STATE OF WASHINGTON
DEPARTMENT OF HEALTH
PO Box 47890, Olympia, Washington 98504-7890
Tel: (360) 236-4030 FAX: (360) 586-7424 TDD Relay Service: 1-800-833-6388

October 21, 2013

TO: The Honorable Jay Inslee
Governor

FROM: John Wiesman, DrPH, MPH
Secretary of Health

SUBJECT: Directive of the Governor 13-12

This directive instructed us to open rulemaking to review the Certificate of Need program's rules about when changes in the control of a hospital should require Certificate of Need review. You instructed us to consider ways to improve access for consumers to hospital policies on non-discrimination, end of life care, and reproductive health care services. You also instructed us to report on our progress to date by October 31, 2013.

Summary of Progress – On October 17, 2013, we filed the attached proposed rule language to change the Certificate of Need rules to define sale, purchase, or lease to include those types of transactions that result in a change of "control" of a hospital. Examples of these transactions include affiliations, mergers, and corporate restructuring. We also propose to change our hospital licensing rules to require hospitals to submit admission, non-discrimination, end of life care, and reproductive health care services policies for posting on our website. To increase consumer access to these policies, hospitals would also be required to post these same policies to their own websites. We have set a November 26, 2013, rules hearing in Tumwater for these proposed changes. We intend to adopt final rules December 10, 2013.

Background – The directive instructed us to start rulemaking in an expeditious and efficient manner, consistent with the processes in Chapter 34.05 RCW. As part of this rulemaking, we were to consider how the structure of affiliations, corporate restructuring, mergers, and other arrangements among health care facilities result in outcomes similar to the traditional methods of sales, purchasing, and leasing of hospitals. The directive suggested the Certificate of Need process should be applied based on the effect that these transactions have on the accessibility of health services, cost containment, and quality, rather than on the terminology used in describing the transactions or the representations made in the preliminary documents.

The directive also instructed us to consider ways to improve transparency for consumers to information and ease of use. Specifically, we must ensure hospitals supply non-discrimination, end of life care, and reproductive health care policies; and we must ensure that consumers have access to the policies on our webpage. Our rulemaking process must consider the factors in RCW 43.06.155, and principles and policies guiding the implementation of health care reform, including the guarantee of choice for patients.

In July 2013 we circulated a concept draft of proposed changes to the Certificate of Need rules. This draft adds a definition for sale, purchase, or lease that included any change in control of the hospital. The draft requires hospitals to provide us with admission, non-discrimination, end of life, and reproductive health care services policies. These policies would be posted on our website as well as the hospital's website. If services are limited or unavailable because of any of its policies, the hospital would be required to submit a listing of those services for posting on our website.

On August 5 we held a stakeholder workshop to discuss the rulemaking project, which was well attended. The attendees included legislative committee staff, associations, labor unions, health care professionals, Department of Social and Health Services staff, consultants, advocacy organizations, and private citizens. Comments received at the workshop were carefully considered. There were comments that opposed changing the rules that would result in affiliations, corporate restructuring, mergers, and other arrangements being subject to Certificate of Need review. There were other comments that opposed requiring submission of hospital policies as part of the rules. Hospitals were concerned that developing a meaningful listing of services that were either limited or unavailable would be too complex and potentially misleading. Some comments included support for the draft changes to the rules; however, most supporters said the draft changes did not go far enough and would prefer requiring hospitals to provide certain health care services. There were comments supporting the draft changes because the impact of many current non-reviewed affiliations has ultimately resulted in the change of control of outpatient clinics within the community.

As a result of the comments, we revised the draft rules to move the submission and posting of hospital access policies from the Certificate of Need rules to the hospital licensing rules. The policies should outline the current practice at the hospital for admission, non-discrimination, end of life care, and reproductive health care services. We determined the least burdensome approach is to strike from the draft rules the requirement of a list of services that are limited or not available as a result of one of the four policies.

Rules – We believe the proposed rules are responsive to the directive. The proposed changes in the Certificate of Need rules define "sale, purchase, or lease" to mean any transaction in which the control, directly or indirectly, of part or all of any existing hospital changes to a different person, including but not limited to by contract, affiliation, corporate membership restructuring, or any other transaction.

The proposed changes to the hospital licensing rules would require hospitals to submit their admission, non-discrimination, end of life care, and reproductive health care services policies to us for posting on our website. To increase consumer access to these policies, hospitals would have to post these same policies to their own websites.

Next Steps – The hearing date for these rule changes is scheduled for November 26, 2013, beginning at 1 p.m. at the Department of Health, 310 Israel Road SE, Point Plaza East, Tumwater WA 98501, rooms 152/153. We plan to file the permanent rules on December 10, 2013.

If you have any questions about this report, please contact Steven Saxe, Director, Community Health Systems, at 236-2902 or steven.saxe@doh.wa.gov.

Attachments

cc: Steven Saxe, Department of Health

AMENDATORY SECTION (Amending WSR 09-07-050, filed 3/11/09, effective 4/11/09)

WAC 246-320-141 Patient rights and organizational ethics. The purpose of this section is to improve patient care and outcomes by respecting every patient and maintaining ethical relationships with the public.

Hospitals must:

(1) Adopt and implement policies and procedures that define each patient's right to:

(a) Be treated and cared for with dignity and respect;

(b) Confidentiality, privacy, security, complaint resolution, spiritual care, and communication. If communication restrictions are necessary for patient care and safety, the hospital must document and explain the restrictions to the patient and family;

(c) Be protected from abuse and neglect;

(d) Access protective services;

(e) Complain about their care and treatment without fear of retribution or denial of care;

(f) Timely complaint resolution;

(g) Be involved in all aspects of their care including:

(i) Refusing care and treatment; and

(ii) Resolving problems with care decisions((;)).

(h) Be informed of unanticipated outcomes according to RCW 70.41.380;

(i) Be informed and agree to their care;

(j) Family input in care decisions;

(k) Have advance directives and for the hospital to respect and follow those directives;

(l) Request no resuscitation or life-sustaining treatment;

(m) End of life care;

(n) Donate organs and other tissues according to RCW 68.50.500 and 68.50.560 including:

(i) Medical staff input; and

(ii) Direction by family or surrogate decision makers((;)).

(2) Provide each patient a written statement of patient rights from subsection (1) of this section;

(3) Adopt and implement policies and procedures to identify patients who are potential organ and tissue donors;

(4) Adopt and implement policies and procedures to address research, investigation, and clinical trials including:

(a) How to authorize research;

(b) Require staff to follow informed consent laws; and

(c) Not hindering a patient's access to care if a patient refuses to participate.

(5) No later than sixty days following the effective date of this section, every hospital must submit to the department its policies related to access to care:

(a) Admission;

(b) Nondiscrimination;

(c) End of life care; and

(d) Reproductive health care.

(6) The department shall post a copy of the policies received under subsection (5) of this section on its web site.

(7) If a hospital makes changes or additions to any of the policies listed under subsection (5) of this section, it must submit a

copy of the changed or added policy to the department within thirty days after the hospital approves the changes or additions.

(8) Hospitals must post a copy of the policies provided under subsection (5) of this section to its own web site where it is readily accessible to the public, without requiring a login or other restriction.

AMENDATORY SECTION (Amending WSR 08-19-018, filed 9/5/08, effective 10/6/08)

WAC 246-310-010 Definitions. For the purposes of chapter 246-310 WAC, the following words and phrases have the following meanings unless the context clearly indicates otherwise.

(1) "Acute care facilities" means hospitals and ambulatory surgical facilities.

(2) "Affected person" means an interested person who:

(a) Is located or resides in the applicant's health service area;

(b) Testified at a public hearing or submitted written evidence; and

(c) Requested in writing to be informed of the department's decision.

(3) "Alterations," see "construction, renovation, or alteration."

(4) "Ambulatory care facility" means any place, building, institution, or distinct part thereof not a health care facility as defined in this section and operated for the purpose of providing health services to individuals without providing such services with board and room on a continuous twenty-four-hour basis. The term "ambulatory care facility" includes the offices of private physicians, whether for individual or group practice.

(5) "Ambulatory surgical facility" means any free-standing entity, including an ambulatory surgery center that operates primarily for the purpose of performing surgical procedures to treat patients not requiring hospitalization. This term does not include a facility in the offices of private physicians or dentists, whether for individual or group practice, if the privilege of using the facility is not extended to physicians or dentists outside the individual or group practice.

(6) "Applicant," means:

(a) Any person proposing to engage in any undertaking subject to review under chapter 70.38 RCW; or

(b) Any person or individual with a ten percent or greater financial interest in a partnership or corporation or other comparable legal entity engaging in any undertaking subject to review under chapter 70.38 RCW.

(7) "Bed banking" means the process of retaining the rights to nursing home bed allocations which are not licensed as outlined in WAC 246-310-395.

(8) "Bed supply" means within a geographic area the total number of:

(a) Nursing home beds which are licensed or certificate of need approved but not yet licensed or beds banked under RCW 70.38.111 (8)(a) or where the need is deemed met under RCW 70.38.115 (13)(b), excluding:

(i) Those nursing home beds certified as intermediate care facility for the mentally retarded (ICF-MR) the operators of which have not signed an agreement on or before July 1, 1990, with the department of social and health services department of social and health services to give appropriate notice prior to termination of the ICF-MR service;

(ii) New or existing nursing home beds within a CCRC which are approved under WAC 246-310-380(5); or

(iii) Nursing home beds within a CCRC which is excluded from the definition of a health care facility per RCW 70.38.025(6); and

(iv) Beds banked under RCW 70.38.115 (13)(b) where the need is not deemed met.

(b) Licensed hospital beds used for long-term care or certificate of need approved hospital beds to be used for long-term care not yet in use, excluding swing-beds.

(9) "Bed-to-population ratio" means the nursing home bed supply per one thousand persons of the estimated or forecasted resident population age seventy and older.

(10) "Capital expenditure": Except for WAC 246-310-280, capital expenditure means an expenditure, including a force account expenditure (i.e., an expenditure for a construction project undertaken by a nursing home facility as its own contractor), which, under generally accepted accounting principles, is not properly chargeable as an expense of operation or maintenance. The costs of any studies, surveys, designs, plans, working drawings, specifications, and other activities (including staff effort, consulting and other services which, under generally accepted accounting principles, are not properly chargeable as an expense of operation and maintenance) shall be considered capital expenditures. Where a person makes an acquisition under lease or comparable arrangement, or through donation, which would have required certificate of need review if the acquisition had been made by purchase, this acquisition shall be deemed a capital expenditure. Capital expenditures include donations of equipment or facilities to a nursing home facility, which if acquired directly by the facility, would be subject to review under this chapter and transfer of equipment or facilities for less than fair market value if a transfer of the equipment or facilities at fair market value would be subject to the review.

(11) "Certificate of need" means a written authorization by the secretary's designee for a person to implement a proposal for one or more undertakings.

(12) "Certificate of need program" means that organizational program of the department responsible for the management of the certificate of need program.

(13) "Commencement of the project" means whichever of the following occurs first: In the case of a construction project, giving notice to proceed with construction to a contractor for a construction project provided applicable permits have been applied for or obtained within sixty days of the notice; beginning site preparation or development; excavating or starting the foundation for a construction project; or beginning alterations, modification, improvement, extension, or expansion of an existing building. In the case of other projects, initiating a health service.

(14) "Construction, renovation, or alteration" means the erection, building, remodeling, modernization, improvement, extension, or expansion of a physical plant of a health care facility, or the conversion of a building or portion thereof to a health care facility.

(15) "Continuing care contract" means a contract providing a person, for the duration of that person's life or for a term in excess of one year, shelter along with nursing, medical, health-related, or personal care services. The contract is conditioned on the transfer of property, the payment of an entrance fee to the provider of the services, or the payment of periodic charges for the care and services involved. A continuing care contract is not excluded from this definition because the contract is mutually terminable or because shelter and services are not provided at the same location.

(16) "Continuing care retirement community (CCRC)" means any of a variety of entities, unless excluded from the definition of health care facility under RCW 70.38.025(6), which provides shelter and services based on continuing care contracts with its residents which:

Maintains for a period in excess of one year a CCRC contract with a resident which provides or arranges for at least the following specific services:

(a) Independent living units;

(b) Nursing home care with no limit on the number of medically needed days;

(c) Assistance with activities of daily living;

(d) Services equivalent in scope to either state chore services or medicaid home health services;

(e) Continues a contract, if a resident is no longer able to pay for services;

(f) Offers services only to contractual residents with limited exception during a transition period; and

(g) Holds the medicaid program harmless from liability for costs of care, even if the resident depletes his or her personal resources.

(17) "Days" means calendar days. Days are counted starting the day after the date of the event from which the designated period of time begins to run. If the last day of the period falls on a Saturday, Sunday, or legal holiday observed by the state of Washington, a designated period runs until the end of the first working day following the Saturday, Sunday, or legal holiday.

(18) "Department" means the Washington state department of health.

(19) "Effective date of facility closure" means:

(a) The date on which the facility's license was relinquished, revoked or expired; or

(b) The date the last resident leaves the facility, whichever comes first.

(20) "Enhance the quality of life for residents" means, for the purposes of voluntary bed banking, those services or facility modifications which have a direct and immediate benefit to the residents. These include, but are not limited to: Resident activity and therapy facilities; family visiting rooms; spiritual rooms and dining areas. These services or facility modifications shall not include those that do not have direct and immediate benefit to the residents, such as: Modifications to staff offices; meeting rooms; and other staff facilities.

(21) "Established ratio" means a bed-to-population ratio of forty beds per one thousand persons of the estimated or forecast resident population age seventy and older established for planning and policy-making purposes. The department may revise this established ratio using the process outlined in WAC 246-310-370.

(22) "Estimated bed need" means the number of nursing home beds calculated by multiplying the planning area's forecasted resident population by the established ratio for the projection year.

(23) "Estimated bed projection" means the number of nursing home beds calculated by the department statewide or within a planning area, by the end of the projection period.

(24) "Ex parte contact" means any oral or written communication between any person in the certificate of need program or any other person involved in the decision regarding an application for, or the withdrawal of, a certificate of need and the applicant for, or holder of, a certificate of need, any person acting on behalf of the appli-

cant or holder, or any person with an interest regarding issuance or withdrawal of a certificate of need.

(25) "Expenditure minimum" means one million dollars for the twelve-month period beginning with July 24, 1983, adjusted annually by the department according to WAC 246-310-900.

(26) "Health care facility" means hospitals, psychiatric hospitals, nursing homes, kidney disease treatment centers including freestanding dialysis units, ambulatory surgical facilities, continuing care retirement communities, hospices and home health agencies, and includes the facilities when owned and operated by a political subdivision or instrumentality of the state and other facilities as required by federal law and rules, but does not include any health facility or institution conducted by and for those who rely exclusively upon treatment by prayer or spiritual means in accordance with the creed or tenets of any well-recognized church or religious denomination, or any health facility or institution operated for the exclusive care of members of a convent as defined in RCW 84.36.800 or rectory, monastery, or other institution operated for the care of members of the clergy.

(a) In addition, the term "health care facility" does not include any nonprofit hospital:

(i) Operated exclusively to provide health care services for children;

(ii) Which does not charge fees for the services; and

(iii) If not contrary to federal law as necessary to the receipt of federal funds by the state.

(b) In addition, the term "health care facility" does not include a continuing care retirement community which:

(i) Offers services only to contractual residents;

(ii) Provides its residents a contractually guaranteed range of services from independent living through skilled nursing, including some form of assistance with activities of daily living;

(iii) Contractually assumes responsibility for costs of services exceeding the resident's financial responsibility as stated in contract, so that, with the exception of insurance purchased by the retirement community or its residents, no third party, including the medicaid program, is liable for costs of care even if the resident depletes personal resources;

(iv) Offers continuing care contracts and operates a nursing home continuously since January 1, 1988, or obtained a certificate of need to establish a nursing home;

(v) Maintains a binding agreement with the department of social and health services assuring financial liability for services to residents, including nursing home services, shall not fall upon the department of social and health services;

(vi) Does not operate, and has not undertaken, a project resulting in a number of nursing home beds in excess of one for every four living units operated by the continuing care retirement community, exclusive of nursing home beds; and

(vii) Has undertaken no increase in the total number of nursing home beds after January 1, 1988, unless a professional review of pricing and long-term solvency was obtained by the retirement community within the prior five years and fully disclosed to residents.

(27) "Health maintenance organization" means a public or private organization, organized under the laws of the state, which:

(a) Is a qualified health maintenance organization under Title XIII, Section 1310(d) of the Public Health Service Act; or

(b) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: Usual physician services, hospitalization, laboratory, X ray, emergency and preventive services, and out-of-area coverage;

(c) Is compensated (except for copayments) for the provision of the basic health care services listed in this subsection to enrolled participants by a payment made on a periodic basis without regard to the date the health care services are provided and fixed without regard to the frequency, extent, or kind of health service actually provided; and

(d) Provides physicians' services primarily:

(i) Directly through physicians who are either employees or partners of the organization; or

(ii) Through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

(28) "Health service area" means a geographic region appropriate for effective health planning including a broad range of health services.

(29) "Health services" means clinically related (i.e., preventive, diagnostic, curative, rehabilitative, or palliative) services and includes alcoholism, drug abuse, and mental health services.

(30) "Home health agency" means an entity which is, or has declared its intent to become, certified as a provider of home health services in the medicaid or medicare program.

(31) "Hospice" means an entity which is, or has declared its intent to become, certified as a provider of hospice services in the medicaid or medicare program.

(32) "Hospital" means any institution, place, building or agency or distinct part thereof which qualifies or is required to qualify for a license under chapter 70.41 RCW, or as a psychiatric hospital licensed under chapter 71.12 RCW.

(33) "Inpatient" means a person receiving health care services with board and room in a health care facility on a continuous twenty-four-hour-a-day basis.

(34) "Interested persons" means:

(a) The applicant;

(b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;

(c) Third-party payers reimbursing health care facilities in the health service area;

(d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;

(e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;

(f) Any person residing within the geographic area to be served by the applicant; and

(g) Any person regularly using health care facilities within the geographic area to be served by the applicant.

(35) "Licensee" means an entity or individual licensed by the department of health or the department of social and health services. For the purposes of nursing home projects, licensee refers to the op-

erating entity and those persons specifically named in the license application as defined under chapter 388-97 WAC.

(36) "Net estimated bed need" means estimated bed need of a planning area changed by any redistribution as follows:

(a) Adding nursing home beds being redistributed from another nursing home planning area or areas; or

(b) Subtracting nursing home beds being redistributed to another nursing home planning area or areas.

(37) "New nursing home bed" means a nursing home bed never licensed by the state or beds banked under RCW 70.38.115(13), where the applicant must demonstrate need for the previously licensed nursing home beds. This term does not include beds banked under RCW 70.38.111(8).

(38) "Nursing home" means any entity licensed or required to be licensed under chapter 18.51 RCW or distinct part long-term care units located in a hospital and licensed under chapter 70.41 RCW.

(39) "Obligation," when used in relation to a capital expenditure, means the following has been incurred by or on behalf of a health care facility:

(a) An enforceable contract has been entered into by a health care facility or by a person on behalf of the health care facility for the construction, acquisition, lease, or financing of a capital asset; or

(b) A formal internal commitment of funds by a health care facility for a force account expenditure constituting a capital expenditure; or

(c) In the case of donated property, the date on which the gift is completed in accordance with state law.

(40) "Offer," when used in connection with health services, means the health facility provides one or more specific health services.

(41) "Over the established ratio" means the bed-to-population ratio is greater than the statewide current established ratio.

(42) "Person" means an individual, a trust or estate, a partnership, ((a)) <u>any public or private</u> corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

(43) "Planning area" means each individual county designated by the department as the smallest geographic area for which nursing home bed need projections are developed, except as follows:

(a) Clark and Skamania counties shall be one planning area.

(b) Chelan and Douglas counties shall be one planning area.

(44) "Predevelopment expenditures" means capital expenditures, the total of which exceeds the expenditure minimum, made for architectural designs, plans, drawings, or specifications in preparation for the acquisition or construction of physical plant facilities. "Predevelopment expenditures" exclude any obligation of a capital expenditure for the acquisition or construction of physical plant facilities and any activity which the department may consider the "commencement of the project" as this term is defined in this section.

(45) "Professional review of continuing care retirement community pricing and long-term solvency" means prospective financial statements, supported by professional analysis and documentation, which:

(a) Conform to Principles and Practices Board Statement Number 9 of the Healthcare Financial Management Association, "Accounting and Reporting Issues Related to Continuing Care Retirement Communities"; and

(b) Project the financial operations of the continuing care retirement community over a period of ten years or more into the future; and

(c) Are prepared and signed by a qualified actuary as defined under WAC 284-05-060 or an independent certified public accountant, or are prepared by management of the continuing care retirement community and reviewed by a qualified actuary or independent certified public accountant who issues a signed examination or compilation report on the prospective financial statements; and

(d) Include a finding by management that the intended expansion project of the continuing care retirement project is financially feasible.

(46) "Project" means all undertakings proposed in a single certificate of need application or for which a single certificate of need is issued.

(47) "Project completion" for projects requiring construction, means the date the facility is licensed. For projects not requiring construction, project completion means initiating the health service.

(48) "Projection period" means the three-year time interval following the projection year.

(49) "Projection year" for nursing home purposes, means the one-year time interval preceding the projection period.

(50) "Public comment period" means the time interval during which the department shall accept comments regarding a certificate of need application.

(51) "Redistribution" means the shift of nursing home bed allocations between two or more planning areas or the shift of nursing home beds between two or more nursing homes.

(52) "Replacement authorization" means a written authorization by the secretary's designee for a person to implement a proposal to replace existing nursing home beds in accordance with the eligibility requirements in WAC 246-310-044 and notice requirements in WAC 246-310-396.

(53) "Resident population" for purposes of nursing home projects, means the number of residents sixty-five years of age and older living within the same geographic area which:

(a) Excludes contract holders living within a recognized CCRC:

(i) With approval for new nursing home beds under WAC 246-310-380(4); or

(ii) Excluded from the definition of a health care facility per RCW 70.38.025(6);

(b) Is calculated using demographic data obtained from:

(i) The office of financial management; and

(ii) Certificate of need applications and exemption requests previously submitted by a CCRC.

(54) "Sale, purchase, or lease" means any transaction in which the control, either directly or indirectly, of part or all of any existing hospital changes to a different person including, but not limited to, by contract, affiliation, corporate membership restructuring, or any other transaction.

(55) "Secretary" means the secretary of the Washington state department of health or the secretary's designee.

((~~(55)~~)) (56) "State Health Planning and Resources Development Act" means chapter 70.38 RCW.

((~~(56)~~)) (57) "Statewide current ratio" means a bed-to-population ratio computed from the most recent statewide nursing home bed supply and the most recent estimate of the statewide resident population.

((~~(57)~~)) (58) "Swing beds" means up to the first five hospital beds designated by an eligible rural hospital which are available to provide either acute care or nursing home services.

((~~(58)~~)) (59) "Tertiary health service" means a specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.

((~~(59)~~)) (60) "Transition period" means the period of time, not exceeding five years, between the date a CCRC is inhabited by a member, and the date it fully meets the requirements of a CCRC.

((~~(60)~~)) (61) "Under the established ratio" means the bed-to-population ratio is less than the statewide current established ratio.

((~~(61)~~)) (62) "Undertaking" means any action subject to the provisions of chapter 246-310 WAC.

((~~(62)~~)) (63) "Working days" excludes Saturdays, Sundays, and legal holidays observed by the state of Washington. Working days are counted in the same way as calendar days.