

**Summary of Comments Received on Proposed Rules  
Including Department of Health Responses  
Governor Directive 13-12 Rules for WACs 246-310-010 and 246-320-141  
Certificate of Need and Hospital Patient Rights and Organizational Ethics  
Public Hearing ~ November 26, 2013**

**Overview:**

Governor Jay Inslee issued Directive 13-12 on June 28, 2013, asking the Department of Health (department) to review its Certificate of Need (CoN) rules to consider “how the structure of affiliations, corporate restructuring, mergers and other arrangements among health care facilities results in outcomes similar to the traditional methods of sales, purchasing, and leasing of hospitals, particularly when control of part or all of an existing hospital changes from one party to another.” The directive also said the rule process must “consider ways to improve transparency for consumer education and ease of use, specifically the department shall ensure hospitals supply non-discrimination, end-of-life care, and reproductive health care policies,” and that consumers have access to those policies.

The rules amend CoN WAC 246-310-010--Definitions to clarify that change in control of a hospital, whether by sale, purchase lease, affiliations, corporate restructuring, mergers and other arrangements, are subject to CoN review. The rules also amend the Hospital Licensing WAC 246-320-141--Patient rights and organizational ethics. The amended rule requires each hospital to send the department its current policies regarding access to care including: admission, non-discrimination, end-of-life care, and reproductive health care for posting to the department web site. Hospitals are already required to have admission, non-discrimination, and end-of-life care policies under other statutes and rules. These rules now require hospitals to have a reproductive health care policy. These rules also require each hospital to provide the public easy access to these policies on the hospital’s web site without having to use a log-in or other restrictions.

The Department circulated draft rules amending CoN chapter 246-310 WAC in July 2013, and held a public workshop on August 5, 2013, to take input on the draft. From this input it was determined that there are statutes requiring hospitals to have policies on admission, non-discrimination, and end of life care. Existing statute and rules, however, did not address reproductive health care. As a result, amendments were also proposed to Hospital WAC 246-320-141 to require hospitals to have policies related to reproductive health care. The proposed rules also required the hospitals to submit their admission, non-discrimination, end of life care, and reproductive health care policies to the department for posting on the department’s website. Hospitals are required to post these same policies on their websites to provide easy access to the public.

To obtain input and help determine impact of the proposed rules, the department sent a survey in September 2013, to Washington hospitals. Specifically, the department sought input from hospitals on:

- (1) Whether the hospital has a reproductive health care policy;

- (2) If not, what costs would the hospital incur to develop a reproductive health care policy and provide it to the department?
- (3) Cost for a hospital to post its policies to the hospital's web site.

Results of this survey are described in the Significant Legislative Analysis and Small Business Economic Impact Statement prepared for the proposed rules.

The proposed rules were filed with the Code Reviser on October 17, 2013 as Washington State Register number 13-21-076.

**Public Comments on the Proposal and Department Responses:**

The department received 1,041 comments on the proposed Governor Directive 13-12 Certificate of Need / Hospital Licensing rules, including written comments and testimony at a November 26, 2013 public hearing. Similar comments were first grouped under general topic areas. Comments containing additional concepts beyond the general topic areas were listed separately. The department has provided responses to all comments. After review and careful consideration of all public comments, the department has decided to adopt the rule as proposed in WSR 13-21-076 without change.

The department thanks all persons who have participated in this rulemaking process.

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**Clarifying the definition of "sale, purchase, or lease".**

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There were comments both for and opposed to the proposed definition.

Examples of these comments included:

- A definition of "sale, purchase, or lease" that encompasses any change of control, regardless of type or size, is contrary to law and contrary to decades of precedent and clear interpretation by the Washington State Department of Health.
- We suggest that the proposed definition be modified to clarify that "sale, purchase, or lease, " includes any transaction in which one partner gains the ability to determine what services are available or what ethical policies will apply in the merged health care facility or entity or any part thereof. To that end, we suggest the following changes to the proposed definition : "Sale, purchase, or lease" means any transaction in which the control, including the ability to determine what services are available and what ethical policies will apply, either directly or indirectly, of part or all of any existing hospital changes, to a different person including, but not limited to, by contract, affiliation, corporate membership restructuring, or any other transaction.
- I am concerned that the proposed definition implies that the Certificate of Need process would only be triggered when control of all or part of a hospital is completely transferred to a different person. This does not appear to address the recent trend of affiliations

between hospitals and other entities in which ownership or governance interests expand to include new entities, but existing ownership and governance interests remain. I suggest the following revision to address this concern: "Sale, Purchase, or Lease means any transaction in which the control, either directly or indirectly, of part or all of any existing hospital changes to include a different person than the hospital's existing ownership, governance or a partial or controlling interest, including, but not limited to, by contract, affiliation, corporate membership restructuring, or any other transaction."

**Department Response:**

The public policies advanced by the certificate of need law are not tied to the use of specific words in transactional documents. Instead, those public policies are better advanced by examining the outcome of the transaction, regardless of the terms used in the transactional documents. To do otherwise, would elevate form over substance, permit evasion of the certificate of need processes, including the opportunity for public notice and comment, by clever drafting of transactional documents, defeating the public policies advanced by the certificate of need law. The purpose of this clarification is to focus on the outcome of these transactions to bring them within CoN review. CoN evaluation includes review of the reduction or loss of services and the community's access to alternatives if there is a reduction or loss. The addition of new language as proposed above could be viewed as a substantive change in the rule which would trigger a delay in the implementation of these rules and is unnecessary to address the need to focus on outcomes when a change in ownership occurs.

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**The Certificate of Need review process when dealing with hospital mergers/affiliations should include additional requirements.**

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These comments generally supported the intent of proposed rules, but suggested further changes.

Examples of these comments included:

- The Certificate of Need process should be updated to address these specific concerns: scope of review--every transaction that involves a change in hospital mission, a curtailment of important services, or a transfer of hospital control should be subject to CoN review. This would include a change in hospital mission if there is a change from a secular to a religious health care mission. Clear standards--clear standards need to be in place to protect accessible and affordable health care for patients. Oversight and enforcement--once a CoN is granted, oversight and enforcement mechanisms must exist to monitor and ensure compliance with its terms and conditions. Transparency--the public must be able to understand the CoN process and be involved in it this process to ensure that vital health care needs are addressed.
- Hospitals as corporations that operate in the public sector should be reviewed for their willingness to provide needed healthcare services. The recent takeovers of secular health care systems by religious ones will impact the availability of needed reproductive and end-of-life services. This change should be reflected in evaluation of certificate of need certifications. Decreases in the availability of reproductive services, including birth

control and abortion, will negatively impact Washington women and should be evaluated before such mergers are approved, and the merger should be predicated on continuation of these services.

- As more mergers involve non-secular institutions becoming part of a secular institution, access to some types of care is becoming restricted. For a non-secular hospital to say that they just refer out to another provider is insufficient. That imposes needless, and sometimes significant, hurdles to getting appropriate care. Non-secular and secular mergers should be prohibited unless the newly formed entity will provide all the options that each institution formerly provided (possibly only in the locations formerly provided.)
- I am in favor of strengthening the proposed rule beyond the issue of transparency. Legal reproductive and end-of-life services must be widely available to patients in communities and at all income levels across Washington State. To help ensure this, I propose strengthening the proposed rule. Requirement: add to the proposed rule that any merger or acquisition must not result in a reduction of patient care and services for reproductive and end-of-life care. Review of Comprehensive Regional Impacts: add to the proposed rule that a review must be completed of comprehensive regional impacts of all such mergers and acquisitions of hospitals and clinics on the availability of patient care and services for reproductive and end-of-life care. Authority: add to the proposed rule the authority for DOH to deny any merger and acquisition of hospitals and clinics that result in reducing legal reproductive and end-of-life care services. Such a review should include impacts on services to those with low incomes.
- The proposed rules are a step in the right direction, but are missing several key practices to protect public interests. Any change in hospital mission, even if not otherwise accompanied by a transaction, should trigger a CoN review. This is required to keep entities from circumventing the spirit of the review process by separating transactions from changes in mission. Transactions that result in a significant decrease in availability of services should be subject to a much higher level of scrutiny, if not prevented outright. This needs to include awareness of services in the hospital's operating area.
- We propose that if a proposed hospital partnership would require one or more of the facilities to discontinue any health care services, state regulators should require an assessment of the likely impact on the community and a plan of affirmative steps to take to ensure patients have continued access to these services.
- We propose that if the Department finds that an approved hospital partnership fails to fulfill a required plan of affirmative steps to ensure continued community access to health care services, the Department should have the authority to take action including assessing penalties or rescinding authorization for the consolidation.
- Strong enforcement and remedies are necessary to ensure compliance with both the CoN process and any disclosure requirements. This enforcement could take the form of closer scrutiny during the CoN process, as well as an affirmative, proactive approach by DOH

that includes robust investigations as opposed to responding solely with a complaint-based approach.

- The state Department of Health and county public hospital districts must ensure that, if a healthcare system chooses not to provide certain services directly, that that system finds another way for citizens to get those services and refers them to the appropriate place to receive them. Otherwise such mergers/affiliations should not be allowed.

**Department Response:**

These comments ask for a rule change that is outside the scope of the proposed rules. Some of the comments are addressing the need for citizens to access some of these services. Currently the review process evaluates the reduction or loss of services in a community and alternatives for access to those services. One of the comments addresses penalties, and the department does not have statutory authority to assess fines, but can suspend or revoke a CoN if a hospital violates the rules or the terms of the CoN.

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**Requesting a moratorium on new and pending mergers/affiliations until the current CoN rules process has been completed.**

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An example of this comment was:

- Temporarily halt further affiliations between secular and religious institutions, conduct a thorough review of existing partnerships, and ensure any current and future associations are strictly secular in nature.

**Department Response:**

This comment is asking for an action that is outside of the authority for the Department of Health.

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**Require hospitals to offer patients a full range of legal reproductive and end-of-life services, particularly if they receive government funding.**

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Examples of these comments included:

- The Department of Health, through the Certificate of Need (CoN) process, must ensure that all patients have access in their local communities to a full range of lawful, medically appropriate services.
- The state, in its proper role of protecting its citizens, should require all hospitals to provide all medical services which they are reasonably equipped to provide, and in the interest of transparency, ensure hospitals provide a list of services that they are not equipped to cover and the reasons for that lack (i.e., funding, staffing, space, local market, etc.).

- Any institution that accepts government funding directly or indirectly via government insured patients should be positively precluded, by law, from using religion or religious values as a basis for choosing which health care services to provide or not provide.
- Hospitals, whether or not they have a religious affiliation or are owned by a religious organization, are providing a public service. Based on the fact that they are the providers of necessary public services, rules must prohibit hospitals from making any health care service policies based on religious grounds.
- All hospitals that receive any taxpayer funding must ethically provide all the services that are legally permissible.

**Department Response:**

These comments ask for a rule change that is outside the scope of the proposed rules. In addition, this request is outside the department’s current statutory authority to regulate hospitals. There is no statutorily required minimum set of services that a hospital must provide.

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**Hospitals posting of specific listing of reproductive and end-of-life services: Pros and Cons.**

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Some commenters said the department should require hospitals to post or provide specific lists of services they provide or do not provide (pro), while other commenters said the department should not require hospital to post or provide such lists (con).

Examples of “pro” comments included:

- Requiring hospitals to post their reproductive and end-of-life policies is too general a requirement and will allow hospitals to hide any restrictions under vaguely worded policies. Hospitals should be required to post what reproductive and end-of-life services they do and do not provide.
- Regarding transparency, and in the interest of the public's right to know, support the suggestion that a checklist of 20 key reproduction and end-of-life services be required to be prominently posted by all hospitals on their websites, in their waiting rooms, and near their admission desks. This posting should be in large print and in lay persons' language clearly indicating the hospital's policies and where any denied services can be obtained nearby.
- The only reason for requiring services to be specifically listed is the religious community’s attempts to be secretive and misleading. The legal rights of consumers must be honored. A list of services must be provided openly. For example: Are all options of birth control offered in this hospital? Yes or no? Is it this hospital's policy to respect and comply with the consumers’ “Do Not Resuscitate Directives?” Yes or no? Is it this hospital's policy to enforce pregnancy over the decisions of the female? Yes or no? Just those three questions would provide a sufficient answer for me and others seeking medical care.

Examples of “con” comments included:

- Developing a meaningful list of services would be too complex and potentially misleading.
- The proposal of transparency--that these religious entities must clearly state which medical treatments they refuse to perform--will do little to help the patient in a rural setting.
- There is no precedent for requiring private businesses to disclose the services they don't provide. Why would there be? Making everyone publish a list of the things they don't do wouldn't be reasonable.
- Requiring health facilities to post policies on what services they provide seems a noble goal, but it oversteps the bounds of government. Does the government require restaurants to provide policies on vegetarian/vegan/low carb/low fat diets and then publically post what kind of kind of meals they provide? The government's role in health care is, and should continue to be, to certify that a particular facility is safe for all those who wish to use it. It should not be telling a business what services it can/should and can't provide. That choice should continue to be up to the facility and consumers should perform their due diligence in choosing where they get their care. The government should likewise stay away from approving mergers, sales, or leases based on what services are provided. Reviewing such an arrangement for purposes of avoiding monopolies is needed, but it is not the responsibility of the government to ensure that all legal services are easily available.
- The proposed changes seem to add little to patient care and, in aggregate, are a large burden on healthcare facilities at large. Let's have common sense prevail in this: anyone seeking care for nearly any malady or condition can ascertain whether or not a local facility can care for them in the way they desire. As this is written, I see a troubling opportunity for a "scorecard" of sorts-- particularly a political one--to be created, and a target painted on the backs of those who don't fall in line with the prevailing winds of political correctness. Please do not endorse this expensive and potentially litigious exercise.
- While the current proposal requires hospitals to publicize any restrictions on services, it doesn't do anything to stop those restrictions from happening. We need a system that both ensures mergers do not result in decreased access to reproductive health care, and includes accountability through monitoring for compliance and the imposition of fines or other sanctions when such a policy is not followed.

**Department response:**

Requiring hospitals to post policies will help inform consumers of hospital services generally provided. Reviewing the policies should help consumers with identifying specific questions they may want to ask of the providers. However, requiring hospitals to create a list of services that they do and do not provide is overly burdensome, too complex, and may be potentially

misleading. Providing consumers with such a list would not preclude them from having additional questions.

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**Hospitals that do not offer a full range of legal reproductive and end-of-life services should have additional requirements.**

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Some commenters said the department should set additional requirements for hospitals which do not provide certain health care services.

Examples of these comments included:

- If all hospitals within a range of 100 miles demand the enforcement of their religious doctrines upon on patients and medical staff, then the state must establish a secular hospital within 100 miles of the religious-affiliated hospital that respects the conscience of a secular patient and have physicians who will honor the conscience of the patient.
- If a hospital doesn't provide a certain legal health care service, they need to direct people to where they can get the care they need, not just say they don't provide it.
- Many elderly and poor people don't have options to travel to other communities to seek healthcare options. All hospitals should be required to offer full range of health care services to their patients if there is not another hospital within a reasonable distance that does offer those health care services.
- If a large geographic area has only one hospital, it should not be allowed to restrict legal health care services.

**Department Response:**

These comments ask for a rule change that is outside the scope of the proposed rules. In addition, this request is outside the department's current statutory authority for Certificate of Need and facilities (Hospital) licensing.

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**The rules impede hospitals being able to decide how they choose to operate**

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Examples of these comments included:

- Religiously-based organizations have a basic right to operate according to their beliefs, and no medical establishment should be required to perform procedures that violate its religious views. The controversial health care services regarding the beginning or ending of life can be obtained elsewhere (which will presumably be clarified with this new rule). But I have serious concerns about the government holding a list of business's beliefs about controversial issues.

- Hospitals should be free to choose which services they want to offer and individuals should be free to choose where they want to go.
- The true threat to access to healthcare will come if larger hospitals that are financially strong enough to help rescue and stabilize smaller, often rural hospitals are prevented from doing so due to targeted religious discrimination via expansion of the state's certificate of need powers.

**Department Response:**

These rules do not dictate the services a hospital must provide nor does it limit an individual's choice of where they seek care. The rules do not differentiate among religious views or beliefs. It requires posting so the public is aware of the hospital's policies.

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**Additional requirements are needed for submitting/posting hospital policy information.**

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Examples of these comments included:

- Require hospitals to identify all the subsidiary entities and practice settings in which restrictive policies would apply, including health-system owned ambulatory surgical centers, nursing homes, hospices, pharmacies, labs, and specialty and primary care medical practices.
- We suggest the WAC revisions include a requirement for health systems to submit any provider contracts, leases, or medical staff bylaws, which establish a requirement on providers to refuse to provide requested medical services. Facilities may incorporate refusal requirements into these documents without reflecting them in policies available to the public - so by requiring disclosure of a broader set of policies, the department will be able to see if the facilities are sending consistent messages to providers and the general public.
- We request that you issue additional guidance to hospitals clarifying where the policies should be posted and ensure that the policies are easily accessible on the Department of Health's website. In addition to posting on a hospital's website, the policies should also be prominently posted in the hospital or made available to patients when they receive care.
- The department should develop a policy content formatting template, which hospitals would be required to use in order to promote consistent presentation of policy information.

**Department Response:**

This comment is asking for a rule change that is outside the scope of the proposed rules. In addition, this request is outside the department's current statutory authority to regulate provider systems. Developing a template that would work for all hospitals would be difficult and complex due to the diversity of hospital services, capacity and community needs.

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**Add a RCW reference for the Death with Dignity law into WAC 246-320-141.**

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An example of this comment was:

- In regards to WAC 246-320-141, add a reference to RCW 70.245.190(2)(a), which requires any provider refusing to participate in Washington's Death with Dignity Act to provide notice to its employees and to the general public. Many hospitals are already in compliance with this statutory disclosure requirement, and referencing it may help establish statutory support for this portion of the proposed WAC changes.

**Department Response:**

The department assumes that all facilities are complying with the requirements of RCW 70.245.190(2)(a) if appropriate. This comment is asking for a rule change that could be considered a substantive change to the proposed rule. The department will take this comment under consideration in future revision of the rules.