Further Comments on Department of Health Rulemaking: Certificate of Need and Hospital Licensing

Thank you for the opportunity to provide further comments on the Certificate of Need and hospital licensing rulemaking currently underway. We provided initial comments at the concept rule workshop but have had time for further research and conversation with our members. Following are some important considerations as the Department of Health continues the rulemaking process.

HOSPITAL MERGERS

There are many reasons mergers and affiliations are happening.

Health care is in a time of intense change. Exciting new technology is available, care is becoming better coordinated, the way care is reimbursed is changing, and patient safety and quality in all settings is improving. The federal government is making big cuts to hospitals as an incentive to be more efficient. A major goal of the Affordable Care Act (ACA) is to encourage the separate pieces of the health care system to collaborate so patients get better care. In addition to making large cuts to hospital payments (approximately $3.7 billion over 10 years in Washington State), the ACA makes changes to the way providers are reimbursed to encourage more coordination. In addition to those changes, every community in Washington has its own evolving health care needs.

Hospitals are responding to the call for better coordinated, high-quality care by moving away from a structurally fragmented care system. They are meeting that expectation by building a continuum of care that involves physicians and other caregivers to improve patient care. Health care that is coordinated between doctors, clinics, hospitals, and other providers benefits patient health. Some hospitals are finding that the best way to provide that coordination is by forming relationships with health care systems. Hospitals are collaborating with others ultimately to benefit the patients and communities that hospitals serve.

Mergers and affiliations are preserving core hospital services.

Without another hospital partner, some hospitals will either have to dramatically cut services or could even close – meaning the community will lose access to essential hospital services. The narrow focus in the rulemaking process on a slice of hospital services threatens to jeopardize the broad scope of hospital services in favor of a limited set of services.

Many hospitals do not have extra funds to update their buildings and patient rooms, invest in quality and safety innovations, expand services, or even compete for top-quality doctors and nurses. Hospitals in Washington State and across the country have closed their psychiatric services, maternity services, long-term care units, emergency rooms, or closed all together. When hospitals close or cut services, the impacts go beyond serious issues for people who need health care. The whole community suffers with job losses and the loss of an important economic anchor.

By joining with another hospital or a health system, a hospital can get access to more resources that will help serve patients. They may also be able to reduce administrative costs by sharing services such as payroll or financial record keeping. Joining with another hospital provides opportunities to improve efficiency and improve patient care. A hospital that affiliates with another system can tap into telehealth services, electronic medical records, and broad referral networks, all of which directly improves patient care.

Some recent examples of improvements resulting from partnerships include:

- When Good Samaritan Hospital in Puyallup joined the MultiCare Health System, the two systems were able to create operational efficiencies by integrating many clinical services as well as financial and other business support services. Additionally, MultiCare and Good Samaritan were able to combine their resources which paved the way for the construction of a new nine-story, 357,000 square-foot patient care tower on the MultiCare Good Samaritan Campus and the significant expansion of health care services in East Pierce County.
- When Jefferson Healthcare in Port Townsend affiliated with Swedish Medical Center, Jefferson gained affordable access to Epic, a state of the art electronic medical record system. Jefferson Healthcare went live on Epic in June of 2013 and its patients and community now benefit from a far more robust and integrated electronic medical record than could have been implemented without the affiliation.

The prevalence of faith-based hospitals has been overstated.

While it is correct that a number of hospitals have chosen to join with a faith-based hospital to preserve and enhance the services they provide, the information being provided to the public and to the Department overstates the case. For example, Jefferson Healthcare in Port Townsend and Olympic Medical Center in Port Angeles are consistently labeled as "100% Religiously Affiliated." These hospitals have a shared electronic medical record and a referral network to better coordinate care. They remain independently governed by elected Boards of Commissioners and are not bound by any religious directives.

In addition, while Catholic health care may have gained some market share in Western Washington recently, it has lost market share in other parts of the state. For example, Providence no longer operates a hospital in Yakima, and PeaceHealth pulled out of Wenatchee. There is no Catholic presence in the central part of the state.

THE CERTIFICATE OF NEED LAW

The proposed change to require CON review for transactions that involve a change of control other than a purchase, sale, or lease is contrary to law.

State law requires a Certificate of Need for a "sale, purchase, or lease of part or all of any existing hospital."[i] The existing rule uses the same language.[ii] The concept rule proposes to expand this language to include any transaction in which there is a change of control of all or part of an existing hospital.

The phrase "sale, purchase, or lease" is well-defined in Washington law. It does not include all changes of control. When a change of control is meant to be encompassed by statutory language, the language says so. A plain, clear, and unambiguous statute cannot be construed; its meaning is strictly interpreted from the words of the statute itself.[iii]

The proposed change to require CON review for transactions that involve a change of control other than a purchase, sale, or lease is also contrary to decades of precedent and clear interpretation by the Washington State Department of Health.

The Department has long understood that the language "sale, purchase, or lease" does not encompass other transactions. In previous rulings, the Department has explicitly acknowledged that a change in ownership and control of a hospital that occurs either through a corporate reorganization or through a transaction that falls short of a transfer of title to the assets of a licensed hospital does ***not*** result in the purchase or sale of a hospital and is ***not*** reviewable under the CON law.

In 2000, a transaction between Swedish and Providence resulted in a change of ownership in and control of Providence Seattle Medical Center. The transaction also involved a corporate reorganization by Providence Health System-Washington and a subsequent merger of a newly formed holding company, PSMC, LLC, into Swedish Health System. The Department recognized clearly that this resulted in a "transfer [of] ownership and control" of Providence Seattle.[iv] However, the Department concluded: "***had the CON law been intended to apply to mergers it would have specifically so stated.***" (emphasis ours)

The Department has consistently found, over a period of more than 20 years, that mergers and affiliations do not require CON review. It has issued many other determinations of non-reviewability in cases involving corporate reorganizations and changes in ownership interest and/or control of a hospital, ranging from changes in the entity that owns the hospital to changes that occur at levels above the hospital.[v]

The legislature has taken no action to redirect the Department's decisions, and has enacted other related statutes that declined to address these issues.

If the legislature had intended the Certificate of Need law to apply to a change of ownership interest and/or control of a hospital, then the CON law would have included this language in defining what requires CON review. In addition, if the legislature believed the Department was misinterpreting what the legislature intended, it could have enacted a new statute to redirect the Department's actions. This also did not happen.

It is worth noting that the legislature has enacted a separate statute, the hospital conversion statute, that defines "acquisition" as an "acquisition by a person of an interest in a nonprofit hospital, whether by purchase, merger, lease, gift, joint venture, or otherwise, that results in a change of ownership or control of twenty percent or more of the assets of the hospital, or that results in the acquiring person holding or controlling fifty percent or more of the assets of the hospital." However, the law goes on to say, "acquisition ***does not include*** an acquisition if the acquiring person: (a) Is a nonprofit corporation having a substantially similar charitable health care purpose as the nonprofit corporation from whom the hospital is being acquired, or is a government entity; (b) is exempt from federal income tax under section 501(c)(3) of the internal revenue code or as a government entity; and (c) will maintain representation from the affected community on the local board of the hospital."[vi] Again, the legislature had the opportunity to include the kinds of transactions the Department is currently contemplating in its rulemaking process but instead, it explicitly excluded them.

Changing the CON review guidelines would be arbitrary and unlawful. Changes of this magnitude require legislative action.

Given this history, if the Department were to change the rule now to encompass transactions which it previously clearly stated are not captured by the statute, it would be acting in an arbitrary and unlawful manner. The fact that the Department has issued interpretations over the years explicitly saying that changes of control when structured as something other than a purchase, sale, or lease is *not* within the statutory or regulatory language is strong support for the argument that an expansion now, absent a change in the statute, is arbitrary.

While courts often defer to an agency's interpretation of its own rules, when the rules are significantly changed without any change in the legislative language and in the face of earlier, contrary interpretations by the same state agency, it is unlikely this deference would be granted. In addition, because these changes are not supported by the statute, this revision of the rules could easily be undone by another administration.

A change of this scope clearly requires a legislative change, not a change in the rules while the statute remains unchanged.

The current draft is so broad that it would require a multitude of arrangements to flow through Certificate of Need. The timing of the Certificate of Need process would stifle hospitals' efforts to modernize and streamline.

Because the concept rule seeks to regulate changes in control of all or part of a hospital, it could be read to encompass a wide variety of transactions and arrangements. The requirement for review would be remarkably burdensome. Hospitals are seeking ways to streamline their services and cut costs while maintaining quality. These decisions often lead to arrangements with outside groups who can perform the service more efficiently. Outsourcing Human Resources, joining a group to manage supply chain, or contracting with a provider group – it seems that all of these could be considered a change in control over part of the hospital. Even intra-company agreements could be swept up in this rule, which could impede a hospitals' ability to manage efficiently.

The Certificate of Need process is a lengthy one. Requiring approval for all these types of arrangements would be costly and significantly slow hospitals' ability to make important changes.

Attempting to ensure or require the provision of certain reproductive and end-of-life services through the Certificate of Need program would lead to great administrative difficulties – and ultimately would be unworkable.

If the Department uses its rules to ensure that certain services (abortions and assisted suicides) are widely provided, it will create a process that leads to an unworkable result.

Under the current standards, projects are reviewed on four criteria: need, cost containment, financial feasibility, and structure and process of care. To decide need, the Department must determine at least two things: how much of a service is needed and how much of that service is provided in a planning area already. This means the Department needs to decide how many abortions and assisted suicides a community needs. This seems like a very difficult – not to mention highly controversial – determination to make.

The Department would then need to also determine how many abortions and assisted suicides are provided by current providers. The problem, however, is these services are not regulated by CON and most providers are not hospitals. How can the Department measure the extent of an unmet need if it doesn't regulate all (or even most) of the providers today? Will it survey providers? Will providers not subject to CON review answer such surveys? Will those answers be reliable? Will they be made public?

The services being contemplated are, by and large, not hospital services. In other states, there is a strong push *against* them being considered hospital services in order to preserve the ability to provide them in a more accessible and less expensive setting.

The Department has expressed a desire to ensure an adequate supply of abortion and end-of-life services. However, in most cases, the services being considered are not provided by hospitals. They typically do not require the expertise or equipment a hospital brings. Also, through the currently proposed rulemaking, the Department would not acquire the ability to require these services.

Interestingly, a related debate is raging in other parts of the country. Some states, particularly in the South, recently have adopted laws that require that abortion providers comply with minimal clinical standards (such as those that apply to ambulatory service centers). These states would also like to mandate that abortion providers have admitting privileges to hospitals – something that in almost every case, they do not.

There has been a great outcry by those who favor the provision of abortion services in response to this kind of legislation. They state that these are not rightfully hospital – or even ambulatory surgical center – services, and that hospital admitting privileges are not necessary.

CONSCIENCE CLAUSES AND RELIGIOUS FREEDOM

The proposed rule does not take into account the impact of the conscience clauses contained in numerous places in state statute.

Washington State has a long history of enacting "conscience clauses" designed to ensure no provider, either institutional or individual, is required to provide abortion or end-of-life services if they are not comfortable doing so. Having these conscience clauses was important for the passage of both I-120 and I-1000. An important message during both these campaigns was "no one will have to do this if they do not want to."

The conscience clauses have a real-world impact on the provision of services. It can be difficult (particularly in a smaller hospital) to assemble a team willing to perform an abortion, for example. Typically, the hospital must find among its staff a physician, a registered nurse or anesthesiologist who administers sedation for the procedure, and one or more technicians to provide the necessary care. Unlike staff at abortion clinics, these staff went to work at a hospital to provide a variety of services. Hospitals must allow staff to opt out of providing these services if it is against their personal beliefs.

Some hospitals have permissive policies related to the Death with Dignity Act, but they do not have providers willing to prescribe the medication – a situation that has been frustrating for patients.[vii] Even if the institution were compelled to provide a service (an idea we oppose), there would still be the requirement to find individual providers willing to deliver that service – and hospitals are not allowed to compel any of their individual providers to do so, nor can they require it as a condition of hiring or privileging.[viii]

Attempting to require the provision of certain reproductive and end-of-life services raises Constitutional issues.

Any effort to compel services raises serious concerns under the U.S. and Washington Constitutions. The First Amendment to the U.S. Constitution guarantees the "free exercise" of religion; Article 1, Section 11, of the Washington Constitution guarantees "[a]bsolute freedom of conscience in all matters of religious sentiment, belief and worship." Rules that target acquisitions, mergers, or other transactions involving faith-based hospitals do not pass Constitutional muster because they would target a specific religion and impose restrictions based on faith-based hospitals' exercise of religious beliefs.

POLICY COLLECTION

The way the concept rule is drafted is overly broad.

We understand the Department has opened a new CR 101 to place the policy collection requirement into the hospital licensing statute rather than Certificate of Need regulations. Our comments here would apply regardless of the placement of the requirement.

We suspect the Department's intention in collecting certain policies from hospitals is specifically to document abortion services and Death with Dignity Act services, but the concept rule is drafted so that the impact is far broader. We point in particular to the requirement for policies on admissions and creation of lists about services "authorized by law" that are not provided by a particular hospital.

Many health services are "authorized by law" in some way. The law regulates trauma care, cardiac care, podiatry, acupuncture, midwifery, transplants, and many other services. In some cases, that regulation actually prohibits hospitals from providing certain services – for example, trauma care beyond the hospital's capability or invasive cardiac care. In other cases, the hospital clearly does not have the capacity to provide a service – for example, very few hospitals provide transplant services.

There is wide variation among hospitals about services offered and services not offered, and which patients a hospital can and will admit. The concept rule seems to require hospitals to create exhaustive, ever-changing, and probably unknowable lists about everything they do and do not offer, and every service they will and will not admit a patient to receive.

The requirement to submit policies has the potential to create extraordinary administrative burden with very little value to the patient.

Patients would have great difficulty wading through complicated hospital policies. An analogous document is the Notice of Privacy Practices that every provider is required to provide to patients. Very few patients read this document and even fewer understand it. The policy collection proposed here has the potential to be equally unhelpful to patients, who are more likely to choose a hospital based on insurance coverage, recommendations from friends and other physicians, proximity and quality of care – not by reading hospital policies on the Department's website. This seems like a substantial body of work with little benefit to patients.

Requiring publication of these policies could take away important flexibility.

The nuances in direct care delivery, specific clinical considerations, and the physician-patient relationship could never be reflected in the requirement for a specific list. Delivery of health services must be flexible in order to meet the needs of the patient. What is and what is not offered is sometimes not a hard line, black-and-white decision, and may include directing the patient elsewhere for services.

Hospital policies alone would provide a very limited inventory of available services.

Abortions and assisted suicides are largely provided outside hospital settings and patients often seek these services from other providers. Collecting policies from hospitals only and presenting them on the Department's website as the list of places to get services would provide a very narrow view – and could have the unintended consequence of leading a patient to believe a service is not available in their community when it actually is available from a non-hospital provider. If the Department's goal is to collect these policies as a way to catalog where the services are provided, it should do so from all relevant health care providers – physician offices, ambulatory surgical centers, health centers, and clinics. However, not all these providers are regulated by the Department.

The use of the collected policies is unclear.

The Department proposes to collect a broad set of policies and post them on its website. It is unclear from the concept rule whether these policies will be used to inform decision-making at the Department, and if so, how.

THE ROLE OF OTHER BRANCHES OF GOVERNMENT

The Department of Health is not charged with regulating antitrust and competition concerns.

Some of the commentators appear to believe that the CON rules should be used to block transactions that are seen as anticompetitive. But the CON rules are not the way to promote competition. This is the purview of state and federal antitrust legislation, enforced by federal and state enforcement agencies. We oppose any efforts to duplicate one governmental agency's work in another agency. This creates additional bureaucracy and is an inefficient use of government resources.

The goal of antitrust review is to ensure that patients will continue to have choice about where to seek care. Antitrust agencies also want to see that hospitals and health systems continue to compete with one another and with other providers to provide the best value and the highest quality care.

CON regulation, far from being a way to enable competition, typically is seen as hindering competition, because its very purpose is to restrict entry. For this reason, the Federal Trade Commission and Antitrust Division of the Department of Justice, under both Democratic and Republican administrations, consistently have called for the abolition of CON regulation. It is not the role of a statute whose goal is to restrict competition to promote competition.

Local governance bodies are the correct groups to make decisions about the hospital's future.

Much of the controversy around hospital mergers and affiliations centers around public hospitals. Public hospital district commissioners are elected by their community. When considering whether to merge or affiliate, they take many factors into account – for example, the views of their constituents, the long-term viability of the partner, the resources the partner brings to the table, access to electronic health records, and the quality and accessibility of the referral network they will receive. Fundamental policy decisions, such as choosing the best affiliation partner, belong to the people and the elected commissioners of that district.

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[i] RCW 70.38.105(4)(b).

[ii] WAC 246-310-020.

[iii] *Bravo v. Dolmen Cos.*, 125 Wn.2d 745, 752, 888 P.2d 147 (1995). "Words in a statute are given their ordinary and common meaning absent a contrary statutory definition. Courts may resort to dictionaries to ascertain the common meaning of statutory language." *Budget Rent-a-Car Corp. v. State*, 144 Wn.2d 889, 899 (2001) (internal citations omitted). *Webster's* defines "purchase" as "to acquire real estate by means other than descent" or "to obtain by paying money or its equivalent: buy for a price." *Webster's Third New International Dictionary* 1844 (11th ed. 2004); *see also Black's Law Dictionary* 1354 (9th ed. 2009) ("the act or instance of buying"). Similarly, "sale" is defined as "the act of selling: a contract transferring the absolute or general ownership of property from one person or corporate body to another for a price (as a sum of money or any other consideration)." *Webster's Third New International Dictionary* at 2003; *see also Black's Law Dictionary* at 1454 (9th ed. 2009) ("The transfer of property or title for a price."). Both terms clearly incorporate the elements of transfer of title for consideration.

[iv] *See* Department determination of non-applicability letter, at page 2, dated June 26, 2000.

[v] In 2009, the Department concluded that the affiliation of Northwest Hospital Medical Center with UW Medicine did not require CON review. UW became the sole corporate member of NWHMC (which changed its name to "UW Medicine/Northwest"). The affiliation involved no transfer of title. The hospital continued to be owned, operated by, and licensed to Northwest Hospital Medical Center (albeit under the new name). UW Medicine made no payment as part of the transaction.

In August 2006, the Department determined that a transaction involving the affiliation of Good Samaritan Hospital in Puyallup, Washington into MultiCare Health System was not subject to CON review. That transaction was structured as a corporate affiliation in which MultiCare became the sole corporate member of Good Samaritan Community Healthcare. GSCH was the sole corporate member of Good Samaritan Hospital, which owned and operated an acute care hospital in Puyallup, Washington. After the transaction, GSCH continued to operate Good Samaritan Hospital within the family of MultiCare affiliated organizations. The Department concluded that the corporate affiliation was not a purchase or sale of a hospital and was therefore not subject to CON review.

In September 2005, the Department determined that a transaction in which HCA, Inc. transferred to Capella Healthcare, Inc. its ownership interest in certain subsidiaries that owned and operated hospitals, including Capital Medical Center in Olympia, Washington, was not subject to CON review. That transaction involved a two-step process in which HCA first reorganized its subsidiaries' holdings and then transferred ownership and control in its subsidiaries to Capella.

In a similar determination in June 2005, the Department determined that a stock transaction in which Ardent Health Services, L.L.C. sold to Psychiatric Solutions, Inc. 100% of the stock of Ardent's subsidiary, Ardent Health Services, Inc. (AHS), did not require CON review. AHS was the ultimate parent of an entity that owned and operated Fairfax Hospital in Kirkland, Washington. The Department then concluded that the entity subject to the stock sale, AHS, was not a hospital under state law and, therefore, the stock purchase between Psychiatric Solutions, Inc. and Ardent and resulting change of control of Fairfax Hospital was not subject to CON review.

In 1997, Tenet Healthcare Corporation acquired OrNda Healthcorp by issuing over 81 million shares of its common stock in a tax-free exchange for all of OrNda's outstanding common stock such that OrNda became the wholly-owned subsidiary of Tenet. OrNda was the parent organization of Puget Sound Hospital in Tacoma. The Department determined that the Tenet-OrNda transaction did not require prior CON review and approval.

In 1992, the Department concluded that the statutory merger of Ballard Community Sound Hospital did not require CON review. As part of the restructure, AHM sought to transfer the shares of PSH to AHM Capital Management, Inc., another wholly-owned subsidiary of AHM. The Department found that the transaction did not constitute the

sale, purchase or lease of all or part of a hospital because PSH remained the owner and operator of Puget Sound Hospital and the transaction did not involve the exchange of compensation for the corporate stock shares of PSH.

[vi] RCW 70.45.

[vii] "Man's final wish for death with dignity unfulfilled," Wenatchee World, April 9, 2009.

[viii] RCW 9.02.150 states: No person or private medical facility may be required by law or contract in any circumstances to participate in the performance of an abortion if such person or private medical facility objects to so doing. No person may be discriminated against in employment or professional privileges because of the person's participation or refusal to participate in the termination of a pregnancy.