans, agreements, and contracts to be used in the proposed new area, including information described in §13.422(c)(2)(D) of this title;

(7) separate and combined sources of financing and financial projections as described in §13.413(d)(1) – (3) of this title; and

(8) any new or amended reinsurance agreements, insurance, or other protection against insolvency, as specified in §13.413(d)(4) of this title.

(c) The department will not accept an application for review until the application is complete. An application to modify the certificate of authority is considered complete when all information required by §13.422 of this title, this section, and §13.481 and §13.482 of this title (relating to Quality Improvement Structure for HCCs and Quality Assurance and Quality Improvement, respectively), that is reasonably necessary for a final determination by the department has been filed with the department.

(d) A service area expansion or reduction application will be considered only if both the existing and proposed service areas of the HCC comply with the requirements of §13.481 and §13.482 of this title, and §13.483 of this title (relating to Credentialing).

(e) If the filing for proposed service area change might materially affect the HCC's ability to arrange for or provide health care services, or might materially change the antitrust analysis of the HCC, the department may require the HCC to file an application for renewal before the date required by Insurance Code §848.060(a).

§13.424. Certificate of Authority Renewal Requirements.

(a) Not later than 180 days before its certificate anniversary date, the HCC must file with the commissioner an application to renew its certificate.

(b) The filing must include:

(1) the Original/Renewal Application for Certificate of Authority to do the Business of a Health Care Collaborative (HCC) in the State of Texas form; and

(2) the financial statements for the HCC, as of the close of the preceding calendar year.

(c) For purposes of this section, an HCC is not required at renewal to make a duplicate filing of any document or information item specified to be and filed as part of the original application for certificate of authority under §13.413 of this title (relating to Contents of the Application) that has not been amended, modified, revised, canceled, terminated, replaced, or otherwise changed since the original or most recent renewal certificate of authority was issued. A transmittal form specifically identifying the documents and items that have not changed since the original or most recent renewal certificate of authority was issued must be filed as a part of the renewal application and accompanied by an attestation executed by an officer or other authorized representative of the HCC certifying that the documents and items identified in the transmittal form have not changed.

(d) The provisions of subsection (c) of this section also apply to the duplicate filing of any document or information item specified to be and filed pursuant to provisions of §13.422 of this title (relating to Filing Requirements That Apply After Issuance of Certificate of Authority) that has not changed since its filing was approved or accepted by the department, as applicable.

(e) The department will accept for review an application for renewal when the filing is complete.

(1) The department will send written notice of an incomplete initial filing within 20 days of the filing, stating that the filing is not complete and has not been accepted for review.

(2) The notice must specify the information, documentation, and corrections necessary to make the filing complete.

(f) If a completed application for renewal is filed under Insurance Code §848.060 and this section, the commissioner will conduct a review and take official action on the completed application in accord with the provisions of Insurance Code §848.060. The review will be conducted under Insurance Code §848.057 as if the application for renewal were a new application.

§13.425. Compensation Arrangements.

(a) An HCC must comply with Insurance Code §848.053, including requirements relating to committee membership, charges, fees, distributions, or other compensation assessed for services provided by HCC participants, and to the sharing of the data among nonparticipating physicians and health care providers.

(b) An HCC must establish and enforce procedures to maintain the confidentiality of charge, fee, and payment data and information between HCC participants and any individual or entity outside of the HCC, including information to be transmitted to the department.

(c) A participant in an HCC is prohibited from using charge, fee, and payment data collected by the HCC in any negotiation of charges, fees, or payments if the HCC is not a party to the negotiation.

§13.426. Confidentiality.

(a) An HCC must establish and administer procedures and internal controls to safeguard and ensure against the sharing of any confidential information with or among participants.

(b) The requirements of this section include establishing and enforcing collection, custodial, retrieval, and transmittal procedures to ensure that information that the HCC or its participants must maintain as confidential is protected as confidential both as to entities and individuals outside the HCC, and between or among participants. The requirements of this section apply to confidential information that:

(1) the HCC maintains as custodian; or

(2) the HCC or any of its participants submit to the department under Insurance Code §848.057 or to the attorney general under Insurance Code §848.059.

§13.429. HCCs Subject to Insurance Code Chapters 541 and 542 and Related Rules.

HCCs must comply with Insurance Code Chapters 541 and 542, and rules promulgated by the department pursuant to Insurance Code Chapters 541 and 542, as applicable, in the same manner as insurance companies or HMOs.

DIVISION 4. FINANCIAL REQUIREMENTS

§13.431. Reserves and Working Capital Requirements.

(a) An HCC must maintain working capital composed of current assets with a ratio of current assets to current liabilities of 1.25:1, based on the greater of the prior year's actual liabilities or the projected liabilities for the subsequent year, subject to the following requirements, as applicable:

(1) an HCC consisting of physicians and one or more facilities must maintain unencumbered net equity of not less than $200,000; and

(2) an HCC must base its ratio of assets to liabilities on the projected liabilities for the subsequent year if the HCC has not been certified for more than one year.

(b) An HCC must have reserves sufficient to operate and maintain the HCC and to arrange for services and expenses it incurs. An HCC must maintain financial reserves computed in accord with Generally Accepted Accounting Principles in an amount not less than 100 percent of incurred but not paid claims of nonparticipating physicians and providers.

(c) Any HMO or insurer certified by the department that forms an HCC pursuant to Insurance Code §848.001(2)(C)(iii) and (iv) or enters into a contract with an HCC pursuant to Insurance Code §848.103 must maintain a reserve that is:

(1) equivalent in value to three months of prepaid funding or capitation payments;

(2) phased in over a no-more-than 36-month period;

(3) maintained separately from and in addition to all other reserves and liabilities of the HMO or insurer;

(4) unencumbered and dedicated to assure its availability for its intended purpose; and

(5) reported in the aggregate separately from all other reserves and liabilities of the HMO or insurer.

(d) For the purpose of meeting the minimum working capital requirements of this section, current assets of an HCC are limited to U.S. currency, certificates of deposit with fixed terms of one year or less, money market accounts, accounts receivable from government payors, and other accounts receivable that have remained due 90 days or less. Accounts receivable must be reported net of all allowances. Assets with a maturity period or fixed term that is greater than one year are not current assets for purposes of this section.

(e) For the purpose of meeting the minimum reserve and minimum net equity requirements of this section, investments in capital assets, mortgages, notes, and loan-backed securities must be excluded from the calculation of reserves and net equity in determining satisfaction of minimum requirements.

§13.432. Fiduciary Responsibility. A director, member of a committee, officer, or representative of an HCC who is charged with the duty of handling or investing its funds is prohibited from intentionally:

(1) depositing or investing the funds, except in the corporate name of the HCC or in the name of a nominee of the HCC as may be allowed elsewhere in this subchapter; or

(2) taking or receiving to his or her own use any fee, brokerage, or commission for, or on account of, a loan made by or on behalf of the HCC, except that the individuals referenced in this section may receive reasonable interest on amounts loaned to the HCC.

DIVISION 5. HCC CONTRACT ARRANGEMENTS

§13.441. General Provisions.

(a) An HCC's contracts with physicians and health care providers must not impede application of provisions in Insurance Code Chapters 843 (Health Maintenance Organizations) and 1301 (Preferred Provider Benefit Plans), and in Chapter 11 of this title (relating to Health Maintenance Organizations) and Chapter 3, Subchapter X of this title (relating to Preferred and Exclusive Provider Plans), that impose requirements concerning relations with physicians or health care providers.

(b) An HCC is prohibited from using a financial incentive or making a payment to a physician or health care provider if the incentive or payment acts directly or indirectly as an inducement to limit medically necessary services.

(c) If an HCC participant's market share as calculated under §13.414 of this title (relating to Limited Exemption from Certain Information Filing Requirements) exceeds 50 percent in a PSA for any service that no other HCC participant provides to patients in that

PSA, the participant furnishing the service is a dominant provider for purposes of this subchapter. An HCC with a dominant provider is prohibited, in the PSA in which the dominant provider furnishes those services, from:

(1) requiring a private payor to contract exclusively with the HCC; or

(2) otherwise restricting a private payor's ability to contract or deal with other HCCs, networks, physicians, or health care providers.

DIVISION 6. CHANGE OF CONTROL BY ACQUISITION OF OR MERGER WITH HCC

§13.451. Definitions. The following words and terms, for purposes of this division, have the following meanings unless the context clearly indicates otherwise.

(1) Control--The possession, direct or indirect, of the power to direct or cause the direction of the management and policies of an individual or entity, whether through the ownership of voting securities, by contract other than a commercial contract for goods or nonmanagement services, or otherwise, unless the power is the result of an official position with or corporation office held by an individual.

(2) Voting security--Any security presently entitling its owner or holder to vote in the direction or management of the affairs of an individual or entity, or any instrument presently convertible by its owner or holder into a voting security, or the right to acquire a voting security.

§13.452. Determination of Control. For purposes of this division:

(1) control is presumed to exist if any individual or entity, directly or

indirectly, owns, controls, holds with the power to vote or holds irrevocable proxies representing, 10 percent or more of the voting securities or authority of any other individual or entity;

(2) this presumption may be rebutted by a showing made in the manner provided by Insurance Code §823.010 that control does not exist in fact; and

(3) the commissioner may determine, after furnishing all interested parties notice and opportunity for hearing and making specific findings of fact to support the determination, that control exists in fact where an individual or entity exercises directly or indirectly, either alone or pursuant to an agreement with one or more other individuals or entities, such a controlling influence over the management or policies of an authorized HCC as to be deemed to control the HCC.

§13.453. Filing Requirements.

(a) Unless an individual or entity has filed with the department the items as set forth in subsection (b) of this section, the individual or entity is prohibited from:

(1) acquiring an ownership interest in an entity that holds a certificate of authority as an HCC if the individual or entity is, or after the acquisition would be, directly or indirectly in control of the certificate holder; or

(2) otherwise acquiring control of or exercising any control over the certificate holder.

(b) An individual or entity described in subsection (a) of this section must, under oath or affirmation, file:

(1) a Biographical Affidavit form for each individual by whom or on whose behalf the acquisition of control is to be effected; and

(2) a Health Care Collaborative (HCC) Acquisition Form.

(c) The department may require a partnership, syndicate, or other group that is subject to the filing requirements specified in subsections (a) and (b) of this section to provide the information required by subsection (b) of this section for each partner of the partnership, each member of the syndicate or group, and each individual or entity who controls the partner or member.

(d) If the partner, member, or entity is a corporation, or if the entity required to file the documents set forth in subsection (b) of this section is a corporation, the department may require that the information under that subsection be provided regarding:

(1) the corporation;

(2) each individual who is an executive officer or director of the corporation; and

(3) each individual or entity who is directly or indirectly the beneficial owner of more than 10 percent of the outstanding voting securities of the corporation.

§13.454. Commissioner Action.

(a) A proposed acquisition of control will be disapproved if, after notice and opportunity for hearing, the commissioner determines that:

(1) immediately following the change of control, the certificate holder would not be able to satisfy the requirements for the issuance of a certificate of authority;

(2) the competence, trustworthiness, experience, and integrity of the individuals who would control the operation of the certificate holder are such that it would not be in the interest of health care services consumers in this state to permit the acquisition of control; or

(3) the acquisition of control would violate this code or another law of this state, any law of another state, or of the United States.

(b) Notwithstanding subsection (a) of this section, a change in control is considered approved if the commissioner has not, before the 61st day after the date on which the department receives all information required by this division:

(1) acted on the proposed change of control; or

(2) required that the HCC file an application for renewal as a result of the proposed change of control.

§13.455. Change of Control with Increased Market Share. For any change in control of an authorized HCC that results in an increase to its market share in any PSA as provided in §13.414 of this title (relating to Limited Exemption from Certain Information Filing Requirements), the department may require that the HCC file an application for renewal before the date required by Insurance Code §848.060(a). An HCC may, in connection with a filing under this division, submit an application for renewal of certificate of authority.

DIVISION 7. ADMINISTRATIVE PROCEDURES

§13.461. Commissioner's Authority to Require Additional Information.

(a) The commissioner may require additional information from the HCC or any participant in the HCC as reasonably necessary to make any determination required by Insurance Code Chapter 848, this subchapter, and applicable insurance laws and regulations of this state.

(b) The commissioner may require any or all of the additional information set forth in subsection (c) of this section. An HCC or HCC participant is not required to create the items listed in subsection (c) of this section unless and except as the commissioner requires the items to be provided under this section. Once created, the documents must be maintained by the HCC or participant for at least five years.

(c) Additional information the commissioner may require includes the following:

(1) underlying documentation or data supporting any information, reports, or memoranda submitted to the department under the Insurance Code or this title;

(2) contact information for current participants or employees of the HCC, and last known contact information for former participants or employees;

(3) interviews by the department with individuals affiliated with the HCC or HCC participants;

(4) any participant's agendas, minutes, recordings, summaries, handouts, or presentations to the HCC;

(5) documents relating to past, current, or planned fees, risk-sharing, fee schedules, fee conversion factors, withholds, capitation, pricing plans, pricing strategies, or other forms of payment;

(6) documents relating to planned additions to the participation in the HCC

or expansions of participants in the HCC;

(7) de-identified information regarding utilization of services by the HCC's patients or participants, including both medical and financial information;

(8) current bylaws, rules, or regulations of an HCC participant's professional staff or any of its departments or subunits;

(9) questionnaires submitted by participants to applicable professional associations in connection with annual surveys of association members, and to any other association, accreditation agency, or government agency, in connection with any annual or other periodic survey of the participant;

(10) reports prepared by accreditation agencies in connection with accreditation of the HCC or any HCC participant;

(11) revenue-and-cost reports, profitability reports, and other financial reports;

(12) internal or external reports relating to quality of care at any health care service location in each service area by the HCC or its participants, including:

(A) data or reports submitted to or received from or by quality rating organizations;

(B) quality-of-care initiatives;

(C) quality assurance or quality improvement systems; and

(D) the effect of changes in health care service location quality on patient volume and revenue;

(13) financial reports regularly prepared by or for the HCC applicant on any

periodic basis relating to any arranged health care service;

(14) memoranda, excluding engineering and architectural plans and blueprints, relating to plans of the HCC applicant, or any participant, for the construction of new facilities, the closing of any existing facilities, or an expansion, a conversion, or a modification of current facilities;

(15) memoranda relating to plans of, or steps undertaken by the HCC applicant or any participant for any acquisition, divestiture, joint venture, alliance, or merger involving any participant in the service area other than the application for certificate of authority of the applicant;

(16) memoranda analyzing or discussing the effect of any merger, joint venture, acquisition, or consolidation of HCCs in the applicant's service area, including the HCC's application if approved, on the HCC's prices, costs, margins, service quality, or any other aspect of competitive performance, including:

(A) memoranda comparing the actual cost savings or other benefits of the transactions to those previously projected; and

(B) memoranda discussing how the benefits were or might be achieved;

(17) a description relating to the consolidation or realignment of any medical and health care services arranged by or through the applicant whether completed, in progress, or planned among the participants;

(18) the names and addresses of all contracting physicians, in Excel-compatible format;

(19) documents created or used by, for, or on behalf of the applicant for the purpose of soliciting physicians or health care providers to join the applicant as an employee or participant, promoting continued participation in the applicant, or otherwise offering, promoting, or advertising the applicant's services or activities on behalf of physicians or health care providers, and all documents supplied by the HCC to newly recruited physicians or health care providers;

(20) contracts between the HCC applicant or any of its participants and any private payor, all attachments to the contracts, and all documents relating to the contracts, including:

(A) documents sufficient to show the name, contact person, and telephone number of each health plan contracting with the applicant for physician services;

(B) documents relating to fees, fee schedules, fee conversion factors, withholds, capitation, pricing plans, pricing strategies, or other forms of payment;

(C) documents discussing actual or potential negotiations, offers, or responses to any contract, fee schedule, or risk-sharing arrangement with a third-party payor;

(D) copies of internal memoranda relating to:

(i) the development or negotiation of contracts with payors or participants, and internal HCC decisions regarding negotiating positions;

(ii) competition to obtain contracts;

(iii) decisions to terminate contracts;

(iv) draft, contingent, or expired contracts, including contracts not entered into, not yet finalized or in force, or no longer in force; and

(v) contract amendments or modifications; and

(E) the beginning date and termination date, as applicable, for each contract;

(21) documents relating to plans, interests, or steps undertaken by the HCC applicant for any acquisition, divestiture, joint venture, alliance, collaboration, license, or merger with any HCC or other health care provider, including:

(A) any notes or minutes taken; or

(B) reports, memoranda, or correspondence regarding meetings between the HCC applicant and any other HCC or other health care provider;

(22) documents reflecting:

(A) actual or planned lease, management contract, or other agreement for the HCC applicant to operate a facility in the service area that is, or will be, owned in whole or in part by another individual or entity; and

(B) formal or informal commercial or operational relationships or affiliations that have existed, exist, or are planned between or among any facilities, or facilities and any physician organizations in the service area, including purchases by the HCC applicant of services from other facilities or from physician organizations, and vice versa;

(23) for each participant, summaries and interpretations of contract terms

and methodologies used to determine the payment due to the participant under a contract with a payor in effect at any time during the previous three years for each treatment, office visit, or other medical or health care service provided or delivered in the service area;

(24) a list and description by Current Procedural Technology code, if available, of each medical or health care service arranged by or through the applicant in the HCC's service area, and for each code listed, a statement of:

(A) the number of procedures performed;

(B) the amount of revenue received by the applicant;

(C) the ZIP code for each patient receiving the procedure or service; and

(D) the location of the office where the procedure or service was performed; and

(25) documents reflecting participants' contribution margins or identifying or quantifying fixed or variable costs for the provision of any health care service in the service area.

DIVISION 8. OTHER REQUIREMENTS

§13.471. Notification of Change in Payment Arrangements. An HCC must notify all affected payors in writing of a material change in the payment arrangement for physicians, health care providers, or both within 30 days of any change in the type of payment arrangement for any type of service (for example, from capitation to fee-for-service, from fee-for-service to capitation). The notification of the change must include a description of

the payment arrangement that has been changed and a description of the new payment arrangement.

§13.472. Requirements for Certain Delegation Contracts. An HCC that delegates responsibility by contract with a delegated entity, delegated network, or delegated third party, as those terms are defined in Insurance Code §1272.001 through reference to contracts with HMOs, must:

(1) submit to the department a monitoring plan setting out how the HCC will ensure that all delegated HCC functions are implemented in a manner consistent with full compliance by the HCC with all regulatory requirements of the department;

(2) conduct an on-site or desk audit of the delegated entity, delegated network, or delegated third party no less frequently than annually, or more frequently on indication of material noncompliance, to obtain information necessary to verify compliance with all regulatory requirements of the department. Written documentation of each audit required by this paragraph must be made available to the department on request; and

(3) take prompt action to correct any failure by the delegated entity, delegated network, or delegated third party to comply with regulatory requirements of the department relating to any matters delegated by the HCC and necessary to ensure the HCC's compliance with the regulatory requirements.

§13.473. Organization of an HCC.

(a) The governing body, which must comply with the requirements described in

Insurance Code §848.052, must have ultimate responsibility for the development, approval, implementation, and enforcement of administrative, operational, personnel, and patient care policies and procedures related to the operation of the HCC.

(b) The HCC must have a clinical director who:

(1) is currently licensed in Texas or otherwise authorized to practice in this state in the field of services offered by the HCC;

(2) resides in Texas;

(3) is available at all times to address complaints, clinical issues, utilization review, and any quality-of-care issues on behalf of the HCC;

(4) demonstrates active involvement in all quality management activities; and

(5) is subject to the HCC's credentialing requirements, as appropriate.

(c) The HCC may establish one or more service areas within Texas. For each defined service area, the HCC must:

(1) provide a delivery network that is adequate and complies with Insurance Code Chapter 848, and demonstrate to the department the ability to provide continuity, accessibility, availability, and quality of services that the HCC has contracted or will contract to provide within the HCC's service area, including the following, as applicable:

(A) participants that are sufficient in number, size, and geographic distribution to be capable of furnishing the contracted health care services, taking into account the number of potential patients, their characteristics, and their medical and health care needs, including the following:

(i) current utilization of covered health care services within the prescribed geographic distances outlined in this section; and

(ii) projected utilization of covered health care services;

(B) an adequate number of participants available and accessible to patients 24 hours a day, seven days a week;

(C) sufficient numbers and classes of participants to ensure choice, access, and quality of care;

(D) an adequate number of participating physicians who have admitting privileges at one or more participating hospitals to make any necessary hospital admissions;

(E) emergency care that is available and accessible 24 hours a day, seven days a week;

(F) services sufficiently available and accessible as necessary to ensure that the distance from any point in the HCC's designated service area to a point of service is not greater than:

(i) 30 miles in nonrural areas and 60 miles in rural areas for primary care and general hospital care; and

(ii) 75 miles for specialty care and specialty hospitals;

(G) urgent care available and accessible within 24 hours for health and behavioral health conditions;

(H) routine care available and accessible:

(i) within three weeks for health conditions; and

(ii) within two weeks for behavioral health conditions;

(I) preventive health services available and accessible:

(i) within two months for a child, or earlier if necessary for compliance with nationally recognized recommendations for specific preventive care services; and

(ii) within three months for an adult;

(2) specify the counties and ZIP codes, or any portions of any counties, included in the service area; and

(3) maintain separate cost center accounting for each service area to facilitate the reporting of divisional operations as required for HCC financial reporting.

(d) The HCC must maintain in force in its own name a fidelity bond on its officers and employees.

(1) The fidelity bond must be in an amount of at least $100,000, or another amount prescribed by the commissioner, and issued by an insurer that holds a certificate of authority in this state.

(2) The fidelity bond must obligate the surety to pay any loss of money or other property the HCC sustains because of an act of fraud or dishonesty by an employee or officer of the HCC, acting alone or in concert with others, while employed or serving as an officer of the HCC.

(3) Subject to the same coverage amount and conditions required for a fidelity bond under this subsection, an HCC may, instead of obtaining a fidelity bond:

(A) obtain and maintain in force in its own name insurance coverage in a form and amount acceptable to the commissioner; or

(B) deposit with the Texas Comptroller of Public Accounts readily marketable liquid securities acceptable to the commissioner.

§13.474. Requirements for HMO or Insurer Delegation of Functions to HCCs.

(a) An HMO's delegation of functions to an HCC is subject to the requirements of Insurance Code Chapter 1272 and Chapter 11, Subchapter AA of this title (relating to Delegated Entities).

(b) An insurer's delegation of functions to an HCC is subject to the requirements of Insurance Code Chapter 1272 and Chapter 11, Subchapter AA of this title as if the insurer were an HMO.

(c) If a provision of this subchapter imposes a compliance requirement that is greater than or in conflict with those contained in Insurance Code Chapter 1272 or Chapter 11, Subchapter AA of this title, the requirement of this subchapter governs.

(d) A delegation agreement between an HMO or insurer and an HCC must mandate that the HMO or insurer disclose in all provider listings distributed to insureds or enrollees those providers participating in the HCC within the HMO's or insurer's approved service area.

(e) If an insurer contracts for services with an HCC on a basis other than fee-for-service, the insurer must disclose the nature of its payment arrangement with the HCC in either the insurance policy and certificates or in any provider listing distributed to insureds.

DIVISION 9. QUALITY AND COST OF HEALTH CARE SERVICES

§13.481. Quality Improvement Structure for HCCs.

(a) An HCC must develop and maintain an ongoing quality improvement (QI) program designed to objectively and systematically monitor and evaluate the quality and appropriateness of health care services that it arranges for or offers, and to pursue opportunities for improvement. Unless the HCC has no patients, the QI program must include the active involvement of one or more patient(s) who are not employees of the HCC.

(b) The governing body is ultimately responsible for the QI program. The governing body must:

(1) appoint a quality improvement committee (QIC) that includes the clinical director, practicing physicians, and, if applicable, other individual health care providers;

(2) approve the QI program;

(3) approve an annual QI plan;

(4) meet no less than semiannually to receive and review reports of the QIC or group of committees and take action when appropriate; and

(5) review the annual written report on the QI program.

(c) The QIC must evaluate the overall effectiveness of the QI program.

(1) The QIC may delegate QI activities to other committees that may, if applicable, include practicing physicians and individual health care providers and patients from the service area.

(A) All committees must collaborate and coordinate efforts to improve the quality, availability, and accessibility of health care services.

(B) All committees must meet regularly and report the findings of each meeting, including any recommendations, in writing to the QIC.

(C) If the QIC delegates any QI activity to any subcommittee, then the QIC must establish a method to oversee each subcommittee.

(2) The QIC must use multidisciplinary teams when indicated to accomplish QI program goals. For example, an HCC could include only a narrow range of specialty health care services, making the use of multidisciplinary teams impractical.

§13.482. Quality Assurance and Quality Improvement.

(a) An HCC must establish, implement, and administer a continuous quality assurance and quality improvement program that includes defined policies and processes to:

(1) promote evidence-based medicine and best practices;

(2) secure patient engagement;

(3) promote coordination of care across a continuum of care; and

(4) measure and report the quality of health care services and the impact on cost.

(b) Unless otherwise approved by the commissioner, the program must include:

(1) appropriate practice evaluation tools applicable to the services provided by the HCC, including:

(A) Consumer Assessment of Healthcare Providers and Systems surveys developed by the Agency for Healthcare Research and Quality;

(B) Agency for Healthcare Research and Quality standards, as available; and

(C) National Quality Forum-endorsed standards;

(2) periodic review; and

(3) policies for coordinating with the HCC's quality improvement committee to make necessary updates and adjustments.

(c) The patient engagement process must include, as appropriate:

(1) evaluating the health needs of its enrolled population;

(2) communicating clinical knowledge to patients and patient representatives clearly and understandably;

(3) promoting patient engagement, including engagement in treatment decisions; and

(4) establishing written standards for patient communications.

(d) The processes to promote coordination of care across a continuum of care must include, as appropriate:

(1) a method or system to identify high-risk individuals; and

(2) processes to manage care throughout an episode of care and during transitions.

(e) The processes for measuring and reporting quality of health care services and impact on cost must include:

(1) measurement and evaluation of health care services and processes described in subsection (a)(1) – (3) of this section; and

(2) as appropriate, a process for medical peer review and arrangements for sharing pertinent medical records between participants and ensuring the record's confidentiality.

§13.483. Credentialing. An HCC must implement a documented process for selection and retention of contracted participants. The credentialing process must comply with the standards promulgated by the National Committee for Quality Assurance, URAC, the Joint Commission on Accreditation of Hospital Organizations, or the Accreditation Association for Ambulatory Health Care, as appropriate, to the extent that those standards are applicable and do not conflict with other laws of this state.

DIVISION 10. COMPLAINT SYSTEMS; RIGHTS OF PHYSICIANS; LIMITATIONS ON PARTICIPATION

§13.491. Complaint Systems.

(a) Each HCC must implement and maintain a complaint system that complies with Insurance Code §848.107 and this division that provides reasonable procedures for resolving an oral or written complaint initiated by a complainant concerning the HCC or health care services arranged by, or offered through, the HCC.

(b) For purposes of this subchapter, a complaint is any oral or written expression of dissatisfaction by a complainant to an HCC regarding any aspect of the HCC's operation.

(c) The HCC's complaint system must address a complaint initiated:

(1) by or on behalf of a patient who sought or received health care services by a participant; or

(2) by a participant.

(d) The complaint system for complaints initiated by or on behalf of patients must include a process for the notice and appeal of a complaint.

(e) The commissioner has discretion to examine a complaint system for compliance with Insurance Code §848.107 and this subchapter and will require the HCC to make corrections that the commissioner considers necessary.

§13.492. Complaints; Deadlines for Response and Resolution.

(a) Not later than seven calendar days after receipt of an oral or written complaint, the HCC must:

(1) acknowledge receipt of the complaint in writing;

(2) acknowledge the date of receipt; and

(3) provide a description of the HCC's complaint procedures, its appeal process for complaints filed by patients, and deadlines associated with each.

(b) An HCC must investigate each complaint received in accord with the HCC's policies and in compliance with Insurance Code §848.107 and this subchapter.

(c) After an HCC has investigated a complaint, the HCC must issue a resolution letter to the complainant not later than the 30th calendar day after the HCC receives the written complaint or the close of any hearing held under §13.493(2) of this title (relating to Rights of Physicians) that:

(1) explains the HCC's resolution of the complaint;

(2) states the specific reasons for the resolution;

(3) states the specialization of any health care provider consulted; and

(4) states, if the complainant is a patient who is dissatisfied with the resolution of the complaint, that the complainant may file an appeal of the complaint resolution, or may file a complaint with the department.

(d) In situations in which a patient complaint has been appealed, the HCC must issue a decision letter after considering the appeal that includes specific reasons for the decision and states that if the complainant is dissatisfied with the resolution of the complaint, the appeal, or the complaint process, the complainant may file a complaint with the department.

(e) An HCC must maintain a complaint log that captures each complaint by category, including at least the following:

(1) quality of care or services;

(2) accessibility and availability of services, providers, or both;

(3) complaint procedures;

(4) physician and provider contracts;

(5) claims processing and bill payment disputes; and

(6) miscellaneous.

(f) Each HCC must maintain the complaint log required under subsection (e) of this section and documentation on each complaint, complaint proceeding, and action taken on the complaint until the third anniversary after the date the complaint was received.

§13.493. Rights of Physicians. Before a complaint against a physician under Insurance Code §848.107 is resolved, or before a physician's association with an HCC is involuntarily terminated, the HCC must provide the physician an opportunity to dispute the complaint or termination through a process that includes:

(1) written notice of the complaint or basis of the termination;

(2) opportunity for hearing not earlier than the 30th day after the physician receives notice under paragraph (1) of this section;

(3) the right to provide information at the hearing; and

(4) a written decision that includes specific facts and reasons for the decision.

§13.494. Limitations and Prohibition.

(a) An HCC may limit a physician or physician group from participating in the HCC only if the limitation is based on an established development plan approved by the HCC board of directors. The HCC must provide each applicant physician or group with a copy of the development plan.

(b) An HCC is prohibited from taking a retaliatory or adverse action against a physician or health care provider that files a complaint with a regulatory authority regarding the action of an HCC.

CERTIFICATION. This agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on March 11, 2013.

Sara Waitt, General Counsel
Texas Department of Insurance

The commissioner adopts new §§13.401–13.404, 13.411–13.417, 13.421–13.426, 13.429, 13.431–13.432, 13.441, 13.451–13.455, 13.461, 13.471–13.474, 13.481–13.483, and 13.491–13.494.

Eleanor Kitzman
Commissioner of Insurance

Commissioner's Order No. 2363
MAR 11 2013