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VIA U.S. MAIL AND ELECTRONIC MAIL

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JEAN ROBINSON BOARD PRESIDENT

KATHLEEN TAYLOR

Re. Comments on Department of Health Proposed Rules to Certificate of Need Regulations and Hospital Licensing Regulations, Implementing Governor's Directive 13-12

Dear Ms. Sigman:

The ACLU of Washington offers the following comments on the Department of Health (DOH) Proposed Rules to the Certificate of Need Regulations and Hospital Licensing Regulations, implementing the Governor's Directive 13-12. We appreciate DOH's and Governor Inslee's efforts to modernize the Certificate of Need (CON) process in response to significant concerns over restrictions in health care resulting from the unprecedented pace of mergers of religious health care entities with secular ones.

The Proposed Rules do not ensure that patients have access in their local communities to a full range of lawful, best care medical services, without limitations based on the religious doctrine of the organization controlling the hospital, clinic, or other medical facility. The Proposed Rules require significant change in order to meet the Governor's objective to "promote, maintain, and ensure the health of all citizens in the state by providing accessible health services, health facilities, and other resources."

Specifically, the Proposed Rules fail to: (1) sufficiently expand the scope of CON review; (2) adopt clear CON standards; (3) create oversight and enforcement mechanisms; (4) make the CON process more transparent; and (5) adequately increase consumer transparency. Religious-secular hospital mergers in Washington have already resulted in reducing patient access to reproductive health services and end-of-life care services. Among other needed policy changes, the CON review process must be updated to help ensure this does not continue to happen.



In our August 5, 2013 letter laying out our comments to DOH's preliminary proposed rules, we stressed the critical importance of comprehensively updating the CON process. Unfortunately, none of the suggestions put forth in our August letter have been implemented in the Proposed Rules. We are reiterating those suggestions, and are providing additional comments below. The CON review must be applied to proposed transactions in the health care industry based on their impact on "accessibility of health services, cost containment and quality."

A. Scope of Review

We applaud the goals of ensuring that the CON review applies to both public and private corporations and that transactions cannot evade review based on the structure or terminology. Unfortunately, the definitional changes are far from sufficient to accomplish those goals. The Proposed Rules do not ensure that every transaction that involves a curtailment of important services, a change in hospital mission, or a transfer of hospital control is subject to CON review.

As an initial matter, many of the religious-secular hospital mergers that have already been completed have been described as "mergers," "affiliations," "corporate restructurings," strategic partnerships," "alignments" or "joint ventures." We recommend that the definition of "sale, purchase, or lease" should include all transactions, and, for clarity purposes, explicitly include these terms.

Secondly, the Proposed Rules must make clear that whenever services or significant policies will be curtailed or changed as a result of a hospital transaction, a CON review is automatically triggered. Recent hospital mergers that have resulted in the denial of patient access to medical services have managed to evade CON review. For example, when Highline Medical Center (secular) in South King County affiliated with Franciscan Health System (religious), it prohibited information about and referrals for aid-in-dying and restricted a wide range of reproductive health services, including birth control, tubal ligations, and abortions. Yet DOH failed to require that the transaction undergo CON review.

To that end, we recommend expanding WAC 246-310-020 ("Applicability of chapter 246-310 WAC") to address this issue. Hospitals requesting a determination of non-reviewability should be required to provide notice of any curtailment of services or changes in policies that will occur as a result of a proposed merger. For your consideration, we have attached as "Attachment A" a checklist of services and policies that hospitals should be required to complete when requesting a non-reviewability determination.

Further, not only should a partial or complete change in hospital control trigger CON review, as suggested by the Proposed Rules, but so should a change in hospital mission. In executing this, the definitions in WAC 246-310-010 should make clear that moving from a secular hospital mission to a religious hospital mission constitutes

¹ Directive of the Governor 13-12.

a change in mission. The Ethical and Religious Directives for Catholic Health Care Services (ERDs) that apply to all Catholic-affiliated health care systems demonstrate some of the stark differences between secular and religious health care. See for example ERD 23, that states that advance directives that are contrary to Catholic teaching will not be honored, and ERD 45, which states that abortion will never be permitted. The Department of Health has an obligation to ensure that these services, which were specifically approved by the voters of Washington, are available throughout the state.

B. Standards

We reiterate the importance of clear and appropriate standards for CON review to protect accessible and affordable health care. WAC 246-310-210 already specifies the criteria for determining whether a CON should be granted. These rules should be applied to ensure that medically appropriate care is not limited by religious doctrine. The regulations should also require hospitals to provide sufficient information to enable DOH to conduct the thorough review that state public policy requires but is currently lacking. For example, the ACLU filed public records requests to obtain documents related to recently completed mergers and found the volume of documents that were reviewed by DOH to be astonishingly thin.

C. Oversight and Enforcement

Currently, no standard oversight mechanism exists to monitor compliance with the terms and conditions of a CON. There are also no enforcement mechanisms to ensure that health care facilities abide by the representations made in their CON applications. Without oversight and enforcement, DOH and the CON program do not protect patients' access to health care services.

DOH should regularly monitor health care facilities to ensure they are complying with the representations made in their CON applications. Patient complaints to DOH regarding restrictions or limitations on reproductive, end-of-life, or LGBT health care services that a hospital purported to provide and promised in its CON application to continue should automatically trigger an investigation by DOH. 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. Such consequences could include fines, or even revocation of the CON.

D. Transparency of CON Process

The people of Washington have a right to be informed about government decisions that affect their access to best care medical services. Yet few members of the public even understand DOH's role in regulating health care facilities, the CON process, or the potential impact that hospital mergers may have on services. Thus, there has been a relative lack of public comments on CON applications and requests for a determination of non-reviewability. Currently there is also little or no way for the public to understand the CON decision-making process. The public needs to be part

of the process to ensure relevant health needs are addressed. We again request that DOH make the CON review process transparent and easier to understand for the lay public.

E. Consumer Transparency

While the Proposed Rules require hospitals to provide to DOH their policies relating to reproductive health care services, end-of-life care services and non-discrimination, and to post these policies on their websites, ² this provision falls short of adequate transparency for consumers. It is even weaker than the Draft Changes, which were already insufficient. The Draft Changes would have required hospitals to report and post not only their policies, but also a related list of services not provided by the hospital. DOH claims the requirement to post the list of services was eliminated to reduce the burden on hospitals.

Hospital policies often are unclear and confusing. Patients should not have to "read between the lines" to understand what care they will be able to receive at a hospital. The burden should not be on the patient, who has less access to information and may be facing a stressful, time-sensitive medical emergency, to decipher hospital policies. It is essential that hospitals post on their websites and report to DOH, along with their policies, accurate and up-to-date lists of reproductive, end-of-life and LGBT health services they do or do not provide, so that patients know where they can obtain care.

To address DOH's concern about the burden on the hospitals, we suggest that DOH require hospitals to complete a simple checklist pertaining to reproductive, end-of-life and LGBT health services. The completed checklist would be required to be submitted to DOH and posted on the hospital's website. An example of such a checklist is attached as "Attachment B." Hospitals should be aware of the services they provide, so it should not be difficult or burdensome for them to provide this information.³

Further, while the ACLU-WA commends DOH for attempting to address consumer transparency in the Proposed Rules, consumer transparency does not address the critical, underlying issue — patient access to services. Even if a rural resident can now read on a website that the only accessible hospital has stopped providing reproductive or end-of-life services, the resident will be no closer to actually obtaining those services. Substantive changes and government oversight are needed.

² DOH's prior Draft Changes included this consumer transparency requirement under WAC 246-310 WAC - Certificate of Need. The Proposed Rules instead address consumer transparency under WAC 246-320 – Hospital Licensing Regulations.

³ DOH already requires hospitals to report Comprehensive Hospital Abstract Reporting System (CHARS) data based on hospital inpatient discharge information derived from hospital billing systems. This data source includes codes for each procedure and diagnosis type, demonstrating that hospitals are aware and capable of documenting the services they provide.

F. In Sum: Washington's Agencies and Leaders Must Ensure Accessible, Affordable Quality Health Care Unimpeded by Religious Doctrine

To address patient access to health care services, comprehensive changes must be made to the CON review process, including:

- Ensuring that the scope of the CON review includes all transactions that significantly impact access and affordability in local communities to a full range of lawful, best care medical services;
- Ensuring that appropriate standards apply to protect accessible and affordable health care;
- Establishing a standard mechanism for monitoring compliance with the terms and conditions of a CON and developing consequences for entities that violate representations made in their CON application or conditions of a CON granted; and
- Providing transparency for both the CON process and the services provided or not provided by health care facilities.

The State of Washington, by law, has significant responsibility in ensuring that access to medically appropriate health care is affordable and accessible for all its residents. Therefore, the state's responsibility to Washingtonians should not end with improving the antiquated CON process. If and when the significant improvements detailed in this letter are made to the CON review rules, the Department of Health and other state agencies should then review the remaining health regulatory regimes and programs to ensure that medically appropriate care, not limited by religious doctrine, is available for all Washington patients. Washington's leaders must step up to fulfill that critical responsibility.

Sincerely,

Kathleen Taylor
Executive Director

Leah Rutman Policy Counsel

Attachment A Checklist of Curtailed Services & Changes in Policies

Will the following services be curtailed, or policies changed due to the proposed 'sale, purchase or lease?' In instances where the answer is 'yes,' please provide detailed descriptions of the curtailment or change.

Services	Yes	No	Comments (if you answered 'yes' please provide a detailed description of the curtailment)
Contraceptive counseling and prescriptions			
HIV/AIDS treatment and counseling that includes discussion of condom use			
Counseling for intersexuality			
Anal health counseling and care			
Provision of contraceptive devices			
Tubal ligations and other forms of female sterilization			
Vasectomies			
Treatment of miscarriages, including but not limited to, counseling about miscarriages and treatment options			
Treatment of ectopic pregnancies, including but not limited to, counseling about ectopic pregnancies and treatment options			
Provision of emergency contraception in compliance with RCW 70.41.350. (If you provide emergency contraception please note in comments whether an ovulation or pregnancy test is required prior to dispensing)			
Abortions			
Fertility treatment, including but not limited to, In Vitro Fertilization			
Preventative mastectomies			
Transgender health services, including but not limited to, genital reconstructive surgery; chest reconstructive surgery; and prescriptions for appropriate medications and feminizing and masculinizing hormones			
Contraception provision related to drug trials			
Contraception provision related to non- contraceptive benefits, including but not limited to, cancer treatment, heavy periods, endometriosis, and fibroids.			
Pharmacy dispensary			
Palliative sedation			
Palliative care/nursing support for patients who choose to stop eating and drinking to allow natural death			
Removal of ventilator support, dialysis or other advanced life support			
Removal of artificial hydration and nutrition			

Services	Yes	No	Comments (if you answered 'yes' please provide a detailed description of the curtailment)
Information about Washington's Death with Dignity Act			
Referral to support organizations or cooperating providers to assist a patient in using Washington's Death with Dignity Act			
Allow medical providers to participate in Washington's Death with Dignity Act including, providers employed, contracted, with privileges, lessee, other			
Changes to Existing Policies	Yes	No	Comments (if you answered 'yes' please describe any change in policy)
Changes to policies concerning future medical advances (such as advances involving embryonic stem cells)			
New requirement for employees, or providers with privileges, or lessees, or those contracted with the health facility to adhere to the Catholic Ethical and Religious Directives (ERDs) or any interpretation of the ERDs			
New requirement for employees, or providers with privileges, or lessees, or those contracted with the health facility to sign an agreement to adhere to the ERDs or any interpretation of the ERDs			
Changes in ability to provide information, counseling or referrals for prohibited services, including but not limited to, transgender healthcare services, reproductive health care services and end-of-life health care services including Washington's Death with Dignity Act			
Changes in policies regarding adherence to advance directives, including do-not-resuscitate directives			

Attachment B Checklist of Available Services

Do you provide the following services in your facility?

In instances where the answer is sometimes, please provide detailed descriptions of the circumstances under which you do not provide the service.

Services Provided	Always	Never	Sometimes	Comments (if you answered 'sometimes' please provide a detailed description of the circumstances under which you do not provide the service)
Contraceptive counseling and prescriptions				
HIV/AIDS treatment and counseling that includes discussion of condom use				
Counseling for intersexuality				
Anal health counseling and care				
Provision of contraceptive devices				
Tubal ligations and other forms of female sterilization				
Vasectomies				
Treatment of miscarriages, including but not limited to, counseling about miscarriages and treatment options				
Treatment of ectopic pregnancies, including but not limited to, counseling about ectopic pregnancies and treatment options				
Provision of emergency contraception in compliance with RCW 70.41.350. (If you provide emergency contraception please note in comments whether an ovulation or pregnancy test is required prior to dispensing)				
Abortions				
Fertility treatment, including but not limited to, In Vitro Fertilization				
Preventative mastectomies				
Transgender health services, including but not limited to, genital reconstructive surgery; chest reconstructive surgery; and prescriptions for appropriate medications and feminizing and masculinizing hormones				
Contraception provision related to drug trials				
Contraception provision related to non-contraceptive benefits, including but not limited to, cancer treatment, heavy periods, endometriosis, and fibroids.				
Pharmacy dispensary				
Palliative sedation				
Palliative care/nursing support for patients who choose to stop eating and drinking to allow natural death				

Services Provided	Always	Never	Sometimes	Comments (if you answered 'sometimes' please provide a detailed description of the circumstances under which you do not provide the service)
Removal of ventilator support, dialysis or other advanced life support				
Removal of artificial hydration and nutrition				
Information about Washington's Death with Dignity Act				
Referral to support organizations or cooperating providers to assist a patient in using Washington's Death with Dignity Act				
Allow medical providers to participate in Washington's Death with Dignity Act including, providers employed, contracted, with privileges, lessee, other				