**STATE OF WASHINGTON**
**DEPARTMENT OF HEALTH**
**ADJUDICATIVE SERVICE UNIT**

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| In Re: | ) | |
| | ) | Docket No. 05-12-C-2003CN |
| CANCER TREATMENT CENTERS OF AMERICA, INC., and SEATTLE HEALTHCARE PROPERTIES, LLC., | ) | FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER |
| Petitioner. | ) | |

APPEARANCES:

Petitioner, Cancer Treatment Centers of America, Inc, (CTCA) by
Law Offices of James M. Beaulaurier, per
James M. Beaulaurier, Attorney at Law, and
Stamper, Rubens, Stocker & Smith, P.S., per
Brian M. Werst, Attorney at Law

Department of Health Certificate of Need Program (Program), by
Office of the Attorney General, per
Geoffrey W. Hymans, Assistant Attorney General

Intervenors, Auburn Regional Medical Center (Auburn), Good Samaritan Healthcare (Good Samaritan), and Valley Medical Center (Valley), by
Benedict Garratt, PLLC, per
Sally Gustafson Garratt and Kathleen D. Benedict, Attorneys at Law

Intervenor, Overlake Hospital Medical Center (Overlake), by
Ogden Murphy Wallace, P.L.L.C., per
E. Ross Farr, Attorney at Law

Intervenor, Swedish Health Services (Swedish) by
Dorsey & Whitney LLP, per
Brian W. Grimm, Peter Ehrlichman and Nicole Trotta, Attorneys at Law

PRESIDING OFFICER: Zimmie Caner, Health Law Judge

This is an appeal of the Department of Health Certificate of Need Program's (Program) analysis and denial of the Cancer Treatment Centers of America, Inc. (CTCA) certificate of need application to establish a 24-bed hospital. Sustained.

## ISSUE

Did Program correctly deny CTCA's certificate of need (CN) application to establish a 24-bed hospital under chapter 70.38 RCW and chapter 246-310 WAC?

## SUMMARY OF PROCEEDINGS

During the hearing, Program presented the testimony of Program Analysts Karen Nidermayer and Randal Huyck. CTCA presented the testimony of Robert Mayo, Roger Cary, Edgar Staren, M.D., Ph.D., Timothy Birdshall, N.D., Joseph Pizzorno, N.D., Dan Church, Ph.D., Robert McGuirk, Michael Bell, C.P.A., Lynette Bisconti, Kathy Lingo, Arthur Baldwin, Douglas Kelly, M.D., and Mathew Claeys. Swedish Health Services (Swedish) presented the testimony of Albert Einstein, Jr., M.D., Dan Labiola, N.D., and Scott Standjord. Valley Medical Center (Valley) presented the testimony of Paul Hayes, R.N. and Jonathan Birtell, M.D. Good Samaritan Healthcare (Good Samaritan) presented the testimony of Pat Bailey. Auburn Regional Medical Center (Auburn) presented the testimony of Glen Kasman. Valley Medical Center (Valley), Good Samaritan, and Auburn jointly presented the testimony of Robert McCroskey, M.D. The intervening parties jointly present the testimony of Melvin Hurley, Jr.

The followings exhibits[1] were admitted during the hearing and in Prehearing Order No. 4:

Exhibit 1: A copy of the administrative record (AR);

Exhibit 2: A color copy of Good Samaritan's facility brochure (AR 558-565);

Exhibit 8: Washington State Health Plan Volume 2: Performance Standards for Health Facilities and Services;

Exhibit 9: A color copy of Program's evaluation (AR 732-752);

Exhibit 10: Scott Strandjord - Curriculum Vitae;

Exhibit 11: Albert Einstein, Jr., M.D. - Curriculum Vitae;

Exhibit 12: Dan Labriola, N.D .- Curriculum Vitae;

Exhibit 13: Jonathan Birtell, M.D. - Curriculum Vitae;

Exhibit 14: Robert McCroskey, M.D. - Curriculum Vitae;

Exhibit 15: Melvin Hurley Jr, C.P.A. - Curriculum Vitae;

Exhibit 16: Paul Hayes, R.N. - Curriculum Vitae;

Exhibit 17: Douglas Kelly, M.D. - Curriculum Vitae.

Closing arguments were presented through briefs. CTCA filed a "Motion to Strike Portions of AGSV Brief" (Intervenors Auburn, Good Samaritan, and Valley closing brief). Program supports CTCA's motion to strike. The AGSV brief contains evidence from outside of the adjudicative record (new CTCA website materials).[2] Therefore, those portions of the AGSV brief should be stricken. CTCA also moved to strike the portion of the AGSV brief filed in response to CTCA's motion to strike. The AGSV brief filed in

[1] Exhibits 3-6 were marked demonstrative exhibits and not admitted. There is no exhibit 7. Exhibit 18, CTCA's charity care chart, was not admitted.
[2] Page 12, line 4 through page 13, line 8 and page 15, lines 1-10.

response to CTCA's motion to strike contained argument and case sites that should have been contained in the closing briefs. Those portions of the AGSV response brief should be stricken as untimely because the closing brief deadline had lapsed.

## I. FINDINGS OF FACT

*CTCA's Application*

1.1 CTCA filed a CN application to build a new facility (Northwestern Regional Medical Center) in Kent, Washington. The facility would include a hospital with 24 acute care in-patient beds, and 30 residential beds for patients who do not need in-patient care. The proposed hospital would specialize in the care and treatment of cancer patients.

1.2 CTCA's approach to cancer treatment is based on an integrated model using conventional treatment with science based complementary treatments. CTCA presently offers many of the conventional and complementary services through its out-patient facility, Seattle Cancer Treatment and Wellness Center. CTCA's goal is to build the proposed Kent facility with 24 in-patient beds, and close its Seattle facility, transferring the out-patient services to the new Kent facility. CTCA patients could then receive in- and out-patient CTCA services "under one roof."

1.3 CTCA describes its cancer care as "seamless" under one roof and with one set of electronic treatment records to which all CTCA health care providers have access.[3] CTCA describes its method of cancer care as "patient empowerment medicine"; patients choosing services from a full menu of conventional and

[3] Some of the Washington State hospitals have electronic record keeping systems, and at least one intervening hospital is working on expanding and improving its electronic system.

complementary services. Patient care teams with expertise in conventional and complementary treatment would meet three times a week to discuss patients' care and progress. The teams and staff maintain up-to-date communication regarding patient care through these meetings and access to patients' fully integrated electronic records.

1.4 The CTCA medical staff at the proposed hospital would include the conventional cancer disciplines of surgical oncology, radiation oncology, and medical oncology, as well as naturopathic physicians. Through these specialists, CTCA would offer complementary services including nutritional therapy, massage, pain management, mind-body medicine, physical therapy, acupuncture, and spiritual wellness. CTCA's proposed hospital would include an array of advanced treatment modalities and equipment such as Miraluma Breast Imaging, and Spiral Computed Tomography.

1.5 In its application, CTCA offers similar services that are available in King County, and therefore, in the state of Washington. Washington has an excess number of hospital in-patient beds with cancer treatment programs. The approval of CTCA's proposed hospital would result in the unnecessary duplication of cancer treatment services.[4] Some of these services such as expensive diagnostic equipment and technology, need not be available in every cancer treatment facility. Certain expensive equipment and services that are utilized to diagnose or treat cancer patients are more appropriately limited to one or a limited number of hospitals to avoid unnecessary

[4] Some of the equipment and technology CTCA proposes to have available at the new hospital is very expensive. One of the purposes of the CN laws is to avoid the purchase of expensive equipment when it is reasonably available at other facilities. If each facility treating cancer patients were able to provide all types of technology and equipment to help diagnose and treat patients, the costs of treating cancer patients would include unnecessary duplication of services and, therefore, unnecessarily drive up the costs of cancer care.

duplication of services/cost, as long as patients have reasonable access to same or similar services.

1.6 Program denied CTCA's application for a new hospital, finding insufficient need for additional in-patient beds.[5] CTCA appealed Program's denial of its CN application. Five hospitals with cancer treatment programs intervened; Swedish, Overlake, Auburn, Valley General, and Good Samaritan. These hospitals each have the capacity to treat more cancer patients, and are, therefore, concerned with the potential adverse impact a new hospital will have on the existing hospitals. The intervenors support Program's denial of CTCA's CN application.

*Service Area*

1.7 The service area utilized by Program to evaluate CTCA's application is the entire state rather than King County where CTCA's facility would be located. Program historically identifies a county or a portion of a county as a service area for a proposed hospital in this region of Washington State. Program identified the state as the service area because CTCA stated that it would serve patients throughout the state, as well as patients from beyond its borders.

*Existing Hospitals*

1.8 There are 88 hospitals in Washington that provide cancer treatment. AR 605-6. Five of those hospitals intervened in the case at hand because they are concerned with the potential adverse effect CTCA's proposed 24-bed cancer treatment

[5] Program denied CTCA's application, finding that the application failed to meet CN criteria regarding need (WAC 246-310-210), financial feasibility (WAC 246-310-220), structure and process of care criteria (WAC 246-310-230), and cost containment (WAC 246-310-240).

hospital would have on their existing hospitals and cancer treatment programs. The intervening hospitals are located within the vicinity of the proposed CTCA facility: Good Samaritan is located in Puyallup, Valley Medical Center in Renton, Auburn Medical Center in Auburn, Swedish Medical Center in Seattle, and Overlake Medical Center in Bellevue. Each of these intervening hospitals has cancer programs accredited by the American College of Surgeons.

1.9 Forty one of the 88 Washington hospitals that have cancer programs are accredited by the American College of Surgeons' Commission on Cancer at one of four levels. Three hospitals are accredited as National Cancer Institutes: Children's Medical Center, University of Washington Medical Center, and the Cancer Care Alliance.[6] Four hospitals are rated as Teaching Hospital Cancer Programs: Swedish, Virginia Mason Medical Center, VA Puget Sound Health Care Systems, and Madigan Army Medical Center. Sixteen hospitals, including Overlake and Valley Medical Center, are accredited as Hospitals with Comprehensive Cancer Programs. This accreditation rating is the same rating that two of CTCA's existing hospitals received.[7] "Hospitals with Comprehensive Cancer Programs" provide: a full range of diagnostic and treatment services that are available on-site or through referral, in-patient medical oncology unit or functional equivalent with board certified physicians such as oncologists, and cancer-related research.[8] Eighteen hospitals including, Auburn and Good Samaritan,[9] are accredited as Community Hospitals with Cancer Programs.

[6] Fred Hutchinson Cancer Center is a part of the Cancer Care Alliance.
[7] AR 740
[8] AR 739

*Available Cancer Services*

1.10 Generally, there are two categories of cancer treatment, "conventional" treatment such as surgery, chemotherapy and hormone therapy, and "complementary" treatment such as naturopathic medicine and mind body medicine. There are also a number of diagnostic tools. A full panoply of similar treatment options and diagnostic tools that CTCA proposes in its application are available through the existing hospitals and facilities.

1.11 CTCA integrates traditional and complementary/alternative medicine to a higher degree than existing hospitals. This fact alone does not support the need for a new Washington hospital. Several hospitals in Washington offer conventional and complementary services in an integrated manner to a greater degree than other Washington hospitals. The amount of complementary services and the method of service delivery vary from hospital to hospital. The key fact is that similar complementary services that CTCA would offer are presently available in Washington.

1.12 Existing Washington hospitals provide similar services directly or through referrals. Patients are informed of their treatment options with descriptions of potential risks and benefits. Patients then choose their course of treatment (informed consent). Depending on the hospital or the physician diagnosing and/or treating the cancer patient, different treatment options may be described and/or offered to a patient. Full complementary treatment options are not offered at all of the existing hospital cancer

[9] In 2005, Good Samaritan Medical Center opened its new cancer treatment facility with state of the art technology, physicians who specialize in the care and treatment of cancer patients, and a lab that is conducting cancer research. Exhibit 2 and Report of the Proceedings (RP) 1021-2.

treatment programs or through all of the oncologists. In some cases, the patient, the patient's family or friend initiates the discussion of complementary treatment services. In those cases, the physician or someone within the hospital would refer the patient to complementary services provided within that hospital, another Washington hospital or to a health care provider outside of the hospital setting. Often the referral is within the vicinity of or in downtown Seattle. Similarly, CTCA would need to refer patients to Swedish for robotic surgery or to Fred Hutchinson for bone marrow transplants in Seattle from CTCA's proposed Kent hospital. CTCA would not provide a unique array of services that warrant granting CTCA a CN.

1.13 King County alone has 14 hospital based cancer treatment programs. The full range of conventional cancer treatment tools and diagnostic detection tools are available in or through existing hospitals in King County hospitals.[10] These conventional treatments include but are not limited to surgical oncology, radiation therapy, and chemotherapy with split or low dose rates/frequency.

1.14 CTCA will not provide all of the conventional cancer treatment services presently provided by King County hospitals. For example, CTCA would not provide bone marrow transplants,[11] hospice care, DaVinici robotic surgery, Cyber knife therapy, and emergency room care with supporting medical staff who treat co-morbidities[12] that develop with cancer patients.[13] Medical specialists who treat cancer co-morbidities are

[10] RP 732-739
[11] Seattle Cancer Alliance's Fred Hutchinson Cancer Center provides bone marrow transplant services.
[12] Co-morbidities are serious complications that can be fatal with or without the necessary treatment. (i.e. cardiac or respiratory complications resulting from the cancer or the cancer treatment)
[13] Emergency departments are very expensive to operate due to the staffing needs and hours of operations, and as a result are a financial drain on hospitals.

often cardiologists, pulmonologists, gastroenterologists, or nephrologists.[14] CTCA proposes to have medical specialists who would treat co-morbidities available on as a consulting basis. These physicians would have CTCA hospital privileges rather than be CTCA staff physicians. Therefore, these physicians would generally not be as readily available to treat emergent co-morbidity conditions as staff physicians.

1.15 CTCA's proposed specialty hospital is not a full service hospital ready to treat most patients' needs/conditions with a broad array of staff physicians available 24 hours a day, 7 days a week.[15] As a result, unwarranted fragmentation of medical services will probably occur with the emergency treatment of cancer patients who develop co-morbidities, and require treatment in a full service hospital where the specialists are available. Therefore, some of the CTCA in-patients who develop emergent co-morbidity conditions would need to be transferred from CTCA's proposed facility to a full service hospital where the needed specialist is more readily available.[16]

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[14] Swedish provides hospice care services, robotic surgery, Cyber knife therapy, and an emergency department with specialist to treat co-morbidities. AR 31-33; 237.
[15] AR 611
[16] RP 941

1.16 King County hospitals and CTCA's Seattle out-patient facility provide the same complementary services that would be offered at CTCA's proposed Kent facility.[17] For example, Swedish offers the following broad spectrum of complementary services:

a. Nutritional therapy: Licensed dieticians provide nutritional advice and intervention for patients. Naturopaths may collaborate with dieticians to provide more interventional nutritional guidance. Dietary choices are available, such as vegetarian meals.[18]

b. Pain management: A pain management department offering a variety of treatments from analgesics to acupuncture. A naturopathic program that offers complementary services to reduce pain with less pain medications to improve patients' quality of life.

c. Naturopathic Medicine: Three naturopathic physicians specializing in cancer care and the integration of naturopathic care with conventional cancer treatment provide patient care and treatment. These naturopathic physicians have privileges to treat patients at Swedish.[19] They collaborate with other health care providers, such as oncologists, surgeons, and radiation oncologists, through telephone communications, hospital chart entries,

[17] Additional hospitals that did not intervene offer a multidisciplinary approach with traditional and complementary services that included naturopathy (i.e., Virginia Mason, Seattle Caner Care Alliance, and Highline Hospital).
[18] AR 32-33; RP 866
[19] CTCA claimed that its services would be unique; that it would permit naturopaths to treat patients who are admitted into their hospital, consult with the other health care providers on the patient's team and make chart entries. Swedish permits its three naturopaths who specialize in treating cancer patients to practice in a similar manner. RP 868 (Dr. Labriola)

reports, and cancer conferences.[20] A variety of naturopathic services, such as heat, cold, and light therapy, naturopathic manipulation, herbal medicine, and clinical nutrition, are available.

d. Mind-body Medicine: Two board certified psychiatrists provide mind-body medicine. A meditation program and social work counselors are also available.

e. Physical therapy: A 10,000 square foot physical therapy rehabilitation department managed by a medical physician specializing in physical therapy is available. The department is staffed by specialists who help with different types of pain management and physical therapy specifically designed for cancer patients.

f. Spiritual support: Full-time chaplains are available to provide spiritual guidance and facilitate interaction with spiritual providers from patient's individual faith. Visualization and imagery meditation is provided (an overlap with mind-body medicine).

g. Image enhancement support: A resource center is available with personal appearance items that help cancer patients with their appearance (i.e., wigs). A partnership with American Cancer Society helps guide patients to available services.

[20] RP 863-868. CTCA would have one electronic record keeping system that all providers would be expected to use. This would probably provide a more efficient, integrated form of communication and record keeping. One or more of the intervening hospitals are working on expanding and improving existing electronic record keeping systems.

*How services are delivered*

1.17 CTCA argues that it has a unique "patient empowerment" approach, but several of the physicians described practices at existing cancer treatment programs where patients are informed of treatment options, and the patients are the ones to choose the course of treatment. Providers may recommend certain care, but it is up to the patient to decide what care he or she wants. Because Washington patients are "empowered" with their care, CTCA is not unique in the patients' power to select their course of treatment.[21] The breadth of choices provided through each hospital cancer treatment program varies, and the choices offered by each physician or facility vary. The different degree of integration of services proposed by CTCA does not justify a new hospital when there is an excess of in-patient acute care beds in cancer treatment programs that have similar services that CTCA would offer.

*No need for additional hospital beds*

1.18 Pursuant to Program's standard practice, it utilized the 1987 Washington State Health Plan's hospital bed need methodology to determine whether there is a need for a new hospital in the state of Washington. The State Health Coordinating Council developed the Washington Health Plan methodology as a tool for long-term strategic planning of health care resources.[22]

[21] RP 882 (Dr. Labriola)
[22] Under Chapter 70.38 RCW, the State Health Coordinating Council developed the Washington Health Plan methodology as a tool for long-term strategic planning of health care resources. The Plan did "sunset" (lapse) in 1989, but its methodology for hospital bed need forecasting remains a reliable tool for predicting baseline need for acute care beds. Exhibit 12

1.19 CTCA argues that the State Health Plan's methodology should not be applied since CTCA predicts that approximately 70 percent of its patients will be from other states and countries, including Montana, Idaho, Oregon, California, Arizona, Nevada, Hawaii, Alaska, Canada, and "Asian" countries. As a result, CTCA predicts that only 30 percent of its patients will come from Washington. CTCA's hospital bed need projections rely on the Milliman Report. CTCA commissioned this report to analyze the patients who use CTCA facilities in Zion, Illinois and Tulsa, Oklahoma, and from that data project Washington's hospital bed need. CTCA's bed projections are unreliable because the Milliman Report is flawed. To project travel distances and utilization rates, the Milliam Report uses statistics from Illinois and Oklahoma where no naturopaths are licensed, and where eastern complementary medicine is not as readily available as it is in Washington. The Milliman Report fails to take into account that there are over 700 naturopaths licensed in Washington, and two naturopathic schools are located in the northwest, one in the Seattle vicinity and the other in Portland. The Milliman Report also failed to address the percentage of out-of-state patients who use CTCA's existing out-patient facility in Seattle. Only 15 percent of CTCA's Seattle patients are from out-of-state.[23] In addition, Fred Hutchinson, the internationally renowned bone marrow transplants program, only has 51 percent of its patients from out-of-state.[24] As a result of relying on the flawed Milliman Report, CTCA's projection that 70 percent of its patients would be out of state is unreliable. Therefore, Program reasonably rejected CTCA's 70 percent of out of state patient projection and relied upon

[23] AR 751
[24] AR 717

the State Health Plan to calculate present and future need for acute care beds in Washington.

*State Health Plan Need Methodology for Hospital Beds*

1.20 The State Health Plan methodology contains a 12 step analysis to forecast acute care bed need. The first four steps develop trend information regarding utilization of hospital beds to evaluate the need of additional beds in a service area. The next six steps calculate the baseline for calculating the need for non-psychiatric beds. Step 11 addresses short stay psychiatric beds that are not at issue here. Step 12 allows for necessary adjustments in the methodology to reflect the special circumstances of a service area.[25]

1.21 The State Health Plan 12-Step methodology to forecast need for non-psychiatric acute care hospital beds is as follows:

Step 1: Compile state historical utilization data for at least ten years proceeding the base year.[26]

Step 2: Subtract psychiatric patient days from each year's historical data.

Step 3: For each year, compute the statewide and health service area (HSA) average use rates.[27]

Step 4: Using the ten-year history of use rates, compute the use rate trend line, and its slope, for each HSA and for the state as a whole.

[25] Exhibit 8 at C-22 through C-63.
[26] The base year is the "most recent year about which data is collected as the basis for a set of forecasts." Exhibit 8 at C-25.
[27] The state of Washington is divided into four health service areas.

Step 5: Using the latest statewide patient origin study, allocate non-psychiatric patient days reported in hospitals back to the hospital planning areas where the patients live.

Step 6: Compute each hospital planning area's use rate.

Step 7: Forecast each hospital planning area's use rates for the target year by "trend-adjusting" each age-specific use rate. The use rates are adjusted upward or downward in proportion to the slope of either the statewide ten-year use rate trend or the appropriate health planning region's ten-year use rate trend, whichever trend would result in the smaller adjustment.

Step 8: Forecast non-psychiatric patient days for each hospital planning area by multiplying the area's trend-adjusted use rates for the age groups by the area's forecasted population in each age group at the target year. Add patient days in each age group to determine total forecasted patient days.

Step 9: Allocate the forecasted non-psychiatric patient days to the planning areas where services are expected to be provided in accordance with (a) the hospital market shares and (b) the percent of out-of-state use of Washington hospitals, both derived from the latest statewide patient origin study.

Step 10: Applying the weighted average occupancy standards, and determine each planning area's non-psychiatric bed need. Calculate the weighted average occupancy standard as described in the Hospital Forecasting Standard 11.f.[28]

Step 11: To obtain a bed need forecast for all hospital services, including psychiatric add the non-psychiatric bed need from Step 10 above to the psychiatric in-patient bed need from Step 11 of the short-stay psychiatric hospital bed need forecasting method.

Step 12: Determine and carry out any necessary adjustments in population, use rates, market shares, out-of-state use, and occupancy rates. . . .[29]

[28] Standard 11f states: "The occupancy standard applied to each planning area …shall be based, for forecasting purposes, on the current weighted average of the appropriate occupancy standard for each facility in the planning area. This is calculated as the sum, across all hospitals in the planning area, of each hospital's occupancy rates times that hospital's percentage of total beds in the area. . . ." Exhibit 8 at C-39.

[29] Exhibit 8 at C-41-44

1.22 In determining whether the existing hospital will meet the projected populations' needs, the total number of available beds in the proposed service area must be calculated. The State Health Plan outlines which acute care beds should be included in the count of present and future available beds in the proposed service area. Under the State Health Plan, Program correctly counted the existing acute care hospital beds in the state, and projected that Washington State will have a surplus of at least 548 acute care beds through the year 2010. This surplus is even greater when the number of licensed beds that are not operational are counted in the future need projections.

1.23 Under the State Health Plan, Program applied a six-year projection period to calculate future hospital bed need. Although CTCA only applied a three-year projection period in its application, CTCA agues that Program should have selected a longer projection period.[30] A longer projection period is not warranted because CTCA is proposing to construct a relatively small hospital. Larger hospital projects generally have longer construction/operation time lines and larger construction/operating costs. A longer projection period is needed with a larger more expensive project that will take a greater number of years to construct.[31]

[30] To support this argument, CTCA refers to Program's prior analysis and decision regarding Swedish's proposed Issaquah hospital. CTCA's proposed project is much smaller in scale with a shorter construction time line. The Swedish Issaquah application includes approximately 175 beds and a $200 million budget with several stages of construction/operation. CTCA proposes a shorter time line to construct a 24-bed hospital with a $78 million budget (with an unknown portion attributed to the 30 bed non-hospital accommodations). AR 7, 123 and 193.

[31] Program used a seven year projection period when analyzing Franciscan's application to establish a 112-bed hospital in Gig Harbor, and a three year projection period when analyzing Seattle Cancer Care's application for 20 in-patient beds at the University of Washington Medical Center.

1.24 The State Health Plan warns against long-range forecasts beyond seven years. Projection periods greater than seven years are not recommended because medical terminology and standards of practice rapidly change, facilities and equipment become obsolete quickly, and communities and goals change.[32] For example, there is a decreasing need for in-patient care for cancer patients.[33] Over the past ten years, fewer cancer patients were treated on an in-patient basis as a result of earlier cancer detection and increasing percentage of cancer patients treated on an out-patient basis. In part, this is the result of better cancer detection and the development of supportive cancer medications.[34]

*Low income and Elderly Patient Access to Services*

1.25 CTCA's financial policies and projected budget for the proposed Kent facility raises serious concerns regarding low income and elderly patient access to health care services. Pursuant to CTCA's financial policy, CTCA would screen all patients to determine an adequate financial threshold. CTCA's financial policy requires that the Kent facility chief executive officer (CEO) approve any new Medicaid oncology patient. CTCA projects that 70 percent of its revenue will come from sources other than Medicare and Medicaid. Generally Medicaid does not cover the full cost of treatment, and Medicare barely covers costs. Even though CTCA plans on admitting Medicaid patients, CTCA has projected that only one percent of its revenue will be from Medicaid

[32] Exhibit 8 at C-30.
[33] AR 607-608, RP 1026 (Dr. McCroskey), RP 920 (Dr. Britell).
[34] RP 749 (Dr. Einstein) Seventy to 80 percent of Swedish's cancer patients are treated on an out-patient basis. RP 750. Approximately 75 percent of CTCA's patients are treated on an out-patient basis. RP 192 (Dr. Staren).

patients.[35] In light of CTCA's financial policies, few Washington Medicaid patients are likely to have access to CTCA services. As a result, CTCA would probably have a negative impact on the financial performances of local hospitals.[36]

1.26 CTCA's financial policies also limit Medicare oncology patient access to services. CTCA projects that only 29 percent of its revenue will be attributed to Medicare patients.[37] In comparison, 59 percent of the Swedish Providence campus in-patient revenue is from Medicare, and 35 percent of the Swedish Ballard and First Hill campuses in-patient revenue is from Medicare.[38] CTCA's financial policy states that oncology patients with only Medicare A or B coverage are required to have secondary coverage to pay the difference. In addition, CTCA's financial policy states patients wishing to have services not covered by Medicare will be required to "sign appropriate Medicare ABN forms and pay for services prior to receiving them."[39] Based upon CTCA's projected revenue and CTCA's financial policies, Program correctly concluded that Medicare, as well as Medicaid patients will have limited access to CTCA services in comparison with other Washington hospitals.

1.27 CTCA's financial policies raise similar access concerns for the uninsured. Uninsured oncology patients "must demonstrate available liquid assets capable of covering $150,000 in charges."[40] Uninsured non emergent patients may be accepted with a preferred 100 percent advanced payment for elective treatments/tests, or a

[35] AR 248
[36] RP 311 (Strandjord)
[37] AR 237
[38] RP 305-306
[39] AR 237
[40] AR 249

minimum 50 percent deposit with a satisfactory payment arrangement for the balance that may include a credit report/analysis.[41] Although CTCA's general policy states that it does not discriminate against anyone, such as low–income persons or the elderly, the financial policies limit access by those groups. In addition, CTCA projected charity care to be .94 percent of its gross income. This is below King County's three-year average of 1.45 percent.[42] These policies and projections indicate that CTCA's services would not be sufficiently available to uninsured low-income patients. CTCA financial policies discourages low-income and elderly from seeking CTCA services. The majority of those patients would probably obtain treatment elsewhere. As a result, CTCA's financial policies would adversely affect existing hospitals that would care for these patients. Therefore, CTCA failed to present sufficient information indicating that the cost of the project will not result in an unreasonable impact on the cost and charges for health services.

*Financial Feasibility*

1.28 CTCA submitted insufficient information to support the financial feasibility of the immediate and long-range capital and operating costs of its proposed project. Pursuant to general accounting principles and analysis under the following financial ratios,[43] CTCA's project is not financially feasible for its proposed facility:

a. Current assets to current liabilities ratio. This ratio is calculated to assess the liquidity; whether a company is and will be able to pay its

[41] AR 248; AR 743.
[42] AR 743. Program based these figures on CHARS data from 2001-2003.
[43] The Department of Health's Office of Hospital & Patient Data Systems (OHPDS) performed the calculations and analysis under the four financial ratios. AR 826

debts. CTCA falls within the bottom 10 percent of all United States hospitals. Even though CTCA is a for-profit corporation, it should have a better liability to debt ratio.

b. Long term debt to capitalization ratio. CTCA's ratio demonstrates that it has two times as much long term debt in comparison to its equity. CTCA falls within the bottom 25 percent of all United States hospitals.

c. Assets funded by liabilities ratio. CTCA's ratio is approximately two times greater than the average ratio for Washington hospitals. Eighty six percent of CTCA's assets are funded by liabilities, versus the average Washington hospital that funds 43 percent of its assts by liabilities. During its first year of operation, CTCA would fund 121 percent of its assets by liabilities. Therefore, CTCA's liabilities would exceed its assets.[44]

d. Debt service ratio. CTCA's debt service ratio is much worse than the Washington hospital average and is expected to grow worse.

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[44] AR 826

CTCA's financial ratios are well below the Washington hospital average.[45] CTCA's financial ratios are not appropriate ratios within general accounting principles to support the proposed project, and therefore, fail to support CTCA's proposed project.

1.29 CTCA argues that these financial ratios should be ignored because CTCA is a closely held for-profit corporation controlled by a single shareholder, who has more than sufficient access to resources to build and operate the proposed Kent facility.[46] Even though an individual ownership of a corporation may provide the corporation with more flexibility, the corporation must demonstrate the financial feasibility of a proposed project.

1.30 Despite Program's reasonable and routine request for audited financial statements, CTCA failed to submit audited financial statements. CTCA only presented financial statements that provide limited assurance of the accuracy regarding the financial information in the statements.[47] CTCA's statements are not the product of the high level of financial review required by an audited financial statement. Reviewed financial statements do not require a third party, independent certified accountant's review of a corporation's financial system of checks and balances (i.e., review and testing of internal controls and review of transactions). The financial statements

[45] Chip Hurley, a well qualified health care accounting expert agreed with OHPDS. As he explained, CTCA does not have much liquidity, is highly leveraged, and as a result would have a very bad credit worthiness rating pursuant to standards used by major banks. CTCA's financial experts were not as persuasive in their opinions because they were not concerned with unusual financing aspects of this proposed hospital. For example CTCA a substantial portion of CTCA's assets are in "options on a performance hedge fund". CTCA borrowed money to buy these options. This is an extremely speculative type of investment for a hospital. AR 177, 1145-6, and 1413.
[46] CTCA is a for-profit corporation. Program applies the four financial ratios to applications submitted by for-profit as well as not-for-profit corporations.
[47] AR 69

submitted by CTCA during the application process not only fail to provide the requested audited financial statement information, but fail to state a complete list of the assets, lenders, and/or legal entities upon which this project would be financed.[48] Therefore, CTCA's application failed to present reliable and sufficient financial information regarding its financial plan to build and operate this proposed facility. As a result, CTCA failed to demonstrate the financial feasibility of its proposed facility.

## II. CONCLUSIONS OF LAW

2.1 In response to the 1974 National Health Planning and Resources Development Act, the Washington State Legislature adopted Washington's 1979 Health Planning & Development Act. This act created the Certificate of Need Program. Chapter 70.38 RCW and *St. Joseph Hospital & Health Care Center v. Department of Health*, 125 Wn. 2d 733, 735-736 (1995). One of the purposes of the federal and state health care planning acts was to control health care costs by ensuring better utilization of exiting health care facilities and services. *Children's Hosp & Medical Center v Washington State Dept. of Health*, 95 Wn. App. 858, 865 (1999) (quoting *St. Joseph*) and RCW 70.38.105(3). Congress and the Washington Legislature were concerned that competition in health care "had a tendency to drive health care costs up rather than down, and government therefore needed to restrain market place forces. *St. Joseph* at 741. As the Washington Supreme Court clearly stated;

> Congress was concerned "that market place forces in this industry failed to produce efficient investment in facilities and to minimize the costs of health care." (cite omitted)

[48] The financial statements CTCA provided appear to be incomplete and reflect different groups of entities between 2003 and 2004. AR 180-1, 397-8.

> Congress endeavored to control costs by encouraging state and local health planning. It offered grants to state agencies provided the agencies met certain standards and performed certain functions. Among the specified functions was the administration of a CN program.

*St. Joseph* at 735-736.

2.2 The CN statutory scheme is designed in part to control rapid rising health care costs by limiting competition within the health care industry and therefore protects existing facilities from competition "unless a need for additional services" can be demonstrated. *St.Joseph* at 742.

> The CN program seeks to control cost by insuring better utilization of existing institutional health services and major medical equipment. Those health care providers wishing to establish or expand facilities or acquire certain types of equipment are required to obtain a CN, which is a nonexclusive license.

*St. Joseph.* at 736.

2.3 The CN statutory requirements limit provider entry into health care markets so the development of health care resources is "accomplished in a planned, orderly fashion, consistent with identified priorities and without unnecessary duplication or fragmentation." RCW 70.38.015(2). This health planning process strives to provide accessible health care services while avoiding unnecessary duplication and unnecessary costs that may drive up health care costs. RCW 70.38.015(1) and (5). Unnecessary duplication, such as an unneeded hospital, should be avoided to prevent the potential increase in health care costs. RCW 70.38.015.

2.4 The Department of Health Certificate of Need Program is responsible for implementing this statute. RCW 70.38.105(1). A CN shall be issued or denied in

accordance with the Health Planning and Development Act and the Department of Health rules that outline the review procedures and criteria for the Certificate of Need Program in chapter 246-310 WAC. RCW 70.38.115(1).

*Burden of Proof*

2.5 The CN applicant bears the burden to establish that the application meets all applicable criteria. WAC 246-10-606.[49] Program then renders a decision whether to grant the requested CN in a written analysis that contains sufficient information to support Program's decision. WAC 246-310-200(2). The person challenging the decision bears the burden of showing that Program's decision is incorrect. The burden of proof is a preponderance of the evidence. WAC 246-10-606. Evidence is the kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs. RCW 34.05.452(1).

2.6 The general certificate of need criteria apply to a new hospital application. RCW 70.38.115(2) and WAC 246-310-200 outline the criteria that the Program must address in determining whether it should grant or deny a certificate of need. Those criteria are "need" (WAC 246-310-210), "financial feasibility" (WAC 246-310-220), "structure and process (quality) of care" (WAC 246-310-230), and "cost containment" (WAC 246-310-240).

[49] Chapter 246-10 WAC procedural rules supplement the hearing process statutes and rules in chapter 70.38 RCW and chapter 246-310 WAC.

*Need - WAC 246-310-210*

2.7 The CN rules contain methodologies for determining need of some types of new facilities or services, but not for new hospitals or for additional acute care beds and services. RCW 70.38.115(2)(a) and chapter 246-310 WAC. Pursuant to WAC 246-310-200(2)(b),[50] Program may rely on "applicable standards" developed by other "organizations with recognized expertise" in health care planning. Program relied upon the 1987 State Health Plan methodology to calculate need for additional hospital beds as CTCA proposed. Under Chapter 70.38 RCW, the State Health Coordinating Council developed the Washington Health Plan methodology as a tool for long-term strategic planning of health care resources.[51] Even though the Washington Health Plan did "sunset" (lapse) in 1989, its methodology for hospital bed need forecasting remains a reliable tool for predicting baseline need for acute care beds. Therefore, Program did not err in its reliance on the State Health Plan methodology to determine Washington's present and future in-patient hospital bed need.

2.8 CTCA objects to the Program's use of the State Health Plan's methodology but failed to present a reasonable alternative method to calculate need. CTCA relies upon the flawed Milliman Report in its hospital bed need projections. Therefore, CTCA failed to present a preponderance of evidence that there is a need for

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[50] (2) Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

…

(b) The department may consider any of the following in its use of criteria for making the required determinations:

. . .

(v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; ….

[51] Exhibit 12.

its proposed 24 acute care bed hospital or that Program erred in its conclusion that CTCA's application is not consistent with the need criteria set forth in WAC 246-310-210.

*Unnecessary Duplication of Services - WAC 246-310-210(1)*

2.9 CTCA's hospital would create an unnecessary duplication of services that the CN program was designed to avoid. RCW 70.38.015(2); WAC 246-310-210(1). To encourage the efficient and appropriate use of existing facilities, proposed facilities should not be approved when existing facilities offer similar and reasonably accessible services. WAC 246-310-210(1)(b). The evidence clearly demonstrates that the existing hospital cancer programs offer similar services that are not used to capacity. As a result, approval of CTCA's application would undermine the "efficient and appropriate use of the existing facilities." A preponderance of the evidence demonstrates that the existing hospitals are "sufficiently available or accessible to meet the need" of the population in this service area. WAC 246-310-210(1).

2.10 CTCA argues that its application should be judged in a different manner than other CN hospital applications because its integrated cancer treatment model of care will attract patients from outside the state. The CN statutes, regulations, and case law have not created an exception for specialty hospitals, other than for psychiatric hospitals. Program must consider the "efficiency and appropriateness of the use of existing services and facilities similar to those proposed." WAC 246-310-210(1(b). Therefore, Program did not err when it treated CTCA's application as an application to

establish a 24-bed acute care hospital, and concluded there is no need because there is a surplus of acute care beds in Washington. RCW 70.38.115(2); WAC 246-310-210.

*Special Needs and Circumstances - WAC 246-310-210(3)(a)*

2.11 Relying upon WAC 246-310-210(3)(a), CTCA argues that Program ignored the special needs and circumstances of out-of-state patients. WAC 246-310-210(3)(a) states:

> (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
>
> (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

WAC 246-310-210(3)(a) (emphasis added). CTCA's special needs of out-of-state patients argument fails for two reasons. CTCA's projection that 70 percent of patients would be from out-of-state relies upon the faulty Milliman Report. Therefore, CTCA failed to present sufficient evidence to support this argument under WAC 246-310-210(3)(a). Even if CTCA presented a preponderance of evidence to support its argument, WAC 246-310-210(3)(a) does not support CTCA's out-of-state special need argument. The Washington CN program is designed to determine the needs of people residing in Washington.

2.12 WAC 246-310-210(3)(a) must be interpreted within its statutory context. RCW 70.38.115(2)(a) and WAC 246-210 requires Program to determine whether the "population to be served" has need for the project. Neither Chapter 70.38 RCW nor

Chapter 246-310 WAC define the "population to be served." The purpose of the State Health Planning Resources Development Act (Chapter 70.38 RCW) is to assure accessible health serves for the "people of the state."

> It is declared to be the public policy of this state:
> (1) That health care planning to promote, maintain and assure the health of all citizens in the state, to provide accessible health services, health manpower, health facilities, and other sources while controlling excessive increases in cost, and to recognize prevention as a high priority in health program, is essential to the health, safety, and welfare of the people of the state…

RCW 70.38.015 (emphasis added). The CN rules and regulations are for health care planning for "the people of the state." The legislature did not adopt the CN program to regulate and plan the health care for citizens of other states or nations. It was, therefore, reasonable for Program to conclude that the "people of the state" do not need a new 24-bed hospital that will provide cancer care.[52]

2.13 CTCA also argues that its application satisfies the need criterion under WAC 246-310-210(3)(c), "special needs and circumstances," because there are insufficient non-allopathic (complementary) services available from existing hospitals. CTCA failed to present sufficient evidence to support this argument. Program correctly concluded that sufficient complementary, as well as conventional, services are available in Washington State. In addition, CTCA application fails to meet criteria set forth in 246-310-210(2) regarding accessibility of the services.

[52] All states do not require CN licensure. CTCA could have chosen to establish a facility in another state, especially in light of the number of highly rated King County cancer programs, and CTCA's intent to draw patients from a 500-mile radius and from Asian countries.

*Accessibility to the Poor and Elderly - WAC 246-310-210(2)*

2.14 CTCA's application fails to meet the criteria set forth in WAC 246-310-210(2) that states:

> (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

WAC 246-310-210(2) (emphasis added). A preponderance of the evidence does not support this criteria in light of CTCA's financial policies and CTCA's income projections from Medicare/Medicaid.

*Financial Feasibility - WAC 246-310-220*

2.15 CTCA failed to present audited financial statements that would provide reliable, independently evaluated financial information and a complete list of assets, lenders and/or legal entities upon which CTCA would finance its proposed facility. Therefore, CTCA failed to present a preponderance of evidence to support its argument that Program erred in its decision regarding CTCA's financial feasibility. WAC 246-310-220.

*Structure and Process of Care - WAC 246-310-230*

2.16 As a result of the CTCA application's failure to meet the need and financial feasibility criteria, Program correctly concluded that the proposed project would not promote continuity of care and would "result in an unwarranted fragmentation of services." WAC 246-310-230(4).

*Cost Containment - WAC 246-310-240*

2.17 CTCA failed to demonstrate that its project is the superior alternative in terms of cost, efficiency, or effectiveness in comparison to the available services. WAC 246-310-240(1). CTCA proposes to build a facility that would provide similar services available in Washington State facilities that have the capacity to treat more cancer patients. Such a duplication of services will probably result in "an unreasonable impact on the cost and charges" of providing health care in Washington. WAC 246-310-240(2)(b). This project would not "foster cost containment" and "cost effectiveness" because it will create an unnecessary duplication of similar services. WAC 246-310-240(1) and (3).

*Conclusion*

2.18 CTCA's application did not meet the applicable CN criteria. CTCA failed to present a preponderance of evidence demonstrating Program erred in its analysis and denial of CTCA's application to build a 24 acute care bed hospital.

## III. ORDER

Program's denial of CTCA certificate of need application to establish a 24-bed hospital is SUSTAINED. CTCA's Motion to Strike Portions of AGSV Brief is GRANTED.

Dated this __3__ day of April, 2007.

/s/
ZIMMIE CANER, Health Law Judge
Presiding Officer

## NOTICE TO PARTIES

This order is subject to the reporting requirements of RCW 18.130.110, Section 1128E of the Social Security Act, and any other applicable interstate/national reporting requirements. If adverse action is taken, it must be reported to the Healthcare Integrity Protection Data Bank.

Either party may file a **petition for reconsideration**. RCW 34.05.461(3); RCW 34.05.470. The petition must be filed within 10 days of service of this Order with:

The Adjudicative Service Unit
P.O. Box 47879
Olympia, Washington 98504-7879

and a copy must be sent to:

Certificate of Need Program
P.O. Box 47852
Olympia, Washington 98504-7852

The request must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration is considered denied 20 days after the petition is filed if the Adjudicative Service Unit has not responded to the petition or served written notice of the date by which action will be taken on the petition.

A petition for judicial review must be filed and served within 30 days after service of this Order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V., Judicial Review and Civil Enforcement. If a petition for reconsideration is filed, however, the 30-day period will begin to run upon the resolution of that petition. RCW 34.05.470(3).

The Order remains in effect even if a petition for reconsideration or petition for review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This Order was "served" upon you on the day it was deposited in the United States mail. RCW 34.05.010(19).