Pursuant to the Administrative Procedure Act, CHI Franciscan Health (“CHI”) has submitted a petition to the Department of Health requesting that an exception provision be added to the elective PCI need forecasting methodology set forth in WAC 246-310-745. On May 11, 2017, the Department intends to hold a one-hour PCI workgroup meeting at which CHI will make a presentation in support of its petition.

The Department’s agenda for the meeting does not provide any time for comment upon the presentation by interested parties. Accordingly, Providence Health & Services-Washington (“Providence”) anticipates that the Department will hold an additional meeting in order to permit detailed comment on CHI’s petition and presentation, and to provide an opportunity for discussion among representatives of the Department and interested parties. For now, Providence wishes to identify certain important health care policy considerations that should be addressed as the process moves forward.

1. **Given the statutory definition of “tertiary health service,” particularly its emphasis on the critical role of patient volumes, an exception provision to the elective PCI numerical need methodology should not be adopted unless there is substantial and compelling evidence that a systemwide patient access problem exists.**

The certificate of need (“CON”) statute defines “tertiary health service” as “a specialized service that meets complicated medical needs of people *and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.*” RCW 70.38.025(14) (emphasis added). Elective PCI has been identified as a CON-reviewable tertiary health service by the Department. WAC 246-310-020(1)(d)(i)(E). It is important to note that, in 2015, the Department conducted its periodic review of the list of tertiary health services, and concluded that elective PCI should remain classified as a tertiary health service. *See:* Department of Health 2015 Tertiary Services Review (August 18, 2015), pp. 5-8.

Thus, elective PCI is one of a small group of complex services for which the Department has determined that patient volumes are directly related to the optimization of (1) quality of care, including “improved outcomes of care,” and (2) “provider effectiveness.” In the case of elective PCI, this relationship is explicitly recognized in the CON regulations: a hospital with a CON-approved elective PCI program is required to perform 300 adult PCIs per year (“the minimum volume standard”). WAC 246-310-720(1). In addition, a hospital will not be awarded a CON to establish a new elective PCI program unless all existing programs in the planning area meet or exceed the minimum volume standard. WAC 246-310-720(2)(b).

Given the existence of this volume-quality relationship for elective PCI services, Providence believes that the Department should not adopt an exception provision to the numerical need
methodology unless there is substantial and compelling evidence that a systemwide patient access problem exists.

2. There is no evidence of a systemwide patient access problem with respect to elective PCI services. CHI’s proposal is based solely upon the perceived needs of a single hospital.

In both its June 1, 2016, petition for rule-making and its May 3, 2017, presentation document, CHI bases its argument for the adoption of an exception provision solely upon what it perceives to be the unique needs of Highline Medical Center, one of the 10 hospitals operated by CHI in western Washington. The exception language proposed by CHI is clearly crafted to enable Highline to qualify for an exception to the elective PCI numerical need methodology.

CHI has not presented any evidence that there are regional or statewide patient access issues with respect to elective PCI services. No other hospital, medical group, health care organization, or health care advocacy group has presented such evidence.

Adopting an exception provision based solely upon the perceived needs of a single institution, and directed at obtaining relief for that institution, completely undermines the legislatively-mandated requirement that tertiary health services, which are characterized by a direct relationship between patient volumes and quality of care, should be provided by a limited number of hospitals. In such a situation, there will invariably be some hospitals who feel that their own institutional needs are not being satisfied. But this is an inherent and fundamental feature of the certificate of need regulatory process.

3. The proliferation of elective PCI programs through an exception provision may in fact create access problems by reducing the volumes of existing PCI programs.

In recent years, the overall volume of elective PCI procedures has been relatively flat on a statewide and nationwide basis due to evolving methods of medical treatment, as noted by Dr. Dean at the April 11 PCI workgroup meeting. Accordingly, if hospitals are permitted to open new elective PCI programs through an exception process, this will dilute the volumes of existing programs. This dilution in volumes may have two impacts: (1) it may cause some CON-approved programs to drop below the hospital minimum volume standard, and (2) it may prevent some CON-approved programs from reaching the hospital minimum volume standard. This will put the Department in the position of seeking the closure of programs that do not meet the minimum volume standard.

The 2014 SCAI/ACC/AHA Expert Consensus Document, which concluded that there is a volume-outcome relationship in elective PCI programs without on-site surgical backup, also recognized the adverse consequences associated with the proliferation of elective PCI programs. The Document states:
Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access.


The consequences described in the 2014 Expert Consensus Document confirm the soundness of not adding an exception provision to the PCI numerical need methodology. As noted above, requiring CON approval for the establishment of a new tertiary health service naturally leads to a limited number of providers for each of the services. However, this outcome is necessary (and expected) in order to realize the benefits of the direct relationship between patient volumes and the optimization of “provider effectiveness, quality of service, and improved outcomes of care.”

RCW 70.38.025(14).

4. Conclusion.

At this point, only two PCI workgroup meetings have been held (on August 3, 2016, and on April 11 of this year). The lion’s share of those meetings has been devoted to consideration of the March 14, 2016, petition by Yakima Valley Memorial Hospital (“YVMH”) to reduce the hospital and physician minimum volume standards. A thorough discussion of the issues raised by CHI’s petition to add an exception provision has not yet taken place. Providence believes that such a discussion is necessary in order for the Department to make a fully-informed decision as to whether to adopt a “significant legislative rule” in response to CHI’s petition. RCW 34.05.328.

In addition, we believe that the relationship between YVMH’s petition and CHI’s petition should be discussed and evaluated. Specifically, it is our view that, if the Department decides to reduce the hospital and physician minimum volume standards in response to YVMH’s petition, it would not be appropriate for the Department to consider the adoption an exception provision until the impact of the reduction in the minimum volume standards can be assessed. For example, it is possible that a reduction in the minimum volume standards may lead to the approval of additional elective PCI programs. It would be premature to adopt an exception provision until this impact can be evaluated.