Report and Recommendations

The Certificate of Need Program

October 2017

Publication Number 346-093

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Contents

Executive Summary

As required by the legislature, this report provides data related to the Certificate of Need (CN) program, suggestions for program improvements, and suggestions for increasing access to psychiatric beds.

The Department of Health (department) suggests program improvements that not only acknowledge many of the comments solicited from stakeholders during the drafting of this report, but also reflect improvements the department believes will promote transparency, consistency and efficiency in the CN evaluation process. Program improvements will require dedicated resources and increased capacity within the program, and the department will work to prioritize its recommendations further, reflective of available resources. While the department may be able to pursue many of the recommended program improvements based on existing regulatory and statutory frameworks, legislative authority is required to implement the suggestions to increase access to psychiatric beds.

Introduction

The State of Washington's operating budget for the 2017-19 biennium includes a proviso directing the department to report to the Washington State Legislature regarding the CN program. The report must include the following:

> *"By health care setting, for each of the preceding ten fiscal years, the report must show the total number of applications, the total number of accepted applications, the total number of beds requested, the total number of beds approved, and a summary of the most common reasons for declining an application. The report must include suggestions for modifying the program to increase the number of successful applications. At least one suggestion must address the goal of adding psychiatric beds within hospitals."*[1]

Background

The CN program was created by law in 1971 (chapter 70.38 RCW). The overarching goals of the program are to balance cost, quality and access while ensuring that only needed services are developed in Washington.[2]

The CN program administers regulations to implement the program that requires certain healthcare providers to obtain state approval before building or expanding certain types of facilities or offering new or expanded services.

The CN program application and review process is structured to ensure that facilities and new services proposed by healthcare providers are needed within a particular region or community. CN approval is required for any of the following:

- The construction, development or other establishment of the following new healthcare facilities:
    - Hospitals,

[1] *See* http://lawfilesext.leg.wa.gov/biennium/2017-18/Pdf/Bills/Session%20Laws/Senate/5883-S.SL.pdf
[2] *See RCW 70.38.015(1), "…to promote, maintain, and assure the health of all citizens in the state, provide accessible health services, health manpower, health facilities, and other resources while controlling increases in costs, and recognize prevention as a high priority in health programs."*

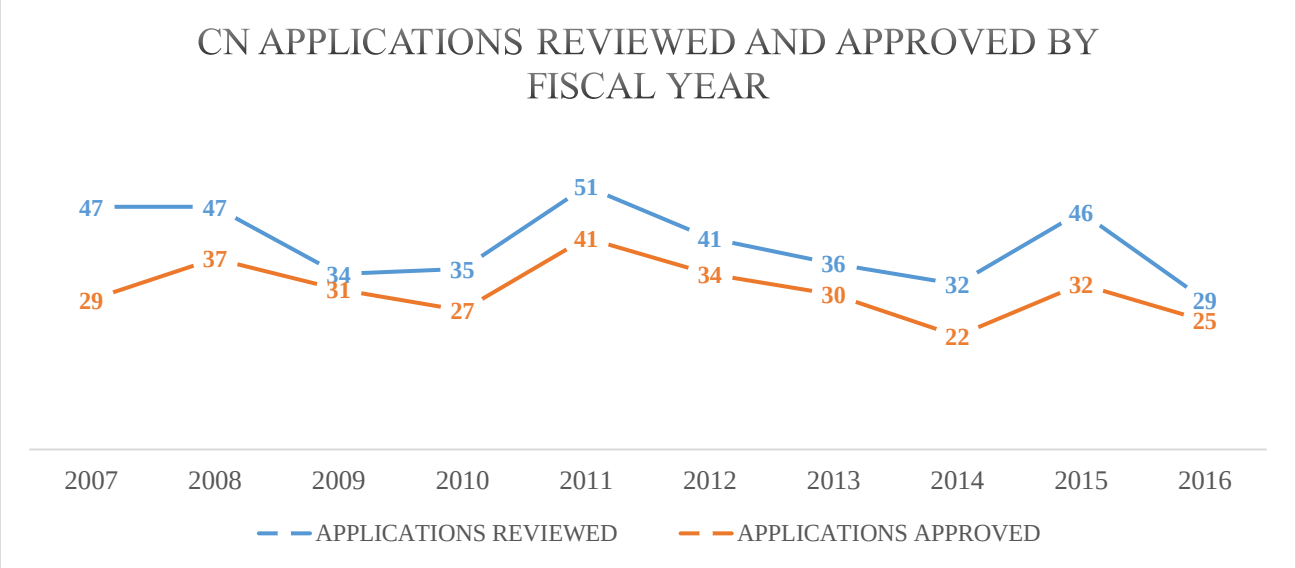
- Psychiatric hospitals,
- Nursing homes,
- Kidney dialysis centers,
- Ambulatory surgical facilities,
- Continuing care retirement communities,
- Hospices, and
- Home health agencies.[3]

- Capacity increases for hospitals, hospice care centers, nursing homes, ambulatory surgical facilities, and kidney dialysis centers;
- Sale, purchase or lease of hospitals;
- Construction, renovation, or alteration of a nursing home that substantially changes the services of the facility or exceeds an expenditure minimum; and
- Provision of specialized healthcare services, referred to as tertiary services such as open heart surgery, elective percutaneous coronary intervention, or organ transplants.

The CN program is supported by applicant fees. The number of applications the CN program receives and reviews fluctuates from year to year.

For fiscal years 2007 through 2016, the department received and reviewed 397 applications, of which 307 were approved.

Figure 1: CN Applications Reviewed and Approved by Fiscal Year



Note: To see CN applications reviewed and approved by health care setting by fiscal year (for the last 10 fiscal years), see Appendix II.

[3] *See WAC 246-310-010(26)*

CN Review Criteria

Each CN application must meet all four basic criteria, which are published in the Washington Administrative Code (WAC):

- WAC 246-310-210: Need[4]
- WAC 246-310-220: Financial Feasibility
- WAC 246-310-230: Structure and Process of Care (Quality)
- WAC 246-310-240: Cost Containment

When applying these criteria, analysts rely on information provided by the applicant, by interested members of the community, and through their own research, including utilization of existing data sources available to the department and the public. In addition to the four criteria above, applicants must meet facility-specific application requirements.

Types of CN Review

As provided in statute, CN analysts have two primary methods for reviewing applications: regular review and concurrent review.[5] How to determine what project type is subject to regular or concurrent review is described in statute and implemented in program rule. Analysts generally review applications separately at the time of submission. However, if two or more applications for similar projects in the same planning area are submitted at or near the same time, analysts perform a concurrent application review. For certain project types, the department has developed a concurrent review schedule to allow for review of these applications at the same time. Appendix III contains visualizations of all possible concurrent review outcomes. Appendix IV shows that the department approved 218 out of 254 (86%) applications under regular review and 89 out of 143 (62%) applications under concurrent review. This discrepancy in percent approved is to be expected, as concurrent applications often compete to meet the same projected numeric need within a community.

Data Summary

Description and Structure of Data

Data presented in this report represent a decade of historical CN applications and decisions. Data are sorted by healthcare setting and are presented summarily below. The same data are presented more fully and longitudinally in attached Appendix II to illustrate trending over the requested 10 fiscal years. Data are summarized by review type in attached Appendix IV. These methods of presentation are offered to provide high level and more granular views of CN data, as a means of contrast and comparison. Data are further separated by regular and concurrent review to clearly demonstrate how final application decisions were made.

The department defines the word "bed" contextually within each specific healthcare setting. For example, in the hospital setting, "bed" is the unit of measurement the program uses to determine the need in a geographic area for the construction or expansion of a hospital facility. Similarly, the unit of

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[4] *Note: Numeric need is not the only indicator of need for additional services in a planning area. This section of a CN review includes, but is not limited to, analyses of existing services in the planning area, an applicant's admission, non-discrimination, patient rights and responsibilities, and charity care policies. It also includes analysis of the impact of the proposed service or facility on existing providers.*

[5] *See RCW 70.38.115.*

measurement to determine the need for the construction or expansion of a kidney dialysis facility is termed a "station." In contrast, a tertiary service, such as a percutaneous coronary intervention program located within a hospital, is measured by the CN program as a single unit because the need for the service within a specific planning area is being evaluated as a "service", as opposed to a number of stationary objects, rooms or beds.

The crosswalk below offers linkages between the requested data elements, the elements of measurement, and naming conventions used by the program to collect the same data:

Table 1: Unit of measurement for each healthcare setting type

Healthcare Setting/Applicant Type	Project Abbreviation	Unit of Measurement
Ambulatory Surgical Facility[6]	ASF	Operating room
Continuing Care Retirement Community	CCRC	Bed
Home Health Agency	HH	Agency
Hospice Agency	Hospice	Agency
Hospice Care Center	HCC	Bed
Hospital	Hospital	Bed
Kidney Dialysis Center	ESRD (End Stage Renal Disease)	Station
Nursing Home	NH	Bed
Psychiatric Hospital	Psychiatric Hospital	Bed
Sale, Purchase, Lease	SPL	None
Skilled Nursing Facility	SNF	Bed
Tertiary Health Service	THS	Service

Data for each setting type are organized in the summary table below, and described by the following headings:

- "Regular Review" and "Concurrent Review" denote the method of review as more fully described above.
- "Healthcare Setting" denotes the specific healthcare setting and CN applicant type.
- "Total Applications Reviewed" denotes the number of applications reviewed during fiscal years 2007 to 2016, and either approved (a CN issued) or denied within that date range. This addresses the proviso request to "show the total number of applications" and is more fully addressed in the tables contained in Appendix II.
- "Total Applications Approved" denotes the number of applications for which a CN was issued during fiscal years 2007 through 2016. This addresses the proviso request to "show…the total number of accepted applications" and is more fully addressed in the tables contained in Appendix II.
- "Total Applications Denied" means the number of applications that failed one or more of the criteria described in chapters 246-310- 210, -220, -230 and/or -240 WAC. This heading addresses the proviso request to provide the "most common reasons for declining an application" and is more fully addressed in the tables contained in Appendix II.
- "Percent approved" represents the overall percentage of applications approved during fiscal years 2007 through 2016.

Additionally, while the data below represent all requested data collected by the program, it also includes a small number of anomalies. For example, in the 2015 End Stage Renal Disease regular

[6] *For the purposes of reviewing Certificate of Need data, the terms "Ambulatory Surgery Centers" (ASCs) and "Ambulatory Surgical Facilities" (ASFs) are interchangeable. The term "ASC" is an indicator of Medicare-certification, while "ASF" refers to the licensure category.*

review category, a provider requested approval for 29 kidney dialysis stations in one planning area, another provider requested approval for the addition of three kidney dialysis stations in a different planning area, while another provider submitted and subsequently withdrew their application. The application for 29 kidney dialysis stations was denied; the application for the addition of three dialysis stations to an existing facility was approved, while the third application was withdrawn. Because the withdrawn application was not denied, it is included within the total “applications reviewed” category, but not in either of the “applications denied” categories. Withdrawn applications and other anomalies are identified below.

Summary of Application Approvals and Denials by Setting (2007-2016 FY)[7]

	REGULAR REVIEW				CONCURRENT REVIEW			
Healthcare Setting	**Total Apps Reviewed**	**Total Apps Approved[8]**	**Total Apps Denied (All)[9]**	**% Approved**	**Total Apps**	**Total Apps Approved[10]**	**Total Apps Denied (All)[11]**	**% Approved**
Ambulat-ory Surgical Facility	49	45	2	92%	4	4	0	100%
Continuing Care Retirement Community	1	1	0	100%	-	-		
End Stage Renal Disease (Kidney Dialysis Center)	50	44	5	88%	103	58	44	56%
Hospice Care Center	8	8	0	100%	-	-		
Home Health	18	10	8	56%	4	4	0	100%
Hospice	15	11	3	73%	-	-	-	-
Hospital	55	54	1	98%	15	10	4	66%
Nursing Home	17	12	3	71%	-	-		
Psych Bed Conversion	1	1	0	100%	-	-		
Psychiatric Hospital	7	5	2	71%	8	4	4	50%
Rehab Bed Conversion	4	2	2	50%	-	-		
Sale/Purch/ Lease	11	11	0	100%	-	-		
Skilled Nursing Facility	1	1	0	100%	-	-		
Tertiary Health Service	17	13	4	76%	9	9	0	100%
Total	254	218	30		143	89	52	

[7] Numbers may not total to 100% due to withdrawn or returned applications.
[8] End Stage Renal Disease (Kidney Dialysis Center)- One application was withdrawn by the applicant. Nursing Home- One application was withdrawn by the applicant; another was returned to the applicant.
[9] Ambulatory Surgery Facility- Two applications were initially approved, but applicants either did not accept department conditions, or failed to commence the project within CN timelines; as a result, the projects were denied. Hospice- One application was returned at the request of the applicant.
[10] End Stage Renal Disease (Kidney Dialysis Center)- One application was withdrawn by the applicant. Hospital- One application denied on unresolved pivotal issue.
[11] End Stage Renal Disease (Kidney Dialysis Center)- Nine applications met all standards described in WAC 246-310-210 through -230, but failed as a result of superiority analysis contained in -240; one application withdrawn after approved.

Declined Applications

The most common reasons for denying a CN application are cost containment described in WAC 246-310-240 and financial feasibility described in WAC 246-310-220.

There are several reasons why an application would be denied under financial feasibility, described in WAC 246-310-220. Reasons include, but are not limited to:

- Failure to document site control, meaning that the applicant does not hold a valid lease for their proposed site, or they do not have clear legal ownership of the site.
- Failure to disclose all major contractual relationships, such as a medical director agreement or a lease agreement.
- Failure to provide realistic utilization projections that would support the financial projections.
- Failure to demonstrate that revenues would exceed expenses.

WAC 246-310-240(1) requires the assessment of cost containment to include consideration of whether "Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable." The department evaluates superior alternatives through a three-step process that is designed to eliminate projects that are not the superior alternative as follows:

- Step one: The reviewer identifies whether the applicant meets the applicable review criteria described in WAC 246-310-210, -220, and -230. If the applicant has not met the applicable review criteria described in these WACs, the application review ends, and the applicant is not the superior alternative. If the applicant meets the applicable review criteria, the application advance to step two.
- Step two: Step two directs department staff to evaluate the alternatives considered by applicant prior to submitting their project. In some cases, this can be as simple as an evaluation of "no project" versus the requested project.
- Step three: This step is only applicable when two or more applicants have passed steps one and two. Step three is a comparison[12] between the applications to determine which is the superior alternative. For example, in kidney dialysis projects, the superiority criteria are outlined in rule. For other application types, the department relies on data provided in the application and makes its determination based on factors including, but not limited to: ability to execute the project quickly and provide services, Centers for Medicare and Medicaid Services quality rating, and access to services by Medicare and Medicaid patients.

[12] *See WAC 246-310-120*

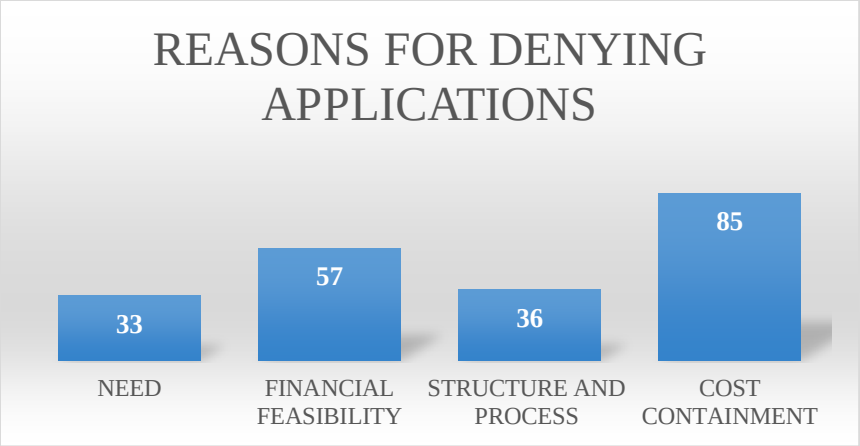

Figure 1 Reasons for Denying Applications: One application may be listed in multiple categories.

Suggestions for Possible CN Improvements

The department offers the following suggested program improvements, which could be expanded by many of the additional suggestions we received from stakeholders captured in Appendix I.

The department is eager to implement the recommended quality improvements. However, the department will need to consider how to best approach program improvements given available resources with the certificate of need program.

I. Improve the quality of CN program rules, policies and processes.

1. Improve program processes, guidelines and assistance:

a) Develop, in consultation with the regulated community, a general how-to guideline for completing a CN application, including a frequently asked questions section, and make it available on the CN website.

b) Develop, in consultation with the regulated community, a step-by-step guide and template for how to complete methodologies and post this guide on the department's CN website.

c) Encourage applicants to take advantage of available CN program technical assistance to help assure complete applications and correct application of methodologies.

d) Develop, in consultation with the regulated community, regular trainings that orient potential applicants to CN rules and processes and how to complete CN applications.

e) Make application forms available online to download in MS Word. Explore the feasibility of allowing applications to be completed online.

f) Design, create, and implement a CN data system that supports review and tracking of applications, the monitoring of compliance with CN decisions and conditions, and the collection and reporting of CN performance measures and reports useful to program staff and manager, the legislature, and the public.

g) Ensure conditions on the approval of a CN application directly relate to the scope of the CN project and are consistent by application type.

h) Review CN decision documents and identify how they can be written in a more reader-friendly format.

2. Increase transparency:

a) Broaden stakeholder engagement to include consumers, consumer advocates, health plans, employers and others in addition to healthcare providers.

b) Provide clear CN guidance and information that is easily accessible to applicants and the public.

c) Regularly update the CN website to increase ease of use and ensure current data and materials are available to applicants.

d) Increase evaluation and decision transparency to support current and future applicants by, for example, the timely posting of decisions on the CN website.

e) Improve public perception through data transparency and education that CN is a process that generates consistent decisions.

3. Update and simplify CN program rules and need methodologies that are used to decide CN applications.

II. Expand access to psychiatric beds.

a) Amend the current psychiatric bed exemption in RCW 70.38.111 and RCW 70.38.260(4) to eliminate the 16 bed restriction for the construction, development, or establishment of new psychiatric hospitals licensed under chapter 71.12 RCW. Please note that this may have reimbursement implications.

b) Amend the current psychiatric bed exemption in RCW 70.38.260(3)(a) to eliminate the 30-bed one time expansion restriction for psychiatric hospital licensed under chapter 71.12 RCW.

Related Reports

Washington State CN Program- 2006 Task Force Report

Performance Audit of the CN Program- 2006 JLARC Report

Effects of CN and Its Possible Repeal -1999 JLARC Report

The Failure of Government Central Planning- Washington's Medical CN Program- 2006 Washington Policy Center Report

Summary of External Suggestions

On July 27, 2017, the department sent an email to all CN topic subscribers and Tribal leaders through GovDelivery inviting participation in this process. We requested, by mail or email, comments and suggestions for program improvement by August 15, 2017. We informed subscribers and Tribal leaders that all responses received by this date would be included in an appendix to the final report.

Summarized below by category and subject matter are suggestions received in response to the department's invitation for comment. For the full submissions, see Appendix I.

Topic A: Program Efficiency and Timeliness
Suggest considering improvement in CN department efficiency and timeliness - decision delays reduce consistency and impact responsiveness from the CN program.
The CN evaluation process is lengthy, sometimes resulting in delayed decisions regardless of project or application complexity. General timelines for application review and evaluation should be revisited to determine whether these processes can be streamlined to increase decision issuance efficiency.
Follow current rules regarding timelines.
Eliminate concurrent review cycles that create only one window of time per year to apply for certain types of projects subject to CN review.
Offer applicants the option to electronically complete quarterly project progress reports.
Increase predictability and clarity of CN surveys. Confirm when, and to whom surveys will be sent.
Topic B: CN Applications
Streamline CN applications by eliminating duplicative and unnecessary questions. Revise application templates to more clearly and concisely describe specific information to be provided by applicants.
Evaluate and reduce volume of screening questions to ensure they serve an essential purpose, are relevant to the department's review, and are appropriate in scope and subject matter.
Revise and update application guidelines. Assure that guidelines are available online.
Provide training, information and materials that prepare applicants participating in the CN review process to meaningfully engage in CN review. Additionally, the department should more frequently publish and post interpretive statements designed to guide application preparation.
Publish or make available online all application materials, including letters of intent, the CN application, screening and public comment/rebuttal documents.
Applications are expensive and do not always represent important factors in facility operation.
Simplify the application process for joint venture proposals.
Topic C: Transparency
Maintain a database of all current and past decisions, organized so that potential applicants have an easy directory of historic decisions by project type to review for guidance and precedent.
Publish monthly status reports on progress of CN decisions.
Publish the CN program budget so applicants and others understand where and how application fees are being used by the department to support the program. Include amounts spent on staff and services from the Office of the Attorney General.

Topic D: Methodology
Use community health impact assessments to improve access to care.
Need methodologies should be updated and based on community need as opposed to numeric need. Decisions should be based on analysis of that community need.
Regularly update methodologies. Create a schedule for updating methodologies.
Create methodologies that are clearly written and understandable.
Remove program reference to and reliance upon the 1987 Washington State Health Plan in methodologies.
Topic E: Rules and Rulemaking
Rulemaking processes for CN should be revisited and designed to coincide with and support facility planning and strategic decision-making.
Establish a rulemaking schedule that would proactively identify when specific issues will be addressed, such as methodologies.
Strengthen CN review criteria. Revise rules to ensure a transparent, meaningful community-based review process.
Modify "discovery" rules; they unduly increase costs and length of time for appeals.
Bring CN rules current. They are inconsistent with current health care system movement as contemplated by the Affordable Care Act.
Ambulatory surgery facilities (ASF) expansion rule treats the expansion of operating rules in hospital outpatient departments (HOPD) and ASF differently. The rule should be abandoned.
New kidney dialysis rules may incorrectly weigh quality measures and do not clearly define "capital expenditures."
Topic F: CN Appeals Process
The appeals process slows the delivery of services.
Allow affected party participation, but raise the bar for appeals.
Topic G: Psychiatric Beds
Review to determine whether extending/expanding Engrossed Substitute House Bill (ESHB) 1547 should be granted.
Review psychiatric bed need methodology to determine if any improvements can be made.
CN should not be weakened past ESHB 1547; the current need for psychiatric beds is adequately addressed through the legislature's extension of ESHB 1547 through June 2019.
Consider solutions specifically tailored to the field of acute psychiatric hospitals.
Allow a temporary exemption for freestanding psychiatric hospitals from the CN process.
Use different statistical figures in determining actual need in each county in line with current epidemics in the field and national averages.
Adopt the national standard of 50 non-forensic beds per 100,000 people.
Topic H: CN Program Scope
CN is not responsive to psych bed needs in Pierce County.
CN does not recognize differences in facility types. Capital costs are different for facility types.
All hospital transactions should be subject to CN review.
Create policy statements that are clearly written and understandable.
Ensure CN rules are followed and that the program does not exceed its authority.

Topic I: Issued CN Conditions
Enforce CN conditions. Issued CNs should include commitments from providers to ensure access to care that are monitored by the department and enforced by the Attorney General. Patient complaints to the department regarding restrictions on health care that were provided at a facility or other CN noncompliance should trigger a department investigation.
Unify or make uniform the scope of conditions issued for CN.
Create ways for the CN program to discuss conditions with applicants. Decision letters and processes allow little opportunity for applicants to discuss concerns about conditions or how conditions are written.
Conditions should be clearly tied to the subject matter and scope of issued CN.
Topic J: General Comments
Support: CN is a necessary and productive tool to minimize the risk of fraud/abuse in healthcare.
Support: Please ensure we retain a CN process in this state! It helps ensure quality care and access for all.
Support: … the CN Program allows for a measured appropriate growth of dialysis providers throughout Washington. Without this guiding structure, rural communities and patients with less financial resources will be harmed.
Support: We very much appreciated the department's close collaboration with us and other dialysis providers in the rulemaking process to ensure that the new rules are fair and appropriate.
Support: The CN process is an essential tool to ensure that proposals to change the health system infrastructure are deliberately reviewed to consider the impact on communities.
Oppose: …recommend scrapping the CN process altogether.
Oppose: CN program is antiquated, creates costs that exclude potentially beneficial services, and should be dismantled.
Oppose: CN is not an effective mechanism for controlling overall health care spending; evidence about the effect of CN on quality is inconclusive; conflicting evidence found regarding the effect of CN on access to health services.
Oppose: The department should work with stakeholders to develop or redesign system that encourages innovation and collaboration, improves access to care, achieves maximum possible outcomes, and encourages high efficiency in the Washington healthcare delivery system.
Oppose: CN supports retention of outmoded systems and thinking, retaining the high cost system of the past instead of encouraging the innovative thinking required for the future.

Appendix I:

Full Suggestions as Submitted

Appendix I: Suggestions

Dear Tim,

Thank you for giving us the opportunity to provide comments. The certificate of need program is a barrier for companies like ours who are not expanding into Medicare Home Health. Our DOH license is for In-Home Services to provide Home Health. In our case, we provide Private Duty Nursing. We are not competing at all with Medicare Home Health agencies. We do not provide Home Health visits.

In order for us to get some insurance contracts to provide Skilled hourly nursing in the home, (not Medicare visits) to adult and pediatric clients, we have to be Medicare certified. However, the way the certificate of need works, it is very expensive, time consuming and the form that is mailed out to other agencies is confusing.

There should be some way to become Medicare certified in order to get contracted without having to go through the certificate of need program. It is very expensive and time consuming. It prevents Washington businesses, like Alliance Nursing from providing critical nursing services, due to the limitations of the program.

We do not see the benefits of a certificate of need program, however, would like to understand it better, perhaps you could email the positives?

Thanks so much for asking for our comments!

Sincerely,

Heather
Heather Navarre, PHR
Human Resources Director
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Hello – I'm Greg Pang, President & CEO of Community Home Health & Hospice. We are a nonprofit Home Health and Hospice provider in SW Washington. We have an annual budget of $25million and 325 employees. I'd like to provide a few thoughts on CON.

- CON is a necessary and productive tool to minimize the risk of fraud/abuse in healthcare. Washington State has the lowest incidence of fraud/abuse (virtually none), highest quality and lower per capita costs thanks in large part to CON.
- I have been through 2 CON issues in my area in the past 10 years, highlighting problems with the current program. Rulemaking must be updated:
    - In 2006, Assured Home Health applied for Home Health CON in Cowlitz County. This was granted. For the next several years, Assured did not provide ANY services in the County. It opened up a fake store front (as required). Then, the owner sold the CON to LHC (Louisiana Health Care). It was clear from the start that the intention of the person who applied for the CON was to sell the CON for a profit despite their public testimony. Suggestion: once a CON is granted, there should be clear standards on operating requirements and surveys to avoid bad players who just want to sell CONs for cash.
    - In 2012, my agency CHHH (find us on the web at www.chhh.org) applied for and was granted a CON to build a Hospice Care Center in Vancouver, WA. Our project was widely supported in writing by every legislator, mayor, and hundreds of individuals/organizations in Clark County. Upon issuance, the "affected party" immediately put in an appeal. This appeal would have locked us into a legal battle for years. We are a small nonprofit. The affected party was a huge hospital system who appealed because they did not want competition for their own hospice care center. Had this gone the distance and we prevailed, there is NO provision for the prevailing party to recover legal fees. Fortunately, in the end the affected party withdrew their appeal upon orders from their Board or Directors and public pressure. Suggestion: Affected Parties have WAY too much power to hold up a bona-fide process whereby the state and public weighed in and proved the community has need for the service. The Affected Party can hog-tie the process and cost the applicant hundreds of thousands of dollars simply because they do not want the competition. My suggestion is that affected parties may weigh in as part of the public process but there must be a higher hurdle for affected parties to put in an appeal. Perhaps the appeal is arbitrated by the CON unit, rather than in the public courts. Perhaps the appeal must be done in writing and then responded to within 30 days.

Thank you for the opportunity to provide feedback, please contact me if you have questions.

Greg Pang

Dear Mr. Farrell,

This is brief but I'm grateful for the opportunity to say, please ensure we retain a Certificate of need process in this state! It helps ensure quality care and access for all.

Thank you,

Candace Chaney RN-CHPN
LHC Group/Assured Hospice/Idaho Hospice
360.523.8690

Washington State Hospital Association

August 15, 2017

Timothy Farrell
Director of Policy and Communications
Health Systems Quality Assurance
WA State Department of Health
Timothy.Farrell@doh.wa.gov

WSHA Suggestions for Improvements to the Certificate of Need Program

Dear Tim:

On behalf of our 107 member hospitals and health systems, the Washington State Hospital Association appreciates the opportunity to provide suggestions on how to improve the Certificate of Need (CON) program and increase the number of successful applicants.

Our comments include process, procedure, and transparency improvement ideas. We do not believe the budget proviso is aimed at comments about Certificate of Need retention or elimination, so have not weighed in on that topic. WSHA has had multiple conversations over the years with members about the efficacy, benefits, and drawbacks of Certificate of Need as a regulatory framework. Based on these conversations, WSHA members have been very clear that the CON process and program do not function well and need significant improvement.

Based on member feedback, WSHA submits the following suggestions for improvements to the CON program and its process. Many of these improvements could be accomplished without statutory or regulatory change. These suggestions will help increase the number of successful applicants and improve the overall process for applicants.

- **Suggestions to address the goal of adding psychiatric beds within hospitals**
  - During the 2017 session, the legislature enacted HB 1547 that allows currently licensed hospitals to add psychiatric beds without going through the CON process. The exemption is valid for two years and the results should be monitored to determine if an extension or expansion by the legislature should be granted.
  - Review the psychiatric bed need methodology to determine if any improvements can be made to help address the need for additional beds.

- **Improve efficiency**
  - Revise and update the CON application forms to remove extraneous questions. In addition, add questions that are commonly or always asked in the program's second screening letter or other follow up questions. An application form should be provided for each type of project for which Certificate of Need review is required. CON application forms and supporting documents asked of applicants should to align with the regulatory requirements and scope of the Program's authority.
  - Make electronic copies of all CON application forms available online and downloadable as Word templates. Currently, only a portion of CON application forms are available online and are provided as PDFs; when applicants request an application template, they are provided

with a photocopy by mail or a PDF by e-mail. This requires applicants to retype or prepare their own editable version of the application form.
    - Limit screening questions to information that is within the scope of the application and the program's authority. Currently, some screening questions are beyond the scope of authority for the CON program.
    - Place CON materials (applications, screening responses, etc.) online for ease of access. Currently, requests for copies must be in writing. This would also increase the transparency of the program.
    - Transition to electronic versions of documents and electronic communication including, but not limited to, CN application forms, progress reports, surveys and data requests. Currently, the CON program mails requests for data in paper version, but recipients must transform these into electronic/type-able document to provide the information and/or call to request an editable document. In addition, data requests and communications are often sent via mail, rather than email, slowing down response times.
    - Develop a routine schedule for surveys conducted by the CON program (e.g. acute care bed survey, annual operating room / procedure room use survey, etc.). Currently hospitals and health system stakeholders cannot predict when they will receive survey requests, nor are the requests provided to a designated point of contact.

- **Increase timeliness**
    - WSHA and our members have observed the program appears understaffed. A lack of well trained staff contributes to a lack of efficiency, timeliness, consistency and responsiveness from the CON program. The program needs to be staffed with well-trained individuals to fulfill its obligation to provide robust, timely CON review per statutory and regulatory requirements.
    - Increase timeliness of application processing and review that, at a minimum, meet the prescribed deadlines in the regulations. The CON program consistently takes the full amount of days for its process steps, even for applications that are straightforward and require minimal review. In addition, it is not atypical for the CON program to inform applicants that the decision for their CON application will be delayed multiple times.
    - Adhere to statutory and regulatory requirements regarding expedited review. An application subject to expedited review should not be extended or moved to regular review without regulatory authorization and required notice with explanation to the applicant. Staffing shortages should not lead to inappropriately handled applications or violation of required timelines.

- **Consistency and clarity in decisions**
    - Increase consistency in the CON review and decision-making processes, including explanations of decisions. Depending on the analyst who is assigned to an application, the number of screening questions, thoroughness of review and/or thoroughness of the written decision may vary. The CON program needs greater consistency between analysts, which may be bolstered by improved training, retrospective case reviews or other quality assurance measures.
    - Increase Department of Health leadership oversight to ensure consistency in staff training, application processing, and decisions. Applicants worry, based on past experience, that CON decisions are outcome-based and that raising concerns can lead to reprisal.

- Present information in CON decisions (grants or denials) in a manner that aids the reader in understanding the factors important to the program's decision. Recent opinions do a poor job of explaining to the primary versus secondary issues that were central to the underlying decision.

- **Transparency and cost effectiveness**
  - Publish the CON program budget so applicants and others understand where and how application fees are being used by the Department to support the CON program. This should include amounts spent on staff and services from the Attorney General's Office.

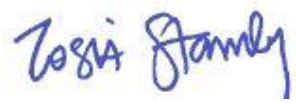
- **Conditions for certificates of need**
  - Based on the experience of applicants and interested parties, the scope of conditions issued for certificates of need have some areas of commonality but can vary widely between applicants in terms of what is expected by the Department.
  - Create avenues for the CON program to explain and discuss potential conditions, including the scope of the conditions, with applicants. CON decision letters and processes allow little to no opportunity or circumstance for applicants to discuss concerns about a condition that has been issued or how it has been phrased.
  - CON conditions should be clearly tied to the subject matter and scope of granted certificates of need. Some conditions imposed on granted CON applications are unrelated to the application or subject matter or are unnecessary, non-value added conditions, such as staffing lists. Unrelated, burdensome conditions that do not relate to the subject or scope of the granted application are unreasonable.

- **Clear and updated methodology**
  - The Department's methodologies and policy statements are unclear and are subject to multiple conflicting interpretations, leading to confusion and inconsistent decisions.
  - Update need methodologies. For example, the acute care bed need methodology has not been updated since the 1980s.
  - Provide a schedule for updating the methodologies and engaging in rulemaking. Currently there is no set schedule for rulemaking or clarity about when areas will be addressed.

We are happy to provide additional details or an explanation on any of the above suggestions.

Finally, we are interested in the data you are gathering to satisfy the proviso and would appreciate the opportunity to discuss the data prior to the report to the legislature.

Sincerely,



Zosia Stanley, JD, MHA
Government Affairs Director
Washington State Hospital Association

Cc: Steve Bowman

Virginia Mason Memorial

August 11, 2017

Timothy Farrell
Director of Policy and Communications
Health Systems Quality Assurance
WA State Department of Health

Virginia Mason Memorial Suggestions for Improvements to the Certificate of Need Program

Dear Tim:

Yakima Valley Memorial Hospital Association (Virginia Mason Memorial) has worked with the Department on Certificate of Need (CON) requests as both an applicant and an interested party. We believe improvements are needed and we appreciate the opportunity to provide comments and suggestions for this report to the Legislature.

For brevity, we have focused our comments and suggestions on two main areas—Timeliness and Clear and Updated Methodology. They are outlined below.

Timeliness

- We would like to see improvement in CON department efficiency and timeliness of processes. Delays contribute to a lack of consistency and responsiveness from the CON program.
- In our experience, delays in processing and review of work are common. These delays prohibit providers/customers from appropriate planning and strategic decision-making. These delays in decisions can preclude an applicant from entry or expansion into new services and thwart competition and innovation. Unfortunately, this may lead to Washington residents lacking choice or delaying their ability to seek care timely or conveniently. Specifically,
    - On March 14, 2016, Yakima Valley Memorial Hospital submitted a rule-making petition, pursuant to RCW 34.05.330 to update the minimum volume standards of the elective PCI CON rules to reflect the 2014 expert consensus document.
    - In June 2016, the CON office issued a CR 101 in response to our petition.
    - As of August 10, 2017, (17 months since the petition was filed) there have been four (4) work sessions, the first on October 3, 2016, without moving forward past the CR_101 phase.

Clear and Updated Methodology

- Once CON rules are established, the Department should identify the appropriate steps to:
    - Update need methodologies and review rule standards on a set schedule.
        - The elective PCI CON rules (RCW 246-310-700 to 755) were enacted on Dec. 19, 2008 and have not been updated or revised.
    - Ensure CON recipients adherence to those established rules. There is a need to track, report, and ensure compliance to published rules.

We hope these suggestions and comments help improve the CON program. We are happy to provide additional details or an explanation on any of the above suggestions.

Sincerely,

Russ Myers

Russ Myers, President and CEO
Virginia Mason Memorial
509-575-8007

HALL RENDER
KILLIAN HEATH & LYMAN

Hall Render Killian Heath & Lyman, PC
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Emily R. Studebaker
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August 10, 2017

Tim Farrell
Director of Policy and Communications
Health Systems Quality Assurance
Washington State Department of Health
101 Israel Road S.E.
Tumwater, WA 98501

RE: Department of Health Request for Suggestions for Improving Certificate of Need Program

Mr. Farrell:

On behalf of Proliance Surgeons, Inc., P.S., this letter responds to the Washington State Department of Health's request for suggestions on improving Washington's Certificate of Need ("CON") program. As further discussed below, the CON program has failed to accomplish its stated goals, and research indicates that CON programs may adversely impact quality for some services; moreover, CON programs impede the types of collaboration required to institute systems of continuous care in our communities and frustrate development of relationships to share information as required to optimize quality of care.

Proliance Surgeons therefore recommends that the CON program in Washington be dismantled as outmoded and that the Department work with community stakeholders to develop or redesign a system that encourages innovation and collaboration, improves access to care, achieves maximum possible outcomes and encourages high efficiency in Washington's health care delivery system.

Background

CON is a program that was intended to address a particular problem at a particular time. During the 1960s and 1970s, the health care system was radically different from today's health care system. Most health care was provided through private physician offices and hospitals, the vast majority of them nonprofit. Providers were paid based on their costs for providing care, known as "fee for service" payment and could furnish any service that they could establish and for which they were qualified. Lawmakers believed that this system led many providers to adopt

a "more is better" approach, adding service after service, machine after machine, hospital after hospital. Costs soared.

Beginning in 1964, states began searching for ways to curb these rising costs, believing that the uncontrolled proliferation of new technologies, combined with cost-based payment for medical services, was encouraging overutilization and increasing costs. New York was the first state to enact a CON law, stating as its goals the control of costs and improvement in quality. Other states followed, and in 1974 the federal government endorsed the approach by enacting the National Health Planning and Resources Development Act of 1974 ("NHPRDA"). This federal statute tied federal funding for certain services to states' enactment of CON laws, and it had its desired effect: by 1980, 49 states had enacted CON laws.

In theory, these laws would cut health costs while increasing access to care for lower income populations. By restricting market entry, went the reasoning, providers could be forced to subsidize indigent care and medical services to the poor. In practice, though, CON laws were used to suppress competition and further raise the cost of care. Recognizing the programs' failure, the federal government repealed the NHPRDA in 1987. Several states followed suit, but some, including Washington, retained their CON laws.

Washington CON: A Failed Attempt to Regulate Costs, Quality, and Access

According to its enabling statute, found at RCW 70.38.015, the purposes of Washington's CON program are (1) to restrain health care costs by regulating the supply of services and facilities; (2) to guide the development of health services to avoid undue duplication or fragmentation; (3) to promote quality of care and access; and (4) to provide for adequate information about the health care system. However, a 1999 study, entitled "Effects of Certificate of Need and Its Possible Repeal," performed for the Joint Legislative Audit and Review Committee ("1999 CON Study")[1] found little to recommend the CON program, and much that supports its repeal.

In regards to the analysis of Washington's CON program, the 1999 CON Study included the following:

> **COST.** The study found strong evidence that CON is not an effective mechanism for controlling overall health care spending. While CON laws can be effective in slowing the expansion of some services, other factors affect health care costs that CON laws do not control. . . . The study also found that CON has restricted the supply of some specific services and that the repeal of CON has been associated with supply surges in some states. The study found no convincing evidence that CON programs restrict the growth of managed care.

[1] "Effects of Certificate of Need and Its Possible Repeal," Health Policy Analysis Program of the University of Washington's School of Public Health and Community Medicine (Univ. of Wash., Jan. 8, 1999).

> **QUALITY.** Evidence about the effect of CON on quality is inconclusive. The evidence is weak regarding the ability of CON to improve quality by concentrating volume of specialized services. . . . Weak, conflicting evidence exists regarding the effect of CON on the market share of for-profit providers and any resulting impacts on quality. CON does not provide an ongoing mechanism to monitor quality.
>
> **ACCESS.** Conflicting evidence was found regarding the effect of CON or its repeal on access to health services. In some instances, CON has been used to protect existing facilities in inner city areas or to prompt providers to locate in those areas. In other instances, CON appears to restrict access by preventing the development of new facilities. . . . CON does not provide an ongoing mechanism to monitor access.
>
> **CHARITY CARE.** CON provides some initial screening regarding a facility's likelihood of providing charity care, but the program in Washington and most other states does not include monitoring for compliance. [N]o studies have been conducted to measure the effect of CON in increasing levels of charity care. Also, financial and market pressures make it increasingly difficult for all types of providers to offer charity care.
>
> **RURAL CARE.** Weak and conflicting evidence was found regarding the effect of CON on access to services in rural areas. One analysis showed that CON did not affect the development of rural networks.

1999 CON Study at *iii*. Washington's CON program has thus failed to control costs, has not appreciably improved quality, has restricted access to services and has had no discernable impact on rural health care services. As was found at the federal level, the CON program is ineffective and should be repealed.

CON Impedes Providers' Efforts to Collaborate and Innovate

While the fate of health care reform at the federal level remains uncertain, it is clear that current initiatives moving toward value-based payment will continue. To institute these value-based payment systems, providers must develop innovative strategies, work with other providers and payers to develop information and care systems, and move toward coordinated care systems that care for defined populations over the continuum of their lives.

CON erects barriers to each of the above mentioned activities necessary to succeed in a value-based environment by imposing regulations that purposely restrain the kinds of relationships that encourage creativity and innovation. By attempting to control health care markets, CON laws necessarily favor care systems already in place and discourage new structures and arrangements. CON thus supports the retention of outmoded systems and thinking, retaining the high cost system of the past instead of encouraging the innovative thinking required for the future.

The CON program presents unnecessary barriers to the innovation required for the future, and should be dismantled.

Recommendation: Work with Stakeholders to Improve Washington Health Care

A study separate from the 1999 CON Study, which was performed in 2006, provides the basis for one possible approach to the future of health care in Washington.[2] The 2006 Task Force Report did not dispute the findings of the 1999 CON Study; rather, the Task Force Report analyzed the types of services regulated by CON and considered whether the CON program was effective in regulating the services it was designed to control. Its basic conclusion can be fairly summarized as finding that the CON program required a complete overhaul, to be accomplished, said the Task Force, by expanding CON's scope and increasing its power to monitor performance.

Proliance Surgeons does not subscribe to the Task Force Report's recommendation because expanding a failed program does not appear to us the right approach. We do, however, support the Task Force's recommendation for a first step: work with stakeholders, including providers, communities and payers, to design a system that encourages innovation and collaboration, increases access, improves quality, rewards efficiency and emphasizes outcomes.

Our recommendation is based on the premise that the experts in our health care system are the providers, payers, and communities who live the system every day. We are actively working with each other, with legislators, and with regulators, and we bring to the table a wealth of creativity and experience that is unparalleled and unequalled. Use our expertise to bring the best in health care to Washington.

Thank you for soliciting our recommendations.

Sincerely,

HALL, RENDER, KILLIAN, HEATH & LYMAN, P.C

Emily R. Studebaker

[2] "Washington State Certificate of Need Task Force Report," Health Care Authority (Nov. 1, 2006; *updated* Nov. 6, 2006) (Task Force Report or 2006 Task Force Report).

NORTHWEST Kidney Centers

August 15, 2017

To: **Tim Farrell**
Director of Policy and Communications for Health Systems Quality Assurance
Washington State Department of Health
101 Israel Road SE
Tumwater, WA 98501

From: **Austin Ross**
Vice President of Planning
Northwest Kidney Centers

Re: **Comments regarding Certificate of Need October Report**

Please find the following comments submitted by Northwest Kidney Centers for the department's report to the Governor and fiscal committees on October 1, 2017.

Northwest Kidney Centers would like to provide insight into the current process for ESRD (End Stage Renal Disease) Certificate of Need applications and the path that has been established starting in 2018. The Certificate of Need (CN) program serves different types of organizations and therefore want to bring focus on the treatment of patients with kidney disease.

To be very clear – the DOH Certificate of Need program allows for a measured appropriate growth of dialysis providers throughout Washington. Without this guiding structure, rural communities and patients with less financial resources will be harmed.

A period of transition: Rule making

Northwest Kidney Centers was pleased that the Department of Health had opened up rulemaking for ESRD CN in 2013 and the collaborative approach that was taken. These sessions were designed to improve the CN process, create clearer, more accurate outcomes (reducing legal challenges) and increase the number of dialysis stations available for patients.

The workshops were attended by Northwest Kidney Centers, Puget Sound Kidney Centers, CHI/Franciscan Health, Olympic Peninsula Kidney Centers, DaVita, and Fresenius. Collectively these organizations provide care to over 93% of dialysis patients in WA State.

The new Rules are to go into effect on January 2018.

Effective in 2018 CN applications now include scoring measures in the following areas –

***Quality*:**

QIP: Medicare QIP (Quality Incentive Program) Total Performance Score
Mortality: All patient four year Standardized Mortality Ratio Performance (SMR)
Hospitalization: All patient one year Standardized Hospitalization Ratio-Admissions (SHR)

***Access*:**

Nursing Home prevalent patients (percent)
Co-morbidities of prevalent patients (Average)
Home Training provided, both home hemodialysis and home peritoneal dialysis are required
Patient care shifts after 5pm provided
Bed available for patients who need this level of care

***Cost*:**

Net Patient Revenue per Treatment (lower net revenue gaining a higher score)

Other guiding principles within the new rules allow for incremental increase in station counts and an increased number of future applications that can be processed – serving additional patients.

Areas of concern

Weighting of QIP - We have successfully incorporated quality measures into the CN review process but the DOH has held firm on giving this one measure 2 times the weight of the other eight measures, including other quality measures. There is significant concern however that giving this one measure this much weight may create incentives for "gaming" of the measures in the future or may simply overstate a measure that is a moving target due to federal rule changes around QIP.

What could be the result of overweighting QIP? Reduction of access for at-risk patients with co morbidities; discouragement of transplantation and home dialysis as providers seek to recruit younger/healthier patients to improve scores. There is a risk of providers only focusing on this one score to increase chances of winning a CN award while overlooking other important measures of patient care.

Capital expenditures and lack of clarity - We have attempted to modify the wording around the definition of "capital expenditures" to clearly exclude the cost of the land as an expense for any project when you own the property (as is normal within Generally Accepted Accounting Principles; land does not depreciate). Land is an investment and not a capital expenditure yet the DOH has not accepted these edits.

Legal challenges – Within the existing Rules the outcome of decisions has resulted in a significant number of legal challenges that has been costly and delayed care for patients. We are hopeful that the new rules will reduce or eliminate these challenges.

To be clear...

Northwest Kidney Centers is very supportive of the Certificate of Need process and is confident that it provides station expansion capabilities that will help patients.

Thank you...

Austin Ross
Vice President of Planning
austin.ross@nwkidney.org
206-720-8505

SIGNATURE HEALTHCARE SERVICES, LLC

August 15, 2017

Tim Farrell
Director of Policy & Communications for Health Systems Quality Assurance
Washington State Department of Health
101 Israel Road SE
Tumwater, WA 98501

Dear Director Farrell,

Thank you for the opportunity to comment on the Certificate of Need (CON) study that the Department of Health (DOH) is conducting in response to the recent budget proviso contained in the 2017-19 Operating Budget. We hope our comments offer insights into what changes can be made to the CON program to improve behavioral health care outcomes and how DOH can take further action to address the critical shortage of acute psychiatric beds in the State of Washington.

In particular, we hope DOH will recognize the unique attributes of psychiatric hospitals (as distinguished from other facilities subject to the CON process) and the unique challenges faced by the behavioral health system in the State of Washington. These unique features argue for solutions specifically tailored for acute psychiatric hospitals that may not be appropriate in other CON applications.

Signature Healthcare Services, LLC was first attracted to the State of Washington as a location to construct and operate acute psychiatric hospitals in 2014 because of the glaring, critical shortage of community psychiatric beds throughout the entire state. While progress has been made in adding some beds in recent years, it is clear that a significant unmet need remains.

We successfully operate 14 acute psychiatric hospitals in five states, but we have yet to find a state where the gap between the need for community beds and the actual beds available to meet that need is as large as that which exists in the State of Washington. That is why we filed separate CON applications to construct and operate acute psychiatric hospitals in Clark, Pierce and Spokane Counties. Though Signature has not been successful yet in obtaining a Certificate of Need in the State of Washington, we remain committed to investing tens of millions of dollars of our own private capital in the State so that we can deliver our unique methods of patient care to address these vast unmet needs. To that end, we have appealed CON decisions in Clark and Pierce Counties, and hope to achieve positive outcomes in both of those locations.

The CON process involves considerable expenditures of time and money by applicants for accountants, attorneys, health care consultants, and other specialists well beyond that which a prudent business will undertake before committing to spend tens of millions of dollars on a new facility – and I guarantee you that we will not commit to an acute psychiatric hospital costing us in the eight figures before exhaustively studying and considering the matter. The criteria used by DOH in CON applications do not always represent important factors in facility operation, and sometimes the staff analyzing applications appear to lack the financial and operational background to fully comprehend a proposal. As a substantive matter,

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the CON administrative appeals process as currently constituted appears to accomplish little more than significantly slowing the delivery of the psychiatric beds so desperately needed in local communities.

In evaluating the current CON process, the Department should recognize that acute psychiatric hospitals are unique, and differ greatly from medical-surgical hospitals, ambulatory surgical centers, kidney dialysis centers, and other facilities that are also subject to the CON process. The stranded capital concern for expensive equipment that underlies part of the justification for the CON process does not exist for acute psychiatric hospitals, and the abundant evidence of a dangerous shortage of psychiatric beds clearly shows that the current CON process is not working, at least in the field of psychiatric hospitals. Since these radically different circumstances warrant consideration of a different process, we strongly encourage you to consider solutions specifically tailored to the field of acute psychiatric hospitals.

Our CON application processes have been ongoing for nearly three years, which acutely highlights the difficulty in getting beds online and available to the communities in the State of Washington today. However, beds *are* desperately needed in the State of Washington today, not two or three years from now. To accomplish that, we believe a temporary exemption for freestanding psychiatric hospitals from the CON process would greatly benefit the State of Washington. Our experience with CON in the State of Washington has revealed both these process issues and substantive problems that are worthy of careful consideration by DOH, the Governor, and the State Legislature.

However, even if the decision is made to continue with the CON process as presently constituted, the DOH needs to use a different statistical figure in determining the actual need in each county to be more in line with both the volume of current epidemics in the field and national averages. The behavioral health system is in crisis for a number of reasons, but one of the reasons is the glaring shortage of acute psychiatric beds in local communities – and the utilization of the current 26 beds per 100,000 people figure is a leading cause of that shortage. For DOH to continue to use the figure of 26 beds per 100,000 people, knowing that a glaring shortage exists, will inevitably lead to needy patients failing to receive the behavioral health services they desperately need from an appropriate provider.

Patients with mental health and substance abuse disorders inevitably fill emergency rooms and jails, which leads to a very high re-occurrence rate (or recidivism rate). That recidivism data shows that patients who continually show up in emergency departments and jails are not getting help treating the underlying issue. Emergency departments and jails are not able to provide the appropriate care to these patients, which ends up perpetuating a vicious cycle with no end in sight. The more emergency departments are housing patients who desperately need specialized care beyond their capability, the less available medical-surgical beds become. If emergency departments had a viable option to transfer their patients, then providers like us could help stem this issue in local communities.

The one step DOH can take in relatively short order to address this critical shortage of psychiatric beds is to adopt the national standard of 50 <u>non-forensic</u> beds (i.e. not criminal beds), as suggested by the National Association of Psychiatric Health Systems and a 2012 Treatment Advocacy Center study. This will in short order allow for a "surge" of acute psychiatric beds throughout the entire state. No changes to health and safety standards need be contemplated, merely a recognition of an appropriate statistical figure. Adopting the national standard of 50 non-forensic beds per 100,000 people will not change the requirement of applicants to submit a CON application. However, it will acknowledge current national standards by experts in the field and support a modification to a goal that better represents the true need for psychiatric beds in the local communities of the State.

As part of your research in preparing the study in response to the budget proviso, we encourage you to consider the study conducted by the Joint Legislative Audit Review Committee in 1999 titled "Effects of Certificate of Need and Its Possible Repeal" and the study's three major findings: 1) "COST The study

found strong evidence that CON is not an effective mechanism for controlling overall health care spending."; 2) "QUALITY Evidence about the effect of CON on quality is inconclusive."; and 3) "ACCESS Conflicting evidence was found regarding the effect of CON or its repeal on access to health services."

We hope that DOH will take advantage of the opportunity provided by this study, and of the suggestions offered by stakeholders from many different backgrounds, to make changes to the CON program, at least in the area of acute psychiatric hospitals. If no changes are made, history will repeat itself and the State of Washington will continue to face shortages in the number of acute psychiatric beds available to serve needy populations in local communities. To achieve a changed result, you need a changed process. We look forward to working with you to accomplish these needed changes.

Sincerely,

Laura Sanders
Senior Vice President & General Counsel

Pierce County

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Jim McCune
Council Member, District No 3

STANDING COMMITTEES
Performance Audit Committee, Chair (PAC)
Public Safety & Human Services (PSHS)
Economic and Infrastructure Development (EID)
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Nisqually River Council (NRC)
Zoo & Trek Authority (ZTA)
Law and Justice Community Oversight Committee (LJC)
Transportation Benefit District (TBD)
WA State Association of Counties Board of Directors (WSAC)

August 9, 2017

Tim Farrell
Director of Policy and Communications for Health Systems Quality Assurance
WA State Department of Health
101 Israel Road SE
Tumwater, WA 98501

Dear Director Farrell,

Thank you for the opportunity to comment on the state's Certificate of Need (CoN) process. It has a long history of providing no benefits to the taxpayers of Washington State. There is statistical evidence of its failure to deliver on its promises to reduce costs and increase access to healthcare across the country. The purpose for requiring a CoN as stated on the DOH site--**The Certificate of Need (CoN) program is a regulatory process that requires certain healthcare providers to obtain state approval before building certain types of facilities or offering new or expanded services**--gives cause to be concerned with the need for such a process. This is a policy that should not be reformed. It should be eliminated.

Since the 1987 repeal of the enactment of the federal Health Planning Resources Act of 1974, there have been efforts by the Federal Trade Commission and the U.S. Justice Department to abandon the laws calling them as bad for competition.

In 1999, Washington's JLARC prepared Report 99-1, Effects of Certificate of Need and Its Possible Repeal. It was found the "CoN has not controlled healthcare spending or hospital costs." I recall that back in 2006 or 2007, the legislature was holding hearings about the process. DaVita's application for a CoN was appealed by Franciscan. During the discussions, a flow chart of the process was handed out. I no longer have that, but I recall how daunting and confusing was the process. I remember some of the stories of how people had to make long drives and wait for extended periods of time for their diabetic treatment.

We should be using history as a guide to the future, not trying to create the future with policies. The Mercatus Center at George Mason University provides an interesting and informative study with maps on the Certificate of Need laws in the past 40 years. The lessons we need to glean concerning the truth about Cons, I believe, can be found in that study.

In Columbia, Missouri, a new mental health facility was rejected by the state's certificate of need board, despite a study clearly showing the need for such a facility. It is reasonable to believe that the same effect would happen here as well.

Mentioned above are but a few of the articles that provide evidence-based research that the CoN policy should be eliminated, not reformed. More research links are provided below to further validate a decision to repeal the state's Certificate of Need law.

RESEARCH & COMMENTARY: MISSOURI SHOULD PURSUE CERTIFICATE OF NEED REFORM

CON-CERTIFICATE OF NEED STATE LAWS

State certificate-of-need laws weather persistent attacks

How Certificate of Need Laws Harm the Health Care Market
Certificate of Need Laws: A Prescription for Higher Costs

Recent university study shows "Certificate of Need"• laws limit access to health services

The Failure of Government Central Planning

Certificate of Need: Does It Actually Control Healthcare Costs?

Tim, thank you for this opportunity to share my thoughts on the state's CoN policy. Now is the time to start fresh with evidence based research that will support the needs of our constituents.

Sincerely,

Jim McCune

Jim McCune
Councilmember
3rd Council District

JM/aac

CHI Franciscan Health

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Tacoma, WA 98401-2197

P 253.426.4101
chifranciscan.org

August 15, 2017

Via email
Timothy.Farrell@doh.wa.gov

Timothy Farrell
Director of Policy and Communications
Health Systems Quality Assurance
WA State Department of Health
101 Israel Road SE
Tumwater, WA 98501

Dear Mr. Farrell:

CHI Franciscan (CHI) operates eight hospitals in Washington State, as well as a number of ambulatory surgery centers, a Medicare certified hospice agency along with a hospice care center. A sister organization operates Medicare certified home health. In addition, CHI recently secured certificate of need (CN) approval, along with MultiCare, to own and operate a psychiatric hospital. CHI also, in partnership with another entity, recently secured CN approval to establish a freestanding acute rehabilitation hospital. Over just the past 10 years, CHI has developed, submitted and been involved in the review of at least 35 CN applications. We are using our experience to respond to your July 26, 2017 request to understand how to increase the number of successful CN applications.

CHI has divided its comments into two areas: process and policy. In terms of process, we highly recommend that the CN Program (the Program):

1) Publish or make available all application materials online, including letters of intent, the CN application, screening and public comment/rebuttal documents, as well as the Program's actual decision. We are aware that this information is commonly available online in other CN states.

2) Maintain a database of past decisions (CN, determination of reviewability, etc.) organized such that potential applicants (and the Program's staff as well) have an easy directory of historic decisions by project type. These decisions should be organized by project type. The purpose of this suggestion is to allow potential applicants to easily access precedential decisions, and base its application on the precedence. This would also assure that the Program's Analysts (Analysts) are aware of these decisions. In our experience, Analysts are often not aware of prior decisions, which impacts review, and can and has resulted in inconsistent decisions between Analysts.

3) Revise and update application guidelines, and assure that current application guidelines are available online. Some of the guideline packets have not been updated in more than 25 years, and still reference documents that sunset decades ago. CHI has also experienced great variation in screening depending upon the Analyst assigned to the project. We believe that the guidelines should be explicit enough to guide Analysts and assure consistency in information and data requested.

4) Follow currently adopted rules regarding timelines.

5) Ensure that the CN WACs are consistently followed and the Program does not overstep or exceed its authority.

6) Until approximately three years ago, the Program published monthly status reports that provided information on where in the review or appeal process a specific project was. That information is no longer available, and the public has no easy means to keep abreast of projects once they have been declared complete, and review has commenced.

In terms of policy, the Program currently operates with guidelines that have not been updated in decades. The Program should operate with current industry evidence and data in support of the evidence. CHI recommends that the Program schedule and undertake regular updates to its methodologies. Data used in application of the methodologies also needs to be collected and widely disseminated on a regularly scheduled basis.

CHI would be glad to meet with the DOH to further discuss our concerns. Please feel free to contact me with any questions.

Sincerely,

Thomas A Kruse
Senior Vice President
Chief Strategy Officer

August 15, 2017

Tim Farrell, Director of Policy and Communications
Health Systems Quality Assurance
Washington State Department of Health
101 Israel Road S.E.
Tumwater, WA 98501

Re: Report to Washington State Legislature on Certificate of Need Program

Dear Mr. Farrell:

On July 26, 2017, the Department of Health (the "Department") requested stakeholder comments regarding suggested improvements to Washington's Certificate of Need ("CN") program. The Washington Ambulatory Surgery Center Association ("WASCA") responds to that request through this letter, and it offers the comments below for consideration by the Department as it prepares its report to the Washington State Legislature on suggested improvements to the program pursuant to Senate Bill 5883.

WASCA provides legal and advocacy services for approximately 200 ambulatory surgical facilities ("ASFs") located across the State. These ASFs have significant concerns regarding the CN program and its effect on both the ambulatory surgery industry in Washington and the state health care delivery system as a whole. As discussed below, WASCA recommends that, at the least, the Increase in Outpatient ORs Rule (defined below) be abandoned, and that the Department consider ways to end the CN program in Washington as antiquated in theory, discriminatory in practice, and inconsistent with the current goals of an evolving health care system.

A. BACKGROUND

The primary purposes of CN programs are to restrain health care costs by regulating the supply of services and facilities, guide health service development to avoid undue duplication or fragmentation of services, promote quality of care and access to services, and provide adequate information about the health care system to consumers and providers of health care services.

These programs seek to accomplish their declared goals through control of the creation and expansion of certain health care facilities and services.

CN programs arose in the early 1970s in a health care system that paid for services using cost-based, fee-for-service reimbursement. Insurers, purchasers and providers had few concerns about or methods to control rising costs. In addition, hospitals were the focus of medical care, consuming the largest portion of resources.

Today, however, the majority of health care is provided under the controls of managed care plans. These plans are under pressure from public and private purchasers to control costs. Additionally, new technologies and innovations have driven services out of the hospital and into lower cost office-based programs, home-based programs, and community-based programs.

What services are provided, who provides them, and where they are provided has thus undergone dramatic change. A frank assessment of whether a CN program established over five decades ago continues to have a constructive role in a dramatically changed health care delivery system is overdue.

B. Washington's Certificate of Need Program

As stated in RCW 70.38.015, the purposes of Washington's CN program are the following: (1) to restrain health care costs by regulating the supply of services and facilities; (2) to guide the development of health services to avoid undue duplication or fragmentation; (3) to promote quality of care and access; and (4) to provide for adequate information about the health care system.

Washington State's program controls the creation or expansion of certain health care facilities and services, including hospitals and hospital-based tertiary services, nursing homes, home health, hospice, kidney dialysis, and ASFs. Criteria for review are set out in legislation or regulation. In order for a CN to be granted, new facilities and certain facilities wishing to expand must demonstrate that current or projected need cannot be met by existing providers and that new services will not adversely affect access or charity care.

Washington's CN program was created in 1971 primarily as a response to rapid medical cost inflation. The program sought to regulate the development of new health care facilities and services in an effort to restrain costs. By requiring that a CN be granted before services could be added or expanded, the program sought to avoid unnecessary duplication of equipment and services, restrain growth in hospital and nursing home bed supply, and prevent excessive reliance on inpatient facilities. The program evolved to respond to federal legislation in 1972 tying Medicare reimbursement to capital spending reviews, and later to bring the program into compliance with the federal 1974 National Health Planning and Resources Development Act.

After 1975, CN programs were the joint responsibility of the state and regional health planning agencies created by the federal 1974 National Health Planning and Resources

Development Act. Four "health systems agencies" conducted financial and need-based analyses, held public hearings, and made recommendations to the state for approval or denial of CN applications.

In 1986, Congress repealed the legislation encouraging local health planning and requiring CN review – responding to the changed reality that most health care is provided under the strong controls of managed care plans that are under pressure to control costs, that new technologies and innovations have pushed many services out of the hospital, and that what services are provided, who provides them, and where they are provided is changing more rapidly than ever before. Since then, many states have repealed their CN programs. Unlike these states, Washington retained its CN program, but eliminated local health systems agencies and most state-level health planning bodies.

C. Health Policy Analysis Program of the University of Washington's School of Public Health and Community Medicine for the Joint Legislative Audit and Review Committee

The Health Policy Analysis Program of the University of Washington's School of Public Health and Community Medicine for the Joint Legislative Audit and Review Committee ("Health Policy Analysis Program") prepared a report on the effects of Certificate of Need and Its Possible Repeal for the State of Washington Joint Legislative Audit and Review Committee (Report 99-1, January 8, 1999). The report is instructive.

1. Cost, Quality, Access

The Health Policy Analysis Program studied the CN program's effect on cost, quality and access. As detailed in the report, no conclusive evidence of any positive impact on cost, quality and access was found. In relevant part, the report states:

> The study found strong evidence that [certificate of need] is <u>not an effective</u> mechanism <u>for controlling overall health care spending</u>.
>
> . . .
>
> <u>Evidence</u> about the effect of [certificate of need] <u>on quality is inconclusive</u>.
>
> . . .
>
> <u>Conflicting evidence</u> was found regarding the effect of [certificate of need] or its repeal <u>on access to health services</u>. In some instances, . . . [certificate of need] <u>appears to restrict access</u> by preventing the development of new facilities.

Report at iii (emphasis added). The CN program thus increases prices by reducing competition, increases costs by constraining lower-cost alternatives, and impedes the development of

managed care. The report states, "The weight of findings over the last three decades is that [certificate of need] laws have had little or no effect in controlling general health care expenditures or hospital costs." Report at 11. The report also notes, "Some studies have even presented evidence that [certificate of need] raises overall costs." Id.

2. Charity Care and Rural Care

The Health Policy Analysis Program also studied the program's effect on charity care and rural care. As detailed in the report, no conclusive evidence of any positive impact on charity care and rural care was found. In relevant part, it states:

> [Certificate of need] provides some initial screening regarding a facility's likelihood of providing charity care, but the program in Washington and most other states does not include monitoring for compliance.
>
> Weak and conflicting evidence was found regarding the effect of [certificate of need] on access to services in rural areas.

Report at iv (emphasis added).

D. CN Program and Role of ASFs in State Health Care Delivery System

CN requires, as a threshold consideration, whether the creation or addition of a particular service in a particular location is needed; that is, whether the same or similar services can be provided using existing resources, so that no need exists for the new service. By requiring a finding of an existing deficit in services, the CN process inherently ignores the potential that a new provider might furnish services in a more effective, higher quality, less costly manner than is available in existing services. The CN program thereby inherently impedes the development and use of improved methods, creative collaborations, and more cost effective strategies for health care services. One obvious and clear example of this approach is the Department's treatment of ASFs through the CN program.

In general, outpatient surgical services may be furnished using two primary types of providers: hospital outpatient departments ("HOPDs") and ASFs. HOPDs operate as an integral part of the hospitals that own them; therefore, HOPDs bring with them the higher facility, staffing, and other operating costs that result from the owner hospital's size and complexity. This relationship means that the cost of furnishing outpatient surgical services in an HOPD is almost always significantly higher than the cost of furnishing the same surgical services in an ASF. Indeed, according to the 2013 Report to Congress entitled "Medicare and the Health Care

Delivery System,"[1] Medicare rates for most outpatient surgical services are *78 percent* higher in HOPDs than in ASFs.

Such findings would seem to recommend that a health care system *encourage* the use of ASFs to provide surgical services whenever appropriate, and *discourage* the use of HOPDs for services that can safely and effectively be furnished in an ASF. Washington, however, does exactly the opposite through its new rule regulating the expansion of existing operating room space, known as the "Increase in Outpatient ORs Rule.".

As explained above, HOPDs perform outpatient surgeries, just as ASFs perform outpatient surgeries. Hospitals generally are subject to CN laws, just as ASFs are subject to CN laws. *See* RCW 70.38.025(6). Any change in CN review that applies to ASFs should thus logically apply to hospitals, which perform the same services in the same type of setting. Under the Rule, however, that is not the case. The Department has inexplicably decreed a change in CN requirements for ASFs, but not for HOPDs, despite their similarity in purpose, function, and service provision.

The Rule mandates that, if an existing ASF wishes to increase the number of operating rooms ("ORs") in which it performs surgeries, the ASF must first apply for a CN. Though such a mandate is clearly inconsistent with the MedPAC Report's finding of ASF superiority, this requirement might perhaps be supportable under the stated purposes of the CN law *if* the requirement applied to all similarly situated providers. It does not. The Department chose to apply the Rule only to ASFs, and not to HOPDs. HOPDs can increase the number of their ORs *ad infinitum* without CN review, according to the Department. The Department's action thus penalizes ASFs and favors HOPDs, in diametric opposition to the stated purposes of CN and the findings of the MedPAC Report.

It would be reasonable for the Department to consider the comparative cost of services between HOPDs and ASFs when determining whether to require additional CN review for both of these facility types; and, arguably, it would be reasonable for the Department to require some type of CN-type review for the higher cost facility, thus encouraging use of the lower cost alternative and discouraging use of the higher cost facility. That the Department apparently failed to undertake any such comparison demonstrates the Department's disregard for the facts and circumstances applicable to the Rule, and justifies the Department's withdrawing the Rule pending further consideration. To date, that has not occurred.

Promulgation of the Rule is also inconsistent with the direction in which our health care system is moving, as envisioned in the Patient Protection and Affordable Care Act, Public Law 111-148 (2010) ("ACA"). The ACA cites cost containment as one of its three primary goals, and establishes multiple systems to encourage innovation and collaboration in its pursuit of lower

[1] *See Gen. Report to the Congress: Medicare and the Health Care Delivery System*, Ch. 2, "Medicare Payment Differences Across Ambulatory Settings" (Medicare Payment Advisory Commission ("MedPAC" Report), June 2013).

cost health care alternatives. The ACA authorized pilot programs whose goals are to form new relationships, establish new strategies, and formulate new methods to provide health care services in creative new structures. As discussed above, the current CN program functions to frustrate these very goals, and works to maintain the *status quo*.

Additionally, the ACA uses these innovative programs primarily as a way to control costs, just as the Department suggests that cost control is its primary concern in regulating health services through the CN program. However, if CN-approved ASFs are prohibited from increasing the number of ORs at their facilities without undergoing CN review, hospitals could immediately, and without CN review, increase the number of ORs in their HOPDs. That action would foreseeably eliminate the need for new ASF based ORs, so that outpatient surgical services would increase in higher cost, CN favored HOPDs – again, the diametric opposite of where the health care system should move, and the opposite of what the Department should encourage.

E. CN Program Creates Costs that Exclude Potentially Beneficial Services

The CN process is prohibitively expensive. Given the cost of simply filing an application, which frequently requires hiring consultants for expensive population and service studies, hiring counsel to ensure compliance with complex rules, and paying fees for consideration by the Department, many providers decide to forgo providing services in Washington rather than submitting to the CN process.

This expense creates a bias toward large providers, which have higher operating costs and market share than small providers, and thereby contributes to the continued upward spiral of costs in our health care system. Again, the CN program contributes to higher costs, rather than working to control costs.

F. Conclusion

The CN program is antiquated. The program favors established providers, and thereby frustrates the innovation that can lower costs and improve the quality of health care in Washington. Worse, the CN program, as administered by the Department, discriminates to encourage the provision of services by hospital-based surgical services while restraining the lower-cost ASF in our state. Finally, the costs attendant to CN application and review serve to exclude smaller providers, resulting in higher costs. For all these reasons, the CN program should be dismantled.

In the alternative, and at the very least, the Rule should be abandoned, and action taken to prevent the Department from promulgating rules that discriminate against ASFs.

If you would like any additional information, or if you have any questions concerning WASCA's comments, please do not hesitate to contact me.

Sincerely,

HALL RENDER KILLIAN HEATH & LYMAN, PC

Emily R. Studebaker

August 14, 2017

Via Email (Timothy.Farrell@doh.wa.gov)

Tim Farrell
Director of Policy and Communications for Health Systems Quality Assurance
Washington State Department of Health
101 Israel Road SE
Tumwater, WA 98501

Re: Report on Certificate of Need Program (SB 5883)

Dear Mr. Farrell:

Thank you for the opportunity to provide comments on the Certificate of Need Program, for purposes of the Department of Health's report to the Governor.

On behalf of DaVita, I was personally involved in the Department's recently completed rulemaking process to update the Certificate of Need rules applicable to dialysis facilities. In this process, the Department thoroughly evaluated, and significantly revised, the criteria for approval of dialysis facilities. This was done with substantial stakeholder input at every step in the process. We very much appreciated the Department's close collaboration with us and other dialysis providers in the rulemaking process to ensure that the new rules are fair and appropriate.

Therefore, our initial comment would simply be to thank the Department again for how it conducted the dialysis rulemaking process, and to consider using the dialysis process as a model for future updating of the Certificate of Need rules governing other types of facilities.

Additionally, we note that Department's report is going to "include suggestions for modifying the program to increase the number of successful applications." We would offer a few suggestions relating to the Certificate of Need process that we believe may help achieve this objective.

With respect to Certificate of Need applications, this clearly is a competitive process in which competing applicants will wish to identify any errors or inconsistencies, however small, in each other's applications. However, when both applicants are well-established, high-quality providers, as is typically the case for dialysis facility applications in Washington, it generally does not serve the public interest for applications to be denied based on immaterial mistakes that do not call into question the project as a whole. Instead, the public interest would be best served if decisions are made based on an analysis of which project will better meet the community need. If the Department agrees with this premise, we would offer two suggestions that might result in more successful applications.

First, the Department might consider revising its application forms to clarify, and simplify, exactly what information is to be submitted. This would ensure that all applicants are providing the right information, and the same information, in a consistent format. It likely would reduce errors and allow for easier comparison between applications.

Second, the Department could more frequently publish (and post online) interpretive statements that guide applicants on how to prepare their applications (for example, regarding what to include in capital budgets or how to forecast financial performance). Of course, any applicant is free to read the Department's past decisions. However, providing guidance in the form of interpretive statements applicable to all applicants, as opposed to addressing issues on a case by case basis, might result in greater consistency and fewer mistakes by applicants.

With respect to Certificate of Need appeals, it seems to us that the two issues that could most effectively be addressed would be (a) cost and (b) the delay to the project caused by an appeal. We would suggest that the Department engage in rulemaking to modify its "discovery" rules (WAC 246-10-402) for purposes of Certificate of Need appeals. Limiting discovery not only could reduce the cost of such appeals significantly, it also would allow them to be completed more quickly. These appeals involve relatively straightforward disputes based on an existing application record, and in our experience limited discovery (e.g., depositions of hearing witnesses) is important to ensure a fair hearing, but exhaustive discovery of the kind seen in civil litigation is unnecessary, and can unduly increase the cost of an appeal as well as how long it takes to proceed to a hearing. If the Department were to engage in such a rulemaking process, we would be happy to submit specific suggestions as to how the Department's discovery rules might be modified for Certificate of Need appeals.

Thank you again for the opportunity to provide these comments. We look forward to reading the Department's report when it is completed.

Sincerely,

Jason Bosh

August 15, 2017

Submitted via electronic mail to Timothy.Farrell@doh.wa.gov

Tim Farrell
Director of Policy and Communications for Health Systems Quality Assurance
Washington Department of Health
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Tumwater, WA 98501
Timothy.Farrell@doh.wa.gov

Mr. Farrell:

We, the undersigned groups, share a vision in which all Washingtonians have access to high quality comprehensive healthcare services in their own communities. We offer these comments for improving our state's Certificate of Need (CoN) program.

Our goal is to ensure that communities do not face barriers in accessing needed physical or mental healthcare. The lack of healthcare services in underserved communities is one of the primary causes of health inequity. The passage of the Affordable Care Act (ACA) and the resultant increase in health insurance coverage – particularly among low-income, working families and people of color, who comprise the majority of the uninsured – have created new demands on Washington's healthcare infrastructure. The ACA specifically calls upon the state to address issues of access and health equity.

The CoN process is an essential tool to ensure that proposals to change the health system infrastructure are deliberately reviewed to consider the impact on communities. State law requires consideration of the need for services of the population served, the extent to which proposed services will be accessible to all residents of the area to be served, quality of care provided in the past, a hospital's provision of at least the regional average level of charity care, as well as the economic impact among other factors. RCW 70.38.115. All of these are essential criteria to promote equitable access to services.

The legislature has created a narrowly-tailored, time-limited exemption to allow addition of psychiatric beds without a CoN, which this year's Legislature has extended through June 2019 (ESHB 1547). But CoN should not be weakened beyond this; the current need for psychiatric beds is adequately addressed through the legislature's extension and should not undermine CoN.

The Department has asked for suggestions to modify CoN "to increase the number of successful applications" including adding psychiatric beds. Our suggestion is to provide trainings and materials that enable hospitals participating in the process to be well-informed and prepared to engage in CON review. These trainings and materials should also support community-based organizations seeking to participate in the CoN process. It is hoped that this type of assistance can help expedite the process while still insuring that applications meet the CoN criteria and there is a meaningful community review process.

Moreover, we recommend that CoN criteria be strengthened, not weakened. The scope, criteria, and application of CoN must be updated to address emerging issues, and regulated in a way that hospitals are held accountable for meeting them. The increasing consolidation of Washington's healthcare marketplace resulting from the recent wave of affiliations, mergers, and acquisitions, and situations in

which hospitals fail to comply with charity care requirements, pose serious threats to access to many critical physical, psychiatric, and behavioral healthcare services. A robust and reinvigorated CoN program is an important part of the solution. After all, controlling healthcare costs and ensuring access to high quality services are the original central aims of Washington's CoN program.

We believe that, in order to promote access and accountability in the development of Washington's healthcare infrastructure, the CoN program rules need to be revised to address four shortcomings:

1. Ensure a Transparent, Engaged, Meaningful Community-Based Review Process
   The CoN program must ensure that patients and communities have real power and are fully engaged in the review process. Patients and community members must have a genuine opportunity to express their views on whether a proposed change (be it the construction of a new facility or a change in control of an existing facility) meets local needs. Patients and community members must be able to examine and question the application based on four key criteria—quality of care record, affordability, access, and corporate accountability-- and must be able to recommend denial of CoNs for organizations whose records show unlikely success in should play a central role in determining whether a CoN is issued and on what terms. We recommend the creation of clear guidelines for applicants to meet in the four key criteria to facilitate and speed CoN approval where appropriate.

2. Use Community Health Impact Assessments to Improve Access to Care for All
   The CoN review process must ensure access to high quality comprehensive health services for all patient populations, alleviating access barriers for underserved communities including people of color, low-income patients, immigrant and refugee populations, and people living in rural areas. To this end, the CoN review of any proposed project should involve a comprehensive assessment of unmet healthcare needs in the community or communities affected by the project and a demonstration of how the proposal addresses those needs. At this time, when we have a critical need for psychiatric beds, we must ensure that the beds are provided in all areas, not just areas with well-insured or wealthy populations. The issue of equity in access can be addressed in the "access" area of our recommended criteria for applicants; each applicant should be required to address how the proposed beds would address disparities.

3. Subject All Hospital Transactions to CoN Review
   CoN review must apply to every transaction that involves a change in hospital mission or a transfer of hospital control, whether in whole or in part, regardless of the terminology used to describe the transaction. Affiliations, "corporate restructurings," mergers, "strategic partnerships," alignments, and structural changes that go by still other names involve total or partial transfers of hospital managerial or budgetary control from one entity to another; in some cases, such changes involve a change in the mission or purpose of the organization. All such changes have a potentially disruptive impact on communities and should be subject to CoN review.

4. Enforce CoN Conditions
   In the past, the CoN process has rarely included enforceable commitments by CoN recipients regarding access to services. Certificates of need issued to healthcare providers should include binding, meaningful commitments from providers to ensure access to care; such commitments should be monitored by DOH and enforceable by the Attorney General. Patient complaints to

Department of Health (DoH) regarding restrictions on health care services that were provided at a facility or other noncompliance with CoN conditions should trigger a DoH investigation. If a hospital is found to be violating the representations made in its CoN application, there should be consequences in place that will sufficiently deter such behavior.

Furthermore, the state must address a related problem raised by the recent wave of consolidation. Religiously-affiliated healthcare corporations are skirting several rules and regulations that Washington voters have soundly endorsed including prohibitions on discrimination against employees and patients and protections for access to comprehensive reproductive health and end-of-life services. Areas of the state in which healthcare delivery is monopolized by religiously-affiliated corporations could see discrimination against healthcare employees, loss of access to certain healthcare services, and loss of access for certain patient populations, such as the LGBTQ community. This is particularly critical among mental health providers, which must not hold biases against providing full services for all patients. Operators' non-discrimination policies and record of discrimination complaints, if any, must be scrutinized as part of the CoN process.

In closing, we aim to find solutions in the CoN process and encourage the use of other mechanisms to ensure that our healthcare infrastructure provides every Washingtonian access to quality, affordable, comprehensive healthcare. We call on the Governor, the Legislature, and the Department of Health to continue to explore ways to address these shortcomings within the CoN Program.

Sincerely,

National Alliance on Mental Illness- Washington (NAMI-WA)
Northwest Health Law Advocates (NoHLA)
OneAmerica
Puget Sound Advocates for Retirement Action (PSARA)
SEIU Healthcare 1199NW
UFCW 21
Washington Community Action Network (Washington CAN)
Washington State Nurses Association (WSNA)

Department of Legal Affairs
1801 Lind Avenue SW
Renton, Washington 98057

August 15, 2017

Mr. Timothy Farrell
Director of Policy and Communications for Health Systems Quality Assurance
Washington State Department of Health
101 Israel Road SE
Tumwater, WA 98501
Timothy.Farrell@doh.wa.gov

Re: Suggestions to Improve the Certificate of Need Program

Dear Mr. Farrell:

On behalf of Providence Health & Services – Washington, Swedish Health Services, Swedish Edmonds, Kadlec Regional Medical Center, and Pacific Medical Centers, we are submitting suggestions to improve the Certificate of Need Program in response to your email dated July 26, 2017. Based on our experiences with the Certificate of Need Program, we have identified certain aspects of the program that can be improved upon to simplify the process, improve predictability, and reduce administrative obstacles. We recommend the following:

- **Streamline the Application.** Certificate of Need applications should be simplified and streamlined. We recommend eliminating duplicative or unnecessary questions in the application and adding questions that the Department needs to complete its review in alignment with the CN regulations. For example, the application does not request a job description for medical directors, but we are usually asked to provide this during screening. *If* the medical director job description is deemed pertinent information in order to evaluate the application in relation to the CN requirements, then it would be beneficial to ask specifically for this information in the application. Revising the application templates to reflect the specific information that *must* be gathered from applicants would ensure equitable information is gathered for each application and minimize the volume of screening questions. It would also be helpful to eliminate the requirement or find an alternative mechanism to include full copies of all reports referenced in the application, which adds length and bulk to submitted applications. Lastly, we recommend making all applications easily-accessible online with Word versions rather than PDFs.

- **Refine Screening Questions.** At times, it appears screening questions vary greatly by application and may delve into operational details that applicants do not feel comfortable sharing, especially considering that the responses will be made public (e.g. requesting a medical director's salary or executed contracts for purchased services). We recommend a careful evaluation of screening questions to ensure they serve an essential purpose, are relevant to the Department's review, and are appropriate in scope and subject matter given that any responses will be made publicly available.

- **Evaluate Timelines for Review Process.** In our experience, the Certificate of Need process often takes a minimum of nine months, even when all goes smoothly. Unfortunately, this length of time is often not practical. In addition, decisions may be delayed one or more times, causing an applicant to incur additional time and expense, notwithstanding the delay in working toward addressing the health care needs of the community. Even relatively straightforward decisions often take the same amount of time that more complex situations require. We believe a renewed commitment to timely decisions will greatly benefit the Certificate of Need Program. In addition, the general timelines for the review process should be revisited to determine whether opportunities exist for streamlining the full CN process and moving toward more expedient decisions.

- **Establish a Rulemaking Schedule**. At this time, the Department engages in rulemaking to review and update methodologies or other aspects of the CN regulations. To improve the efficiency of these efforts, we recommend establishing a schedule for rulemaking that would proactively identify when the areas will be addressed.

- **Improve Processes.**
  - *Concurrent Review Cycles.* We recommend eliminating concurrent review cycles that create only one window each year to apply for certain types of projects (e.g. hospice care centers). The seven types of projects that can be pursued only once per year do not attract a high volume of applications. Therefore, removing the concurrent review cycles would create additional flexibility for applicants to monitor need and pursue projects when they have a well-designed application. In the event that the Department receives more than one application, the regular concurrent review cycle would still remain in place, so the ability to review applications side-by-side and select the superior alternative would remain.
  - *Progress Reports.* We suggest offering applicants the option to complete quarterly progress reports electronically. It would help expedite the process to have these progress reports available as a Word template that could be completed and submitted online.
  - *State Surveys.* We suggest greater predictability and clarity regarding state surveys. We are never sure when Department surveys will be sent to us, and they are commonly sent to a facility without being addressed to a specific person. As a result, we are unable to track and confirm whether all surveys have been

completed. We recommend increased clarity surrounding when, and to whom, state surveys will be sent, which will allow us to respond in a more timely and organized manner.

- *Certificate of Need Conditions.* We recommend simplifying Certificate of Need conditions. In our experience, the conditions placed upon any given Certificate of Need vary widely and, at times, may not provide value. For example, the Department may request the name and licensure information for medical staff of a new facility, but when staffing changes are made in the future, applicants are not required to provide this level of detailed information, thus raising questions as to whether the condition was value-added to the Department. Although certain conditions appear unnecessary or may raise concerns at times, applicants must nonetheless accept them or risk having the Certificate of Need denied. We suggest simplifying Certificate of Need conditions and creating a process for applicants to negotiate conditions (or express concerns) with the Department.

- **Additional Suggestions.**
  - *Outdated Methodology.* The Department continues to reference and rely upon portions of the 1989 Washington State Health Plan, including the acute bed need methodology. Certificate of need applications contain questions associated with the State Health Plan, which applicants must mark as "not applicable." We recommend making the appropriate updates.
  - *Joint Venture Proposals.* The Department requires a greater amount of information from joint venture applicants. Given that joint ventures offer a promising option for delivering quality care to patients, we recommend simplifying the application process for joint venture proposals.

We appreciate your time and consideration of our comments and suggestions. If there are any questions, or if we can provide additional information that would be helpful, please do not hesitate to contact us. Betsy Vo can be reached at (425) 525-3940 or Betsy.Vo@providence.org. Christina Park can be reached at (425) 525-3930 or Christina.Park@providence.org.

Sincerely,

Ch Pa

Christina Park
Associate Counsel

Pierce County

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Public Safety, Human Services & Budget
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8/03/2017
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RE: Certificate of Need

Dear Secretary Wiesman and Director Farrell:

Per Director Farrell's communication of July 26, 2017, requesting suggestions relative to the state's Certificate of Need program, please be advised that I recommend *scrapping the Certificate of Need process altogether.*

It is well documented that Pierce County has escalating behavioral health issues. As you can see from the enclosed/attached report *Opiod Trends in Pierce County, Tacoma-Pierce County Health Department, February 23, 2017,* the increase in those requiring treatment for opiod use in Pierce County is skyrocketing hitting a peak of 79 per 100,000 treatment admissions (see pg. 5).

Signature Healthcare Services dba Tacoma Behavioral Healthcare Hospital applied to develop a 174 bed psychiatric hospital in the City of Tacoma. Similarly, Multicare Health System/CHI-Franciscan Health dba Alliance for South Sound Health also applied for a Certificate of Need to build a new 120 bed psychiatric hospital, also in the City of Tacoma. Both of these projects are desired and needed but only one of them received approval to move forward because the Certificate of Need process did not take into account our current crisis. We need more beds!

Let the market determine the number of beds and let business take the risk to either fail or succeed. Take the foot of government off the fix.

And more pointedly, that a projection error made as part of the Certificate of Need process is stopping providers from providing needed behavioral health services is unacceptable. This is especially the case given the absence of any good reason to continue the certificate of need process.

Healthcare providers operate in a businesslike manner taking great care when projecting future demands. If investors are willing to risk their capital building a health care facility, the state should not hinder them.

I hope you find these suggestions useful.

Best regards,

Pam Roach

Pam Roach
Councilmember

Cc: Tiffany Speir
Doug Richardson
Dan Roach
Jim McCune
Connie Ladenburg
Rick Talbert
Derek Young

Opioid report referenced above available online at: http://www.tpchd.org/files/library/d5558c66bce89442.pdf

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August 21, 2017

Tim Farrell
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Dear Mr. Farrell

This letter serves as Senator Keiser's comment and suggestions for modifying the certificate of need (CON) program's review process in relation to Section 219 (30) of the 2017 Operating Budget, directing the Department of Health (Department) to prepare and submit a report about the CON program, including suggestions for modifying the program to increase the number of successful applications.

Through the CON process, the Department considers the extent to which a proposed service will be accessible to all residents in the proposal's service area, including an evaluation of the applicant's admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services

However, it is important to ensure that the Department consider economic demographics, diversity of the population and physical access to the facility, when determining the adequacy of access to a planned project. Service areas are often determined such that they encompass multiple economic strata and ethnic groups, especially within King County. Low income, immigrant and migrant populations often are grouped in the same service area as populations that are geographically distant and sometimes quite economically diverse.

To better address accessibility for low-income individuals, immigrants, migrants and minority groups, I suggest that the department takes two steps in shifting the way it reviews access as part of CON:
(1) The Department should review and narrow the geographic scope of service areas to ensure that each does not encompass an area so large or diverse that the CON review of a project would not be able to adequately assess the accessibility for all individuals within its service area; and
(2) The Department should consider the ability of all individuals in a proposed project's service area to physically access the facility through various forms of multi-modal and public transportation. Facilities that are not adequately accessible via various forms of transportation to all individuals in their purported service area should have their service areas narrowed or adjusted accordingly.

Thank you for consideration of my suggestions. Please feel free to contact me if you have any questions.

Sincerely,

Senator Karen Keiser
33rd Legislative District

August 15, 2017

Via Electronic Mail

Tim Farrell
Director of Policy and Communications for Health Systems Quality Assurance
WA State Department of Health
101 Israel Road SE
Tumwater, WA 98501

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JEAN ROBINSON
BOARD PRESIDENT

KATHLEEN TAYLOR
EXECUTIVE DIRECTOR

Re: Certificate of Need

Dear Mr. Farrell,

The undersigned organizations are pleased to offer the following suggestions on how best to improve the Certificate of Need ("CON") program. We appreciate the Department of Health's ("DOH") and the Legislature's interest in reviewing the CON program. Such a review is both timely and necessary.

Health system consolidations impact cost, quality and access to health care for patients. However, unlike in other states, there is very little oversight of health system consolidations in Washington. The Legislature established the CON program to "promote, maintain, and assure the health of all citizens in the state, provide accessible health services, health manpower, health facilities, and other resources while controlling increases in costs." This laudable goal has unfortunately been derailed by dramatic changes in the health care marketplace which have resulted in health system consolidations evading CON review and hospitals failing to abide by conditions imposed by DOH during CON reviews.

To ensure that Washington residents have access in their local communities to a full range of affordable quality health care we strongly recommend: (1) expanding the scope of CON review; (2) adopting clear CON standards and incorporating independent health care impact statements into the CON process; and (3) creating better oversight and enforcement mechanisms. Health system affiliations in Washington state have already resulted in reducing patient access to health services. The CON review process must be updated to ensure this does not continue to happen.

The Changing Health Care Landscape

The health care landscape has undergone dramatic changes over the last 30 years. The passage of the Patient Protection and Affordable Care Act (ACA), the rapid development of electronic medical technology, and the creation of integrated care

systems (e.g. accountable care organizations) have fundamentally changed the nature of hospital consolidations.[1] Further, while the rate of hospital consolidations began increasing in the late 1990s, there has been a significant rise in consolidations since 2010. Hospital transactions grew from 66 in 2010 to 95 in 2014 and to 112 in 2015.[2] From 2001 to 2016 the nation's 25 largest health systems went from controlling 916 hospitals to 1,189 hospitals.[3] Washington state has itself seen a significant number of health system consolidations. To name a few examples:

- In 2011 Southwest Washington Medical Center and United General Hospital affiliated with PeaceHealth
- In 2012 Swedish Health Service became an affiliate of Providence Health & Services
- In 2013 Highline Medical Center became part of the Franciscan Health System
- In 2013 Harrison Medical Center became part of the Franciscan Health System
- In 2016 Providence Health & Services and St. Joseph Health System affiliated to become Providence St. Joseph Health
- In 2017 CHI Franciscan and Virginia Mason formed a strategic affiliation.[4]

As hospital ownership consolidates under fewer and fewer owners, these transactions have an increasingly significant impact on Washington health care consumers, particularly those in rural and low-income communities. Such consolidations result not only in a lack of price competition within a community or geographic region, but also a lack of any meaningful choice among health care providers for the consumer – a serious problem when providers restrict or deny services. In addition, consolidations have resulted in some hospitals' failure to abide by state charity care requirements to provide care at reduced costs to low-income individuals, despite explicit conditions in their CONs.

[1] Khaikin, Christine, & Uttley, Lois. (2016). State Oversight of Hospital Consolidation: Inadequate to Protect Patients' Rights and Community Access to Care. *AMA Journal of Ethics*, 18(3), 272-278. http://journalofethics.ama-assn.org/2016/03/pfor3-1603 html. *See also* Creswell, Julie & Abelson, Reed. (2013, August 12). New Laws and Rising Costs Create a Surge of Supersizing Hospitals, *The New York Times.* Retrieved from http://www.nytimes.com/2013/08/13/business/bigger-hospitals-may-lead-to-bigger-bills-for-patients html?_r=0.

[2] *Id.*

[3] Khaikin, Christine, Uttley, Lois & Winkler, Aubree. (2016). When Hospitals Merge: Updating State Oversight to Protect Access to Care. Retrieved from http://whenhospitalsmerge.org/our-report.

[4] Notably, consolidations are not only occurring in the hospital context but are also impacting clinics and laboratories, increasing the overall impact upon patient care. For example, in 2015 Pacific Medical Centers affiliated with Providence Health & Services and in 2016 the Doctors Clinic in Kitsap County affiliated with CHI Franciscan Health,

To further complicate the issue, in Washington state many of the recent health care system affiliations have occurred between secular health systems and systems governed by Catholic doctrine. This is especially concerning as Catholic health systems are required to follow the Ethical and Religious Directives (ERDs) promulgated by the United States Conference of Catholic Bishops. These directives forbid or significantly restrict many reproductive and end-of-life health services. Facilities that affiliate with Catholic health systems are often required to restrict health services and information on the basis of religious doctrine (examples below).

Certificate of Need Review

Scope of CON Review

Washington state's CON program has not kept pace with the significant changes occurring in the health care arena. In 2016 Washington state's CON program received a "C-" rating in a report produced by MergerWatch that analyzed CON programs across the country.[5]

As explained by the MergerWatch study, one of the foremost problems with the current CON program is the limited scope of what "triggers" CON review. In Washington state CON review of a hospital consolidation is triggered if there is a "sale, purchase or lease of part or all of any existing hospital . . . ." But in today's health market consolidations are rarely as simple as a traditional sales, purchase or leases. Rather modern consolidations are branded as "affiliations," "corporate restructurings," "mergers," strategic partnerships," "alignments," "joint ventures," etc. As such many health system consolidations in Washington state have evaded CON review by not using the term "sale, purchase or lease" to describe the consolidation. For example, the Swedish-Providence affiliation did not undergo CON review and the affiliation resulted in Swedish no longer providing "elective" abortions at its facilities.[6] The Harrison Medical Center affiliation with Franciscan Health System evaded CON review and now doctors at Harrison are no longer able to prescribe medications to assist with Death with Dignity.[7] Further, doctors in Kitsap County have advised that following the Harrison-Franciscan affiliation there has been an increase in costs for health care services.

By evading CON review health system consolidations in Washington state are evading governmental oversight and public input.[8] This is a serious problem as

[5] Khaikin, Christine, Uttley, Lois & Winkler, Aubree. (2016). When Hospitals Merge: Updating State Oversight to Protect Access to Care. Retrieved from http://whenhospitalsmerge.org/our-report.
[6] *See* Martin, Nina. (2013, Oct. 17). Catholic Hospitals Grow and With Them Questions of Care, *ProPublica*. Retrieved from *https://www.propublica.org/article/catholic-hospitals-grow-and-with-them-questions-of-*care; *See also* Swedish, Reproductive Health Care Position Statement, *available at* http://www.doh.wa.gov/Portals/1/Documents/2300/HospPolicies/SwedishRH.pdf.
[7] See Attachment A.
[8] Indeed when the Providence-St. Joseph affiliation occurred, in California the two health systems were required to submit binders of information to the Attorney General, health care impact statements were drafted, and at least eight public meetings were held before the Attorney General approved the affiliation. Providence is one of the largest health providers in Washington state and yet in

health system consolidations (by any name) can have a significant impact on communities' access to affordable quality health care services. It is therefore imperative that the scope of CON review be expanded to include all health system consolidations that significantly impact access to care.

To accomplish this goal we recommend three changes to the CON program: (1) include under CON review "affiliations," "corporate restructurings," "mergers," strategic partnerships," "alignments," "joint ventures" and other terminology used to describe consolidations in today's health care market; (2) ensure that any transfer of control, responsibility or governance of a material amount of the assets or operations of a hospital or hospital system triggers CON review; and (3) revise the CON program so that hospitals seeking a determination of non-reviewability are required to provide notice of any curtailment of services or changes in policies that may occur as a result of a proposed consolidation. If any curtailment of services or significant policy changes are likely to occur, a determination of non-reviewability should not be granted.

CON Standards and Health Care Impact Statements

The Legislature has asked for suggestions to modify the CON program "to increase the number of successful applications" including adding psychiatric beds. We recommend that once CON applies to all appropriate cases, DOH ensures that (1) the program has clear standards; and (2) through the CON process all necessary material is collected to allow DOH to make informed decisions.

In creating clearer standards we recommend an increased focus on the three touchstones of the CON program: quality, affordability and access. These standards may be integrated into the review process under existing criteria such as "Need" and "Quality." Clear standards should make it easier for hospitals to successfully complete the CON process as they will have a better understanding of CON requirements. DOH should also provide trainings and materials that enable hospitals participating in the process to be well-informed and prepared to engage in CON review under these standards. These trainings and materials should also support community-based organizations and individuals seeking to participate in the CON process.

Washington there was no public input or DOH oversight of the affiliation as the affiliation evaded CON review.

Further, it is our understanding that CON reviews are not always as thorough as state public policy requires. Indeed, in the past some of our organizations have reviewed documents related to completed affiliations (through filed public records requests) and found the volume of documents reviewed by DOH to be quite thin. To adequately protect Washington residents' access to care we recommended incorporating independent health care impact statements into the CON review process. These statements should include an assessment of the effect of the agreement on the availability and accessibility of health care services, including reproductive and end-of-life services. These statements should also assess how any changes would impact communities, especially rural communities and underserved and vulnerable populations. Obtaining this information will assist DOH in determining whether a consolidation should move forward and should prove valuable when considering determination of need questions (WAC 246-310-210).

Oversight and Enforcement

Lastly, without adequate oversight and enforcement, DOH and the CON program do not effectively protect patient's access to health care services. DOH should regularly monitor health care facilities to ensure they are in compliance with representations made in their CON application and that they are abiding by any DOH imposed conditions on CON approval. Patient complaints to DOH regarding restrictions on health care services that were provided at a facility prior to consolidation or other noncompliance with CON conditions should trigger a DOH investigation. If a hospital is found to be violating the representations made in its CON application, there should be consequences in place that will sufficiently deter such behavior.

Conclusion

The Legislature has created a narrowly-tailored, time-limited exemption to allow for the addition of psychiatric beds without a CON, which this year's Legislature has extended through June 2019 (ESHB 1547). The CON program should not be weakened beyond this; the current need for psychiatric beds is adequately addressed and should not undermine CON.

We appreciate the Legislature's interest in improving the CON process and its desire to increase the number of successful CON applications. However, given the current status of the CON program, we are not confident that increasing the number of successful CON applications will lead to increased access to quality health care. Rather, by expanding the scope of CON while simultaneously creating clear standards, information requirements and oversight and enforcement mechanisms the Legislature will strike the necessary balance of creating a more efficient CON application process while protecting and enhancing patients' access to care.

Sincerely,

Leah Rutman,
ACLU of Washington

Elaine Rose
Planned Parenthood Votes Northwest and Hawaii

Sally McLaughlin
End of Life Washington

Janet Chung
Legal Voice

Tiffany Hankins
NARAL Pro-Choice Washington

Janet Varon
Northwest Health Law Advocates

ATTACHMENT A

Elizabeth Pring

Subject: RE: Question about Harrison's policies on the Washington Death With Dignity Act

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From: Scott Bosch [mailto:Scott.Bosch@harrisonmedical.org]
Sent: Wednesday, November 13, 2013 3:05 PM
To: 'rmiller@compassionwa.org'
Cc: Michael Anderson; Adar Palis; 'Glen Carlson'; 'Bill Morris'; 'Scott Ekin'
Subject: RE: Question about Harrison's policies on the Washington Death With Dignity Act

Mr. Miller, thank you for contacting me with your questions and concerns. Thru this process we have discovered that indeed, the policy that you reference is outdated and is now in the process of being updated. To answer your questions, while Harrison was initially neutral during the DWD campaign, once passed, we adopted a policy of not participating in the administration of the DWD drugs at any of our sites. This is consistent with many other hospitals in the state. Up until our affiliation with FHS, our employed physicians were allowed to write the prescription for the drugs. This changed Aug 1st, 2013 and HMC employed physicians are no longer able to write these scripts while on duty as an employed doc. These physicians can, if they wish and under their WA license, separately see patients and prescribe the drugs for the DWD. Under these circumstances, these physicians would also have to obtain separate malpractice insurance. Harrison continues to have the policy of full disclosure of patient end of life options with an aggressive palliative care program in place to assist patients and their families in making these difficult choices. One thing that would be very helpful to our providers would be to have a comprehensive list of area physicians that we could refer to that do participate in the DWD act. If you can help us with that, it would be much appreciated. I hope I have been able to clear up any remaining questions about Harrison's participation in the DWD process. Please let me know if you have additional ones. Thanks.

From: Robb Miller [mailto:rmiller@compassionwa.org]
Sent: Tuesday, November 12, 2013 10:46 AM
To: Scott Bosch
Subject: Question about Harrison's policies on the Washington Death With Dignity Act

Dear Mr. Bosch:

We are receiving questions from the community served by Harrison Hospital as well as the physicians and other medical providers you employ about your policies on the Washington Death With Dignity Act now that Harrison is affiliated with Franciscan, which strongly opposes Death With Dignity, prohibits its physicians from participating, and does not provide helpful information or referrals to patients who make inquiries.

Is the policy posted online in your patient handbook (www.**harrison**medical.org/file_viewer.php?id=5163) still valid?

Washington Death With Dignity Act (Initiative 1000). This act, which became Washington state law on March 5, 2009, allows terminally ill adults to request lethal doses of medication from medical and osteopathic physicians. The terminally ill patient must be medically diagnosed with six months or less to live and must be a Washington resident.
Harrison Medical Center respects the relationship between the provider and the patient, and has determined from voter preference that it is in the community's best interest to allow its healthcare providers to participate in the Washington Death With

Dignity Act if they so choose.

All providers at Harrison are expected to respond to any patient's query about life-ending medication with openness and compassion. Harrison believes our providers have an obligation to openly discuss the patient's concerns, unmet needs, feelings, and desires about the dying process. Providers should seek to learn the meaning behind the patient's questions and help the patient understand the range of available options, including but not limited to comfort care, hospice care, and pain control. Ultimately, Harrison's goal is to help patients make informed decisions about end-of-life care.

Harrison's position on the Washington Death with Dignity Act remains neutral, neither supporting nor opposing the option. We seek to make a positive difference in people's lives through exceptional healthcare at all points on the healthcare continuum. We seek to facilitate end-of-life care and provide comfort to our patients when they learn their lives may be affected by a terminal disease or condition.

If this is not still your policy, could you provide me with your new policy?

Thank you,

Robb Miller, Executive Director
Compassion & Choices of Washington
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Appendix II:

Number of Applications, Units Requested/Approved/Denied By Healthcare Setting

Appendix II: Number of Applications, Units Requested/Approved/Denied By Healthcare Setting (FY 2007-2016)

The tables presented below represent a decade of historical Certificate of Need applications and decisions, collected and indexed within the program and stored electronically in various subject matter indexes on various platforms. Data are sorted by health care setting, and presented longitudinally to illustrate trending over the requested ten fiscal years. This method of presentation is offered to provide a means of contrast and comparison, and to better inform decision makers. Data are further separated by regular and concurrent review to clearly demonstrate how final application decisions were made.

The department defines the word "bed" contextually within each specific health care setting. For example, in the hospital setting, "bed" is appropriate to define and describe the unit of measurement the program relies on to determine the need in a planning area for the construction or expansion of a hospital facility. Similarly, the unit of measurement to determine need for the construction or expansion of kidney dialysis facility is termed a "station." In contrast, a tertiary service, such as a percutaneous coronary intervention program located within a hospital is measured as a single unit because the need for the service within a specific planning area is being evaluated by the program, as opposed to a number of stationary objects, rooms or beds.

The crosswalk below offers linkage between the requested data elements and the elements of measurement, and naming conventions used by the program to collect the same data:

Health Care Setting/Applicant Type	Project Abbreviation	Unit of Measurement
Ambulatory Surgical Facility	ASF	Operating room
Continuing Care Retirement Community	CCRC	Bed
Home Health Agency	HH	Agency
Hospice Agency	Hospice	Agency
Hospice Care Center	HCC	Bed
Hospital	Hospital	Bed
Kidney Dialysis Center	ESRD (End Stage Renal Disease)	Station
Nursing Home	NH	Bed
Psychiatric Hospital	Psychiatric Hospital	Bed
Sale, Purchase, Lease	SPL	None
Skilled Nursing Facility	SNF	Bed
Tertiary Health Service	THS	Service

Data for each setting type are organized in the tables below and described by the following headings:

- Fiscal year denotes the requested data date range.
- "Applications reviewed" denotes the number of applications reviewed during the identified date range, and either approved (a Certificate of Need issued) or denied within the designated data date range. This addresses the proviso request to "show the total number of applications."
- "Applications approved" denotes the number of applications for which a Certificate of Need was issued. This addresses the proviso request to "show…the total number of accepted applications."
- "Applications Denied – Failed 210 – 230" means that the application failed one or more of the criteria described in WAC 246-310- 210, -220 and/or -230. This heading addresses the proviso request to provide the "most common reasons for declining an application."
- "Applications Denied – 240" means that applications failed the criteria described in WAC 246-310-240. There are two primary reasons why an applicant would fail under -240. First, an applicant cannot pass 240 if they have failed any of the other criteria found in 210-230. Second, 240 is the criteria under which the department compares two or more applications that are competing for the same need within a planning area. For example, if there is a need for ten dialysis stations in a planning area, and three applicants have applied to meet that ten station need, no more than ten total stations would be approved. The department relies on data within the application to complete a comparative superiority review

between all eligible applicants. The applicant that best meets these superiority criteria would then be approved. This heading also addresses the proviso request to provide the "most common reasons for declining an application."

- "Reasons for Denial" lists the number of times a particular criteria described in WAC 246-310-210, -220, -230 and/or -240 was cited for denial in each health care setting. This heading further addresses the proviso request to provide the "most common reasons for declining an application."

- The headings for units requested and units approved represents the total units requested by applicants and the total number of units approved by the program. This heading addresses the proviso request to "show…the total number of beds requested and the total number of beds approved."

Additionally, while the data below represent all requested data collected by the program, it also includes a small number of anomalies. For example, in the 2015 ESRD regular review category, a provider requested approval for 29 kidney dialysis stations in one planning area, another provider requested approval for the addition of 3 kidney dialysis stations in a different planning area, while another provider submitted and subsequently withdrew their application. The application for 29 kidney dialysis stations was denied; the application for the addition of 3 dialysis stations to an existing facility was approved, while the third application was withdrawn. Because the withdrawn application was not denied, it is included within the total "applications reviewed" category, but not in either of the "applications denied" categories. Withdrawn applications and other anomalies are noted in each affected table.

ASF – REGULAR REVIEW

Fiscal Year	Applications Reviewed	Applications Approved	Applications Denied - Failed (210-230)	Applications Denied - (240)	Reasons for Denial	Operating Rooms Requested	Operating Rooms Approved
2007	2	1	1	1	1 - Financial Feasibility 1 - Structure and Process 1 - Cost Containment	3	0
2008	6	5	1	1	1 - Need 1 - Financial Feasibility 1 - structure and Process 1 - Cost Containment	10	8
2009	2	2	0	0	N/A	4	4
2010	4	4	0	0	N/A	10	10
2011	7	6*	0	0	*Project initially approved, but applicant did not accept service limitation conditions. Project denied.	13	11
2012	6	5*	0	0	*Request to amend CN #1330R because of a change in the approved site; entity was not able to demonstrate substantial completion toward commencement, so a 6-month extension was denied. CN later expired so project was denied.	12	12
2013	5	5	0	0	N/A	12	12
2014	3	3	0	0	N/A	10	10
2015	8	8	0	0	N/A	32	32
2016	6	6	0	0	N/A	8	8
TOTALS	49	45	2	2		114	109

ASF – CONCURRENT REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied- Failed (210 – 230)**	**Applications Denied – (240)**	**Reasons for Denial**	**Operating Rooms Requested**	**Operating Rooms Approved**
2011	2	2	0	0	N/A	0	0
2015	2	2	0	0	N/A	6	6
TOTALS	4	4	0	0		6	6

CCRC – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2014	1	1	0	0	N/A	45	45

ESRD – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied – (240)**	**Reasons for Denial**	**Stations Requested**	**Stations Approved**
2007	13	10	3	3	1 - Need 3 - Financial Feasibility 1 - Structure and Process 3- Cost containment	139	113
2008	6	6	0	0	N/A	19	19
2009	5	5	0	0	N/A	15	15
2010	3	3	0	0	N/A	11	11
2011	4	4	0	0	N/A	16	16
2012	7	7	0	0	N/A	45	45
2013	7	6	1	1	1 - Financial Feasibility 1 - Structure and Process 1 - Cost Containment	39	33
2014	0	0	0	0	N/A	0	0
2015	3	1*	1	1	1- Need 1 - Cost containment	32	3
2016	2	2	0	0	N/A	17	17
TOTALS	50	44	5	5		333	272

*****One application withdrawn by applicant following review.

ESRD – CONCURRENT REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Stations Requested**	**Stations Approved**
2007	20	9	10	11	2 - Need 9 - Financial Feasibility 5 - Structure and Process 11 - Cost Containment	203	63
2008	15	8	5	7	1 - Need 5 - Financial Feasibility 2 - Structure and Process 7 - Cost containment	204	102
2009	3	2	1	1	1 - Financial Feasibility 1 - Structure and Process 1 - Cost Containment	20	15
2010	5	2	2	3	2 - Need 2 - Financial Feasibility 2 - structure and Process 3 - Cost Containment	82	45

2011	7	5	1	2	1 - Structure and Process 2 - Cost Containment	55	40
2012	10	7*	1	2	1 - Financial Feasibility 2 - Cost Containment	139	81
2013	8	5	2	3	2 - Structure and Process 3 - Cost containment	49	32
2014	13	5	6	8	6 - Financial Feasibility 8 - Cost containment	122	32
2015	12	10**	1	1	1- Need 1 - Financial Feasibility 1 - Cost containment	71	50
2016	10	5	5	5	3- Need 4 - Financial Feasibility 5 - Cost containment	265	58
TOTALS	103	58	34	44		1210	518

*Decision issued on 11/18/11; remanded and CN later vacated
**One application was withdrawn by applicant.

HCC - REGULAR REVIEW

Fiscal Year	Applications Reviewed	Applications Approved	Applications Denied - Failed (210-230)	Applications Denied – (240)	Reasons for Denial	Beds Requested	Beds Approved
2007	3	3	0	0	N/A	32	32
2008	1	1	0	0	N/A	0	0
2009	0	0	0	0	N/A	0	0
2010	0	0	0	0	N/A	0	0
2011	1	1	0	0	N/A	15	10
2012	1	1	0	0	N/A	12	12
2013	0	0	0	0	N/A	0	0
2014	1	1	0	0	N/A	15	15
2015	1	1	0	0	N/A	0	0
2016	0	0	0	0	N/A	0	0
TOTALS	8	8	0	0		75	70

HOME HEALTH – REGULAR REVIEW

Fiscal Year	Applications Reviewed	Applications Approved	Applications Denied - Failed (210-230)	Applications Denied - (240)	Reasons for Denial	Agencies Requested	Agencies Approved
2007	2	0	2	2	2- Need 1 - Financial Feasibility 1 - structure and Process 2 - Cost Containment	2	0
2008	1	1	0	0	N/A	1	1
2009	0	0	0	0	N/A	0	0
2010	3	2	1	1	1 - Structure and Process 1 - Cost Containment	3	2
2011	3	0	3	3	2 - Financial Feasibility 1 - structure and Process 3 - Cost Containment	3	0
2012	2	2	0	0	N/A	2	2
2013	2	2	0	0	N/A	2	2
2014	3	2	1	1	1- Need 1 - Financial Feasibility 1 - Cost Containment	3	2
2015	1	0	1	1	1- Financial Feasibility 1 - structure and Process 1 - Cost Containment	1	0

2016	1	1	0	0	N/A	1	0
TOTALS	18	10	8	8		18	9

HOME HEALTH – CONCURRENT REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied- Failed (210 – 230)**	**Applications Denied – (240)**	**Reasons for Denial**	**Agencies Requested**	**Agencies Approved**
2010	2	2	0	0	N/A	2	2
2011	2	2	0	0	N/A	2	2
TOTALS	4	4	0	0		4	4

HOSPICE AGENCY – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Agencies Requested**	**Agencies Approved**
2007	2	1	1	1	1- Need 1 - Financial Feasibility 1 - structure and Process 1 - Cost Containment	2	1
2008	0	0	0	0	N/A	0	0
2009	5	3	2	2	2- Need 2 - Financial Feasibility 2 - structure and Process 2 - Cost Containment	5	3
2010	1	1	0	0	N/A	1	1
2011	4	4	0	0	N/A	4	4
2012	0	0	0	0	N/A	0	0
2013	1	1	0	0	N/A	1	1
2014	0	0	0	0	N/A	0	0
2015	2	1*	0	0	N/A	2	1
2016	0	0	0	0	0	0	0
TOTALS	15	11	3	3		13	9

*One application was returned at the request of the applicant.

HOSPITAL – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2007	2	2	0	0	N/A	50	50
2008	9	8	1	1	1 - Need 1- Financial Feasibility 1 - structure and Process 1 - Cost Containment	395	315
2009	7	7	0	0	N/A	44	44
2010	8	8	0	0	N/A	51	51
2011	11	11	0	0	N/A	242	242
2012	5	5	0	0	N/A	26	16
2013	3	3	0	0	N/A	122	122
2014	5	5	0	0	N/A	43	43
2015	0	0	0	0	N/A	0	0
2016	5	5	0	0	N/A	208	204

TOTALS	55	54	1	1		1181	1087

HOSPITAL – CONCURRENT REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2010	8	4	1	4	1 - Need 4 - Cost Containment	426	234
2011	3	3	0	0		19	19
2012	4	3*	0	0	* One application denied on UPI (unresolved pivotal issue)	165	48
TOTALS	15	10	4	4		610	301

NURSING HOME – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2007	2	2	0	0	N/A	240	240
2008	4	3	1	1	1- Financial Feasibility 1 - structure and Process 1 - Cost Containment	360	240
2009	1	1	0	0	N/A	0	0
2010	0	0	0	0	N/A	0	0
2011	1	1	0	0	N/A	22	22
2012	2	1	1	1	1 - Need 1- Financial Feasibility 1 - structure and Process 1 - Cost Containment	176	56
2013	3	2	1	1	1 - Need 1- Financial Feasibility 1 - structure and Process 1 - Cost Containment	171	126
2014	2	2	0	0	N/A	36	36
2015	2	0*	0	0	N/A	0	0
2016	0	0	0	0	N/A	0	0
TOTALS	17	12	3	3		1005	720

*One application was withdrawn by the applicant; one application was returned to the applicant.

PSYCH BED CONVERSION – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2015	1	1	0	0	N/A	10	10

PSYCHIATRIC HOSPITAL - REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2013	2	2	0	0	N/A	245	245
2014	3	2	1	1	1 - Need 1- Financial Feasibility 1 - Cost Containment	164	84
2015	0	0	0	0	N/A	0	0
2016	2	1	1	1	1- Financial Feasibility 1 - Cost Containment	150	65
TOTALS	7	5	2	2		559	394

PSYCHIATRIC HOSPITAL – CONCURRENT REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2015	7	3	1	4	1- Financial Feasibility 4- Cost Containment	682	264
2016	1	1	0	0	N/A	72	72
TOTALS	8	4	1	4		754	336

REHAB BED CONVERSION – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2015	4	2	2	2	1- Need 2 - Financial Feasibility 1 - Structure and Process 2 - Cost Containment	23	13

SALE/PURCHASE/LEASE – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2007	0	0	0	0	N/A	0	0
2008	3	3	0	0	N/A	0	0
2009	0	0	0	0	N/A	0	0
2010	1	1	0	0	N/A	0	0
2011	1	1	0	0	N/A	0	0
2012	1	1	0	0	N/A	0	0
2013	2	2	0	0	N/A	0	0
2014	1	1	0	0	N/A	0	0
2015	2	2	0	0	N/A	0	0
2016	0	0	0	0	N/A	0	0
TOTALS	11	11	0	0		0	0

SKILLED NURSING FACILITY – REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Beds Requested**	**Beds Approved**
2015	1	1	0	0	N/A	97	97

TERTIARY SERVICE - REGULAR REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied – (240)**	**Reasons for Denial**	**Services Requested**	**Services Approved**
2007	1	1	0	0	N/A	3	3
2008	2	2	0	0	N/A	1	1
2009	2	2	0	0	N/A	8	8
2010	2	2	0	0	N/A	20	20
2011	4	1	3	3	1 - Need 1- Financial Feasibility 1 - Structure and Process 3 - Cost Containment	33	18

2012	1	1	0	0		15	15
2013	3	2	1	1	1 - Need 1- Financial Feasibility 1 - structure and Process 1 - Cost Containment	11	10
2014	0	0	0	0	N/A	0	0
2015	0	0	0	0	N/A	0	0
2016	2	2	0	0	N/A	2	2
TOTALS	17	13	4	4		94	77
TERTIARY SERVICE – CONCURRENT REVIEW							
Fiscal Year	**Applications Reviewed**	**Applications Approved**	**Applications Denied - Failed (210-230)**	**Applications Denied - (240)**	**Reasons for Denial**	**Services Requested**	**Services Approved**
2009	9	9	0	0	N/A	9	9

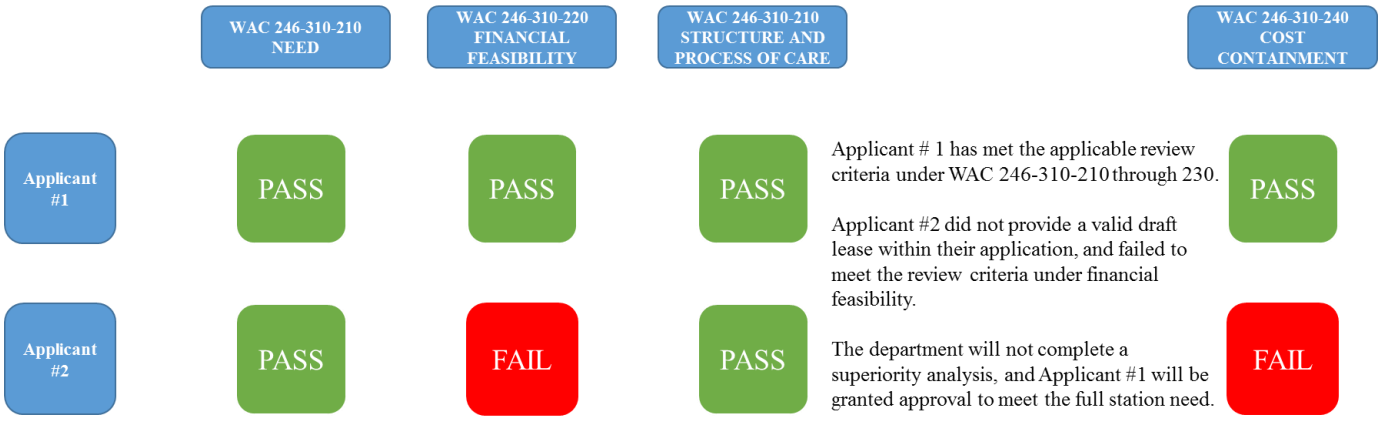
Appendix III:

Concurrent Review Flowcharts

Concurrent Review Scenario A

Total Planning Area Need for 10 Stations

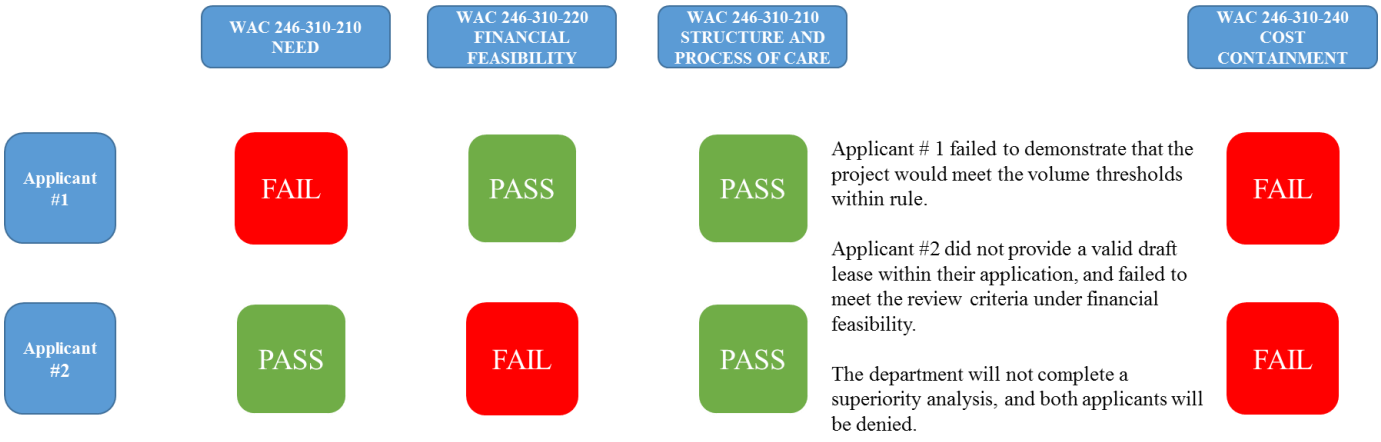
- Applicant #1: Proposing to establish a brand new, 10-station kidney dialysis facility
- Applicant #2: Proposing to establish a brand new, 10-station kidney dialysis facility



Concurrent Review Scenario B

Total Planning Area Need for 10 Stations

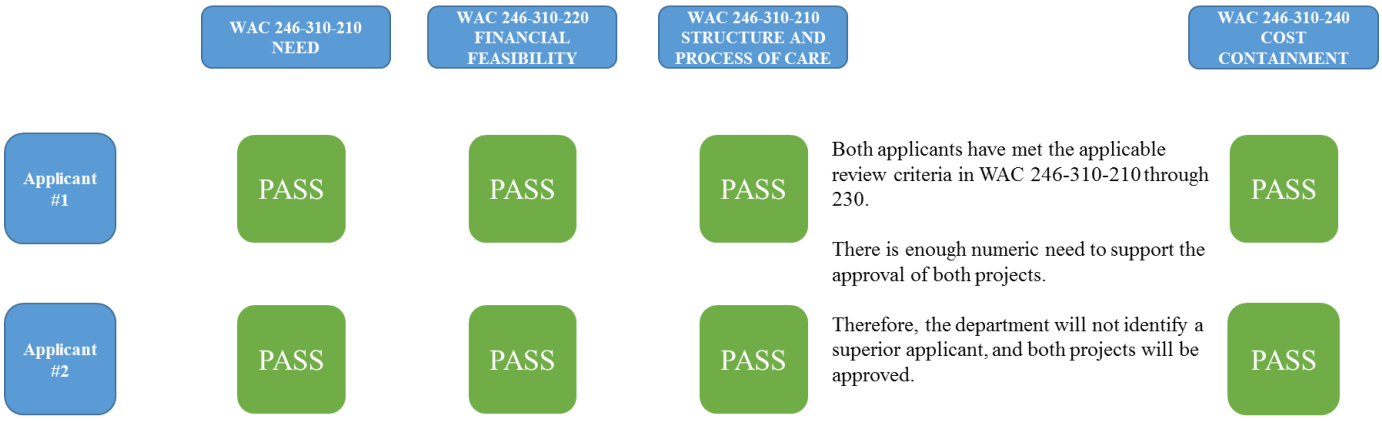
- Applicant #1: Proposing to establish a brand new, 10-station kidney dialysis facility
- Applicant #2: Proposing to establish a brand new, 10-station kidney dialysis facility



Concurrent Review Scenario C

Total Planning Area Need for 10 Stations

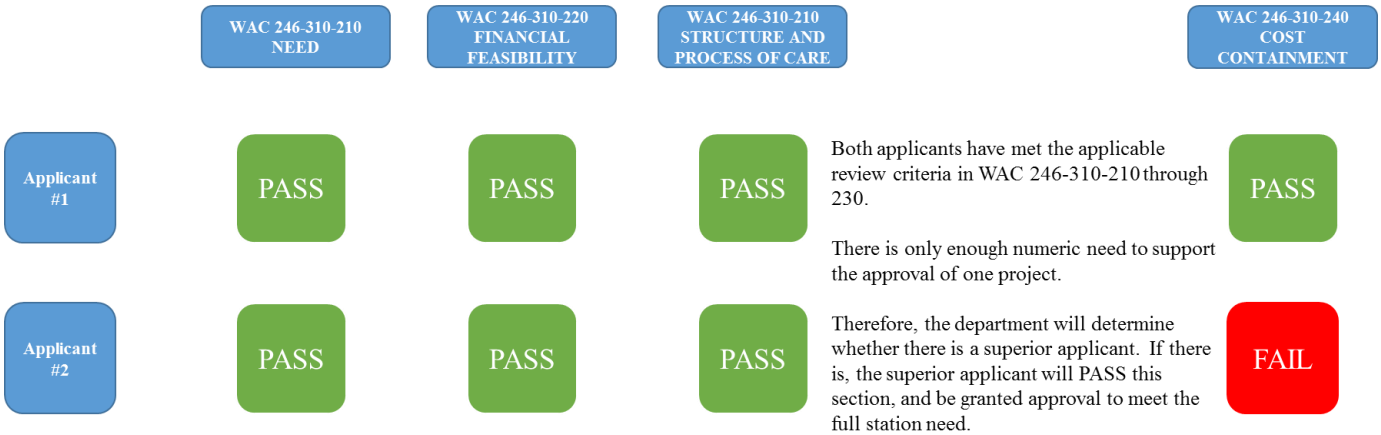
- Applicant #1: Proposing to establish a brand new, 5-station kidney dialysis facility
- Applicant #2: Proposing to establish a brand new, 5-station kidney dialysis facility



Concurrent Review Scenario D

Total Planning Area Need for 10 Stations

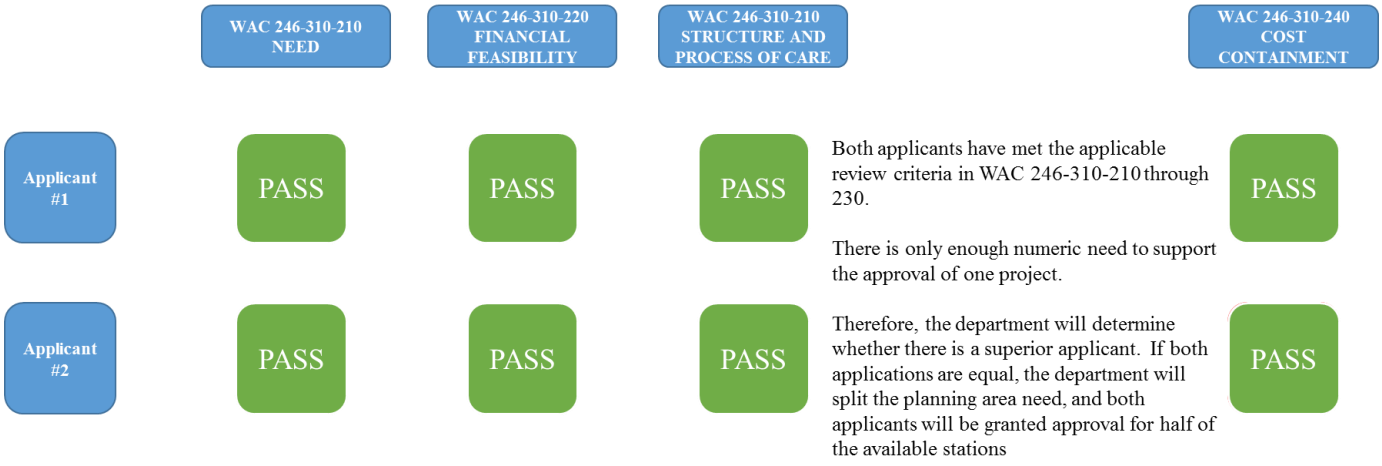
- Applicant #1: Proposing to establish a brand new, 10-station kidney dialysis facility
- Applicant #2: Proposing to establish a brand new, 10-station kidney dialysis facility



Concurrent Review Scenario E

Total Planning Area Need for 10 Stations

- Applicant #1: Proposing to establish a brand new, 10-station kidney dialysis facility
- Applicant #2: Proposing to establish a brand new, 10-station kidney dialysis facility



Appendix IV:

Summary of CON Applications by Review Type

Appendix IV: Summary of CON Applications by Review Type
2007-2016