A meeting regarding the Certificate of Need (CoN) percutaneous coronary intervention (PCI) rules convened on April 11, 2017. The meeting was held at the Department of Health, 111 Israel Road SE, in Town Center 2, Conference Room 158, Tumwater, WA 98501.

PRESENT: Patty Seib, Yakima Memorial  
Jonathan Seib, Yakima Memorial  
Dennis Hoover, Virginia Mason Memorial  
Vicki Eastridge, Legacy Health  
Chris Thomson, CHI Franciscan  
Frank Fox, Providence Health & Services  
Stephen Pentz, Providence Health & Services  
Ian Worden, CHI Franciscan  
Cary Evans, CHI Franciscan  
Jody Carona, HFP  
Zosia Stanley, WSHA  
Larry Dean, MD, UW Medical (by telephone)  
Greg Eberhart, MD, CHI Franciscan (by telephone)  
Tim Strickland (by telephone)

STAFF PRESENT: Steve Bowman, CHS Director  
Nancy Tyson, HCF Executive Director  
Kathy Hoffman, Policy Analyst, OAS  
Jan Sigman, CoN Program Manager  
Karen Nidermayer, CoN Analyst

1:00PM – Open Meeting, welcome and introductions

Review

Kathy: Has everyone had an opportunity to look at the agenda? Great. Before we get going, and to revisit where we’ve been already, we received two rules petitions, one from Yakima Valley Memorial on March 14, 2016 (navigates on overhead screen to DOH CoN rules website and displays petition) and the department responded to that
petition shortly thereafter (demonstrates to group how to navigate to CoN rules website). Here (navigates to document on overhead screen for group) is the department response to that petition. Here (navigates to document on overhead screen for group) is a copy of CHI Franciscan’s petition that was received on June 1, 2016, and here (navigates to document on overhead screen for group) is the department’s response to that petition that was mailed and emailed on July 18, 2016. Here (navigates to document on overhead screen for group) is the CR 101 was that filed on July 7, 2016. We have received one stakeholder comment so far at the August 3, 2016 stakeholder meeting, and at that meeting, we invited additional comment and we also formed a data subcommittee to look at the relationship between volume standards and quality. And so, between that time and now, that subcommittee has done its work, and we’re ready to present that now and have some additional conversation regarding exceptions as was requested. So, I’m going to turn the floor over to Dennis now since he’s sort of our presentation person on the findings of the data subcommittee.

**Presentation – Data Subcommittee**

**Dennis:** The data subcommittee met three different times, twice to define the data request that was submitted to the Foundation for Healthcare Quality/COAP PCI and then once the data was received we met on February 15, 2017 to review that. COAP raw data was distributed and looks like this (holds up data sheets provided to workgroup via email in January, 2017) and because there was no statistical work on it, I worked with our statisticians at the hospital to apply confidence intervals to try to make a little bit of sense out of the large amount of raw data.

So, what I’ve done is attempted to take exactly what was in that data and take what was in the meeting minutes from both our initial stakeholder meeting and the data subcommittee and put together a boiled down, condensed, bottom line of those findings….and so, (referring to PowerPoint) I summarized this with little interpretation, just provided data, any comment that was made was limited to what was present in the minutes form the data subcommittee and stakeholder meeting, the COAP report was submitted directly to the Certificate of Need program as raw data so we applied confidence intervals to that data.

Went back to that initial stakeholder meeting we had in August and said, why did we ask COAP for this data? When you look at the consensus documents that have come out by the professional organizations, they review meta-analysis in their original studies, but Washington is unique in that COAP obtained all the case data or the goal is to get every case or PCI that is performed in the state of Washington. And so, many of these comments, I think, came from Bart Eggen, and he said that we really want ensure that we have high quality care (unintelligible) delivered to the citizens of the state of Washington. And so, really the question became, does COAP data provide any value and confirmation that the programs within the state of Washington are indeed delivering that and particularly, to see if there is a difference in outcomes of Washington state hospitals by volumes. So the data request was by volume of reporting hospitals, and that was also segregated into the three categories of PCIs that are defined as STEMI,
which are the most emergent a person can have, serious changes in their cardiac rhythms (and other symptoms); non-STEMI, which is also an acute event, and non-acute, which is most like elective PCI.

We asked for three years of data. COAP has been in existence for over 25 years, so we looked at the most recent three years and there were almost 38,000 PCIs submitted to COAP over that period. One of the questions that came up in the stakeholder meeting in August was, is there increasing volume or decreasing volume in the state? And so there actually has been an increase in the number of cases reported to COAP in each of those three years, 5.6%. The COAP data was then segregated into the three categories, high volume which is greater than 300 PCIs per year and 16 hospitals fell into that category, those that performed 200 to 300 per year and that was where the most interest was because that’s the rule change window, 6 hospitals were in this category…. (Dennis reads the remainder of the slide aloud). Certificate of Need rules apply to the non-acute category – 18.5%.

Looking at outcome metrics, we looked at mortality. In the literature, mortality is usually risk-adjusted, it is generally recognized that STEMI is the highest risk, N-STEMI is intermediate risk, and elective is lowest risk. COAP data indicates there is a seven-fold difference in mortality between the non-acute and the STEMI category. The numbers were too small to calculate confidence intervals for non-acute as well as for individual metrics for complications so we took all of the complications and used the term “composite adverse event” because they add up enough to make composite comparisons.

In one of the discussions, Dr. McCabe said that because the numbers are relatively small, when you look at individual hospitals, the COAP data isn’t really designed to differentiate between individual hospitals and the difference between acute, and I think he used the terms, they’ve got to be really bad to show a difference. And that’s why we’ve been taking all of the data and then the composite and then applying confidence intervals, you’re able to have at least some analysis in comparison.

Another question that came up at the first meeting is that because the consensus documents do address the individual provider volumes, was COAP able to provide individual provider data? COAP was not able to provide such data.

(Dennis describes data slides). As you would expect with confidence intervals, the higher the volume the narrower the confidence interval, and the lower the volume the narrower the confidence interval. One of the things you can see is that the lower you are on the graph, the lower the mortality rate is. And while the confidence intervals are overlapping, there is an indication that the 200 – 300 is at least comparable. Next slide shows the composite adverse event rate. (Additional discussion of slides).

Last slide: summary. COAP data show comparable mortality and adverse event between a volume of 300 cases per year and 200-300 cases per year; COAP data does
not contradict the consensus documents regarding institutional volume standard recommendations.

Kathy: Thank you. Any questions or comments?

Dr. Dean: It’s important that when you look at this data, when you have confidence intervals that overlap, you cannot make a statement that they are the same. What you have to say is that they are hypothesis generating, it doesn’t prove that you have the same between 200 and 300. If there is more than 300, it’s a trend, therefore hypothesis generating, but it is not a proof that there is a difference. What it really says is that with more patients you might be able to show that they are the same, but with that number of patients you can’t statistically say that there is a difference. I think it’s important for people around the table to understand that. Also, in response to the comment about individual volumes, there’s also a nice article just published in JACC Intervention looking at the N-STEMI ART data set – that has over 2 million PCIs in it and they couldn’t find, they found that mortality was a very poor metric for determining individual practitioner outcome. And I would just refer you to that, it was published last week in JACC Intervention if you really want to look into that, but there is a data set that has got about 2.5 million data points in it and couldn’t show at least mortality difference among operators, so anyway, back to the comments a minute ago, I think this is going to some down to the same conversation that we had several months ago, and that is that there is no proof that there is a difference and the consensus documents are exactly that, consensus documents.

Kathy: Okay. Anyone else?

Jody: I would be ready to vote that we (unintelligible) toward the 200 and thank you for all of your work on the (unintelligible)

Kathy: I really appreciate it, thank you. Do we have consensus that the volume reduction is a good idea?

Dennis: Yes!

Kathy: Sounds like this side of the table is voting for that, Jody is, comments?…

Steve: I wasn’t part of the data subcommittee (unintelligible) I don’t think there have been any new consensus documents?

Kathy: I haven’t found any.

Steve: Any other articles or literature, anything (other than the consensus documents) that we can look at?

Dr. Dean: No, there’s no new consensus document around this particular question outside what’s already been discussed.
Kathy: Thanks, Larry (Dr. Dean).

Frank: I think, from my perspective, I think what we did with COAP does not contradict what we’ve already seen in the consensus documents with respect to institutions, but I do want to point out that we didn’t do anything with individual operators and the consensus documents are weaker there. They talk about volumes of, say, 50 or 36 for individual operators, but they don’t talk about, specifically, opinions about that, so I want to make a point that if we’re bundling these two things together, institutional volumes and operator volumes, and we do have consensus information on institutional volumes, and it’s much weaker on operator volumes...

(Discussion between Frank and Steve (?) regarding operator volumes in consensus docs, short exchange, generally unintelligible).

Dr. Dean: If you read the document itself its very clear that the information around individual operators is not clear and as I just pointed out, for those interested, if you look at the supplementary tables to the article I just talked about, it is relatively interesting when they tried to look at that question and how variable, for example, one operator for one period looked like they had a higher mortality rate than the others, and in another period they would be lower, and then in the next period they would be in the middle. So around individual operators, I think it is very, very unclear as stated in the consensus document from ACC and SCAI.

Steve: I have a question for the department and I wasn’t around to participate in the last one of these, obviously it’s clear that there are institutions out there (unintelligible). My first question is, how does the department go about determining how many procedures hospitals are performing, and number two, and this is why I brought this up, on operator volumes, if we go from 75 to 50, as a realistic matter, is the department ever going to check on that? What is the purpose of having it in there if it’s not checked on? Nothing critical, I’m just saying, I realize that as a practical matter the department is depending on people to report, but what is the purpose of having that in there?

Jody: Why does Providence think that there are hospitals performing PCIs? You can do emergency only, that doesn’t (unintelligible) a Certificate of Need....

Steve: Yeah I know...

Jody: Well you threw that out there…what makes you think that there are hospitals that are doing PCIs...

Steve: Okay, I take it back. Let me focus on operator volume. Why does the department (unintelligible) and does the department plan on monitoring that in the future? Because to my knowledge, and nothing critical, to my knowledge it never has.
Jan: Like with many things with some of those standards, (00:23:18) it is complaint driven. If we get a complaint regarding provider volumes, whether it be the facility itself or the individual provider, we would take a look at that. But we haven’t received any that would cause us to go out there and make a change. We have at least on one occasion, and this was before the rules, where we would have our surveyors go out and look at a hospital when it appeared there was an unusually large number of emergent PCIs and that resulted in changing the Certificate of Need during the review process.

Jody: Jan, I actually think it’s stronger than that. There’s two sets of standards – one if for hospitals that didn’t need a Certificate of Need to get started with their program because they were grandfathered in, and others, there were a group of eight or ten that did need a Certificate of Need back in 2008. And all of those hospitals, there were pretty robust conditions placed on the C of Ns, around QI, around reporting, around partnerships, and so those hospitals are monitoring, at least my clients are monitoring…

Jan: Right, and the conditions and requirements were developed with the consensus of the group that would allow some support establishing PCI programs without open heart surgery. And those were the conditions about what would be needed.

Dennis: If we go back to when the original rules were developed in 2008 and 2009, I was not part of that but we had our representative on that and I received a file drawer full of every document that was discussed, and while I haven’t read every page, the 2007 consensus documents were heavily relied upon to establish those volume standards, and in that document the institutional volume was 400 and the individual operator volume was 75. The consensus document entitled the SCAI/ACA Expert Consensus document was published in June of 2014 on percutaneous interventions without onsite open heart surgery specifically states these 2014 consensus documents update the 2007 documents, and on page 2629, it says, “studies that identified a signal suggest worse outcomes in laboratories performing <200 PCIs annually. The writing committee recommends that operators perform a minimum of 50 PCIs annually including no less than 11 primary PCIs. Ideally these procedures should be performed in institutions performing >200 procedures per year.” (00:26:58). In our petition that Virginia Mason Memorial submitted, since both of those numbers are reflected in the current rules, the consensus documents address both volume standards for both institutions and providers, our petition request was to update them directly from the consensus document. I would tell you and I would agree that nobody is really watching the individual volume. Perhaps the easiest road is just to replace the 75 with what the consensus documents say. There is another option, and that is to just take out the individual providers, that’s more potentially argumentative than the consensus documents that say 50 and so our petition was to reflect the consensus documents. We can probably have lots of discussion around them, but I would appeal to following the consensus documents with the rules of the state of Washington.

Dr. Dean: I was involved in the original rulemaking, in the committee that was involved in that, and as pointed out by others, that was a very exhaustive process. I would also remind the people on the committee this time around that at that time Washington state
was way ahead of the curve because those consensus documents at that period were really talking about institutions with on-site surgery, and the state of Washington was actually “pushing the envelope” so to speak, at that early time because there was no consensus document that had those volumes for off-site surgery. As a matter of fact, it was a Class 3 indication in that document to do elective PCI in an institution that did not have on-site surgery so, again, that process went for about a year, and the numbers were used from that document but that document was not addressing off-site surgical back up like the current Washington state rule does. And another thing just to throw out there, apropos the discussion, is what is the ability of the Department of Health to go into an institution and let’s say we lower it to 200 and there are institutions that then go to 125 cases per year, what is the ability of the Department of Health to go in and shut down a program like that?

Jan: We could take action. It does require a process to revoke a Certificate of Need for failure to meet conditions because all of the CoNs for PCI that were issued carry conditions, and that would be a process that would be appealable. I believe that we have an example recently with Capital Medical Center that they were not meeting their charity care requirements where they were approved and through settlement on their appeal, we suspended their CoN, and through a process now have a different settlement agreement on their meeting their obligations for charity care throughout the community. So, it is possible. We have not taken a lot of activity in terms of revoking CoN for failure to meet the criteria, but we have, from a program perspective, always believed that when you were issued a CoN you executed it and maintained that standards are in place regarding that approved project. These particular rules actually have a component that you will monitor and maintain those standards. I believe that they also maintain that if a facility fails to meet the volume standards that the department may take action, it’s not a required action. And so, we would look at a whole gamut of things in terms of outcomes and such to make that determination as to whether it would be necessary to close a facility. But, we don’t have the resources to proactively go out and try and shut them down. Again, it would be complaint driven. As I recall from the original consensus document, I think in part you are correct, but I think that it was also worded that if you were going to have a program without open heart surgery backup, (unintelligible) the things you would have to look at. I think there was that, sort of, caveat.

Dr. Dean: Yes, I would just point you to the guideline classifications, there is discussion in the documents. And that was the period of time when there was literature that was starting to build suggesting that this could be done, and certainly we’ve done that in the state of Washington. But it was a Class 3 indication in that document, and I’d be happy to be corrected. I remember the discussion about this very vividly because there were representatives from the ACC and the AHA that were not in agreement. However, they went forward and we’ve sort of obviously proven that this can be done. But, that original document did not condone that.

Jan: I don’t disagree with you that it was a Class 3 but it did speak to some volume standards, as I recall, that if it were to be done, and we did not have a choice of not
identifying some of the criteria based on a statute that was passed that we had to implement.

Dr. Dean: Right, it was mandated by the legislature that this be done, and again, it’s kudos to the state of Washington for pushing the envelope and doing this, and so, I just wanted people to be aware of what the conversations were last time this was discussed.

Jan: And I think other things, I think, Dennis, correct me if I’m wrong, I think using the consensus document is also consistent with the statutory requirements that we have, in terms of some of the basis of making the changes.

Dennis: That’s correct, if not to prove a point that is says it shall be done every three years, and it’s been a little bit more than three years.

Jan: Yes, three.

Steve: I apologize, because I’m going to sound like I’m pontificating or nit-picking away, and as far as I know, my client is not opposed, I want to be clear, that we’re necessarily (unintelligible) consensus document, my concern is that you’ve got regulations that are very, that set forth requirements, I mean, just bear with me one moment while I read what these regulations say, and these state that all new elective PCI program must comply with the state of Washington’s PCI volume standards, let’s say, 200 by the end of year three. The projected volumes must be sufficient to assure that all physicians working only at the applicant hospital will be able to meet minimum volume standards of, let’s say 50. That’s fine. Then there’s a separate regulation, 246-310-725 that says, “Physicians performing adult elective PCI procedures at the applying hospital must perform a minimum of 50 PCIs per year. Applicant hospitals must provide documentation that physicians performed 50 PCI procedures per year for the previous three years prior to the applicant’s CoN request.” I understand the resource issues, but why even have this if it is not going to be enforced? (00:36:11)

Jan: The same thing that happened when we had the original one, Steve. We anticipate that the hospitals will do their own enforcement and that they don’t want to be out of compliance with the rules, either.

Steve: Well, I’m not going to name any names, but I am aware of at least one hospital that has never been at 300 procedures and got a CoN. The department has done nothing about it and the department has known about it and I don’t know what that hospital reported itself, but it’s right there staring us in the face. All I’m trying to do is make these regulations rational.

Jody: Maybe what Providence needs to do is request that other sections of the rule be opened because this is not the subject of the conversation today. If Providence has concerns, they should file a petition for rulemaking and ask that sections of the rule (be opened).
**Steve:** I’m just pointing out to the group and to the department…

**Jody:** I understand, but if you want to do something about it, do something about it. But this is not the venue, that rule’s not open here. I mean it just seems like you’re trying to slow down the process.

**Steve:** Jody, I’m not trying to slow down the process at all.

**Jody:** You are raising an issue that we can’t do anything about today, those sections of rule are not open.

**Steve:** I’m talking about sections of the rule that are open.

**Jody:** The requirement that Jan is talking about…

**Steve:** (Unintelligible) My other comment is that I don’t think it’s appropriate to vote up or down on this. I think the purpose is to discuss what is here and (unintelligible) move ahead. This is not a case where providers vote up and then the department (unintelligible)…submit our comments.

**Kathy:** I think we just had people saying they were in favor of it Steve, I don’t think we’re taking a formal vote today.

**Steve:** I heard you calling for a vote.

**Kathy:** No, I was not calling for a vote. Any other comments?

**Zosia:** I just have a general question. If these two numbers change, what is the impact for current CoN PCI holders? Do they still have to meet the 300 standard? I’m just curious.

**Frank:** Currently, of the nine organizations that are approved for Certificates of Need, seven of them are out of compliance with the minimum volume of 300. So if the rule was changed to 200, a number of them would then come into compliance.

**Zosia:** And that would be the standard that would be used…

**Frank:** I would expect so, yes. But there would still be at least a few of them that would still be out of compliance. But of the nine, seven are noncompliant.

**Jonathan:** The conditions are based on WAC and not something that was negotiated, so if the WAC changes, the conditions….

**Zosia:** …the CoN will. Okay, thank you.
Dennis: I believe that five of those seven that are currently below 300 are over 200, so a good portion of them would eventually be compliant. Based on COAP data.

Kathy: Any additional comments or questions? I’ve heard folks say they were in support, I’ve heard other comments with respect to the proposal – anything else we should hear or know about?

Frank: As a statement, I think Providence wouldn’t have an issue with being consistent with consensus documents and I know Multicare would not either because they have a number of hospitals that provide PCIs. I think there would be an issue if you tried to eliminate the operator standard, and so I would read it as Dennis had mentioned, we tie the two together and if one moves the other moves and we would not eliminate (unintelligible). We would be supportive of that.

Jody: Even though we’re not voting, I think everyone around the table is in support.

Kathy: I’m generally sensing that, yes. Great. So I think we can go to the next segment of the meeting today, and that was to offer an opportunity to discuss exception language. And Jody, I’m going to hand the floor over to you for that.

Presentation – CHI Franciscan Exception Language

Ian: Sure, why don’t I start? My name is Ian Worden and I’m the Chief Operating Officer for CHI Franciscan. I’ve been in this state one year and about three months, so you’ll have to excuse my lack of knowledge about this process. I’ve never worked until recently in a state that had CoN, so this is a brand new process for me. And I understand what it’s trying to do, it’s trying to set a minimum level of volume so that we can assure that our patients are safe. One of the things, and I’ve been in health care since 1979, I’ve noticed about technology, is technology makes things safer and so the fact that you are changing your rules from 300 to 200 really reflects the fact that technology in hospitals is just getting safer and safer and safer. That’s not for the new procedures that come out, but you can see it in almost every single procedure that’s been out there, where you put the regulations around (unintelligible) all the way down to hips. So, I appreciate the flexibility. One of the things I wanted to bring to your attention is that we wanted an opportunity to talk about another dimension that’s not captured in the rulemaking, and that is, even if we have policy and regulations that say this is how many we need, there are still vast parts of the population that we can see that we serve in our communities that are underserved because we don’t have certain services within our hospital. We wanted an opportunity at some point in time because we were only given notice of the additional time of the meeting yesterday about (a quarter to one?) and my president, the president of CHI Franciscan, Ketul Patel was on a plane to Denver, we had to kind of mobilize to come here. So we’re really happy to come here and try and present, I would ask for additional time to present. Some of the things the rules aren’t catching is that we believe that in certain of our communities that the immigration into the planning area, we’re not looking at the people within the planning area that are not being served by the current state of elective PCIs and if you look in some of
our communities, there’s a 33% differential between those that are in certain parts of King County with MIIs for those that are being underserved and those are areas of immigrants, color, and socio-economic issues. It’s one of the areas that (00:49:39) we find ourselves within the Burien area where we have a population that right now isn’t quite being served, is quite in effect, underserved. In addition, as physicians in that community are aging, our ability to do even the emergent is going to be diminished simply because you can’t attract physicians in those areas if they don’t have elective. So we wanted to make sure that you understood our data that we would love to give or present to this committee or the appropriate committee that the rules are there for a reason but they’re also missing a huge component of areas that are underserved. We believe that the Burien area is one of those areas. And so, I don’t know what the procedure is in terms of having that opportunity to discuss. We have a few things prepared but we’d like a little bit more time to come back and present the whole picture. I’ll stop here and see if there’s any questions. Or discussion. (Unintelligible)… we could throw out there today, but it would be more important for you to have it in time to read it and digest it.

Kathy: Why don’t you present what you have today and then we can see what you have later, as well.

Ian: Alright, thank you, I’ll be happy to do that. So I’m going to go back and say, in terms of a presentation, let me paraphrase and read a few parts. In June of 2016, we asked in support of Highline Medical Center, we filed a petition for rulemaking. The petition stated that in “…the current rules, the department does not have the latitude to consider approving an application absent numeric need,” it’s what we spent a lot of time on. “This adherence to a numeric methodology means that characteristics unique to the residents of a particular community are being ignored. It also means there are communities in Washington state with the need for adequate access to these services are unmet even in those cases where hospitals are prepared and able to provide safe and ready access. These results are contrary to the underlying Certificate of Need statute. The rule that is currently adopted is indifferent to current socio-economic issues and geographic isolation that materially affect people’s ability to even have access care.” Being new to this community (unintelligible) I mean, moving around this area than what I’m used to so I know that you can have those. “As such, it risks worsening the already significant health disparities among residents statewide. (00:46:25) Such disparities were highlighted recently in the February 2016 report by the Office of Financial Management, which found that, among other things a 2.6-fold difference between the state legislative district with the highest coronary heart disease mortality rate and the district with the lowest.” Ideally, the department would have recognized the potential for this result and preemptively addressed it when adopting the current PCI rules in 2008. Given the priority placed by the Secretary on addressing health disparities, and given that there is now evidence to suggest that a lack of access is

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1 Excerpt from CHI Franciscan petition dated 6/1/16, pg. 1
2 Excerpt from CHI Franciscan petition dated 6/1/16, pg. 1, 2
impacting these disparities and outcomes, the department should immediately remedy this oversight by adopting the proposed amendment." 3

Going further on, the initial rulemaking currently was held in August of 2016, and today is only the second meeting we’ve had and we’d like to be able to have additional time to present a specific rulemaking petition. Some of the things that we’d like to bring to your attention, some of the data, that’s what counts, harnessing the (unintelligible) American communities, produced more than a dozen multi-colored maps of King County highlighting nearly 400 census tracking (unintelligible). Each map features different measurements, showing some income, other life expectancies, (unintelligible) and diabetes rates. (Unintelligible) these maps shows the same pattern, progressively worse problems across the border of south King County. The global to the local project determined that even with some of the best health care in the world, the US has pockets where health conditions mirror those of (unintelligible) countries. In fact, south King County is home to some of the greatest disparity of any American city. King County building equity and opportunity also demonstrated that south King County fares worse across all measures including education, employment, income, life expectancy, and quality of life than the other parts of King County. (Unintelligible) United Way of King County also demonstrated that and the Office of Financial Management showed that cardiac mortality and morbidity rates are significantly higher in the Highline community than the rest of King County for example the acute MI rate is (unintelligible – 36%?) higher. We believe that these data are an additional dimension that needs to be considered than just basic rules. You might have rules, but there are those rules that are excluding a large part of the population (unintelligible). In addition, with planning areas that have more than 50% of the PCIs performed in non-clinical (unintelligible), we think that that methodology masks the parts of those planning areas that are not (unintelligible - actually?) getting services. And in addition to that, when we round down from 299 to zero, it conveys that there’s no need whatsoever, so we do believe that the methodology may not fully account for the other dimension that needs to be considered, and that is quality and access and we believe that it is currently making, actually making it more difficult to provide care for those patients that we serve in that area. Anyways, I don’t know if I…

**Jody:** I think the data is (unintelligible – great/right?). I think what CHI Franciscan is requesting is that the rules allow an applicant, absent numeric need, to be able to put forth an application. The department, the public, can weigh in as to whether the arguments are compelling, whether the data suggests that there are disparities in access and outcome issues. And we would say the language should read something along the lines (00:50:32) of the fact that the applicant has a burden to demonstrate health disparities in quality or lack of access or availability to the population it serves, if the department finds that the burden is met, even after numeric need, CN can be granted assuming all other standards are met. And that takes care of the issue around 200, around 50, those requirements would not be relieved by virtue of the fact that there is no numeric need in a specific planning area. Ian is correct, the major problem with the King West planning area (00:51:14), the planning area in which Highline is located in

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3 Excerpt from CHI Franciscan petition dated 6/1/16, pg. 2
was very nicely detailed in Swedish Issaquah’s, Swedish Cherry Hill’s application where they define the fact that there was so much in-migration into that planning area, 52% of the individuals that receive a PCI in a planning area hospital in King West do not reside in King West, and the methodology does not allow for any adjustment for in-migration or out-migration. So the assumption is that allowing an exception is the way to be able to detail that there are variances within the numbers. The Highline proposal was supported by King County Public Health, King County EMS, SeaMar, HealthPoint, City of Burien, City of SeaTac, everyone that has a laser focus on trying to address...folks haven’t looked at the data. King County is a wonderful place to live if you are healthy (unintelligible) people are generally more affluent. Take a look at South King County and the numbers are staggering. That is not the case in south King County, people are dying at much higher rates, we have the data, we would love the opportunity to put forth the data in an application. Right now we can’t submit it, actually we could submit it but the department does not have the latitude to consider it simply because the rule says absent numeric need no Certificate of Need can be approved. So all we’re trying to do is correct that technical issue in the WAC. Every other rule, every other Certificate of Need methodology in rule has exception language. Open heart surgery has an exception requirement at Step 7 of that methodology; the ASC methodology in rule says “not ordinarily” and that allows an exception; the kidney disease methodology has 287 as an exception; the hospice methodology, in draft, is moving towards an exception. The nursing home bed need projection methodology and 380(5) has an exception. Acute beds and NICU not in WAC but the state health plan has a criterion for exceptions. So we are out there by ourselves with PCI not having any opportunity to even put forth an application for a program because of this absolute wall that was established in the original rules. We are not saying the department has to grant a Certificate of Need we’re just saying that an applicant should be able to put forth the data to substantiate the (need? Unintelligible). Glad to answer any questions. We have about this much data, we’ve been compiling it since last August and we’re hoping we can have another meeting in the not too distant future and we can share that additional information with the program.

Dr. Dean: So, the thing that I want to remind the group is that we’re talking about CoN for elective intervention and I’m an interventional cardiologist and I’ve been doing this for more than 30 years. And the problem that I have with this request is that there is no evidence that elective PCI changes mortality in patients with coronary disease. What changes mortality in patients with coronary disease is access to quality medical care, the cornerstone of which is medical therapy. Not PCIs. So, this notion that this is going to have an impact on morality from coronary disease is not well-informed. And I would absolutely champion adequate access of patients in these groups that you’ve talked about but its access to adequate pharmaceuticals for treatment of the underlying disease process, not a metal jacket in someone’s coronary.

Jody: Dr. Dean, we would love to, you’ve been supportive of a lot of these programs in the past, we would love to have you come down to Highline, take a look. I think one of the other issues that Highline is facing, and I think you know this well, is historically it had, I think it was five cardiologists, all residents of the community, they covered that
hospital 24/7, exchanged vacation times, did whatever, those cardiologists have all retired, there’s two left. The reason why King County EMS is advocating for Highline to be able to do a 24/7 total program, is simply because Highline cannot recruit and retain interventional cardiologists. You know, I know, all the other folks around the table know, they are not willing to go to a hospital where they can’t do what they’ve been trained to do. And so these long-standing cardiologists that have served that community and served it well, are no longer there, and Highline is sometimes not covering that service 24/7 and King County EMS is having to take ambulances out of the area because there is no even emergency capacity, and that’s why there is such high interest by the county to make sure this issue gets addressed. It’s costly, it’s expensive, and it’s in an area with health disparity that exists and it’s a huge problem and CHI Franciscan only sees that problem escalating.

Dr. Dean: As you point out, I am familiar with the practice at Highline. (00:57:18) And I don’t know the answer to this, I struggle with this myself, and that is, and I started to say something a moment ago when we were having the conversation about the volumes 200 and 50, and I know that there was the analysis of the three-year data suggesting that PCI volumes are going up, but they are certainly not going up at the rate they used to, and part of the reason for that is that, and again, there are some variables here that ten years from now might become important, but at least in the current state, acute coronary disease or sudden death, if you look at the data from Medic One, the incidence of a lot of this is flat to declining actually, and the reason for that is medical therapy. I understand the issue of 24/7 access to emergent intervention, and that’s a perplexing conversation, and we had the same conversation in 2008/2009, that was the reason that the state of Washington actually moved forward with giving the access to this technology in communities that did not have on-site surgical backup. With that said, what I understand of the problem, part of the problem is that the disease state is not increasing rapidly enough to keep everyone employed basically, and secondly, medical therapy as I said a moment ago, is what changes the natural history of this disease. That’s irrefutable. And so, trying to keep people out of the emergency room or off the cath lab table is best accomplished by adequate access to medical treatment for the underlying disease. And I certainly share your concerns, and understand that it’s very difficult to attract people into these environments but I don’t think adding the elective piece of this is going to, just like I said in 2008, I don’t think allowing access to the elective piece of this is going to attract the individuals that you are looking for unfortunately at the practice at Highline. The math is difficult for me to come to grips with.

Jody: So Dr. Dean, what you may not know is that two years ago, when that program was fully staffed Highline did 175 emergencies. There are issues in the data that tells us there were a lot of compliance issues with medical therapy. In these ethnic and cultural groups, there’s a lot more care that needs to be provided. The data is compelling, and we would be very happy to have you come down to the hospital and meet with the cardiologists and the other staff and share this information with you.

Dr. Dean: I do understand that, that we have within the UW medical system we have Harborview, and the compliance with medical therapy is an issue as well, it’s an issue in
general but more so in some of the other hospitals. But again, I guess the notion, again, the premise is, if you get a CoN to add elective cases to this, that that’s going to, if you had 187 acute cases at Highline, and you’ve got two individuals that are not only called whether they are interventional cardiologists or not, that is a reasonable volume per operator at least, and close to the 200 mark that’s required by the current CoN and so adding elective intervention to this, and again, I am very familiar with the economics of all of this, and adding elective intervention to this, I’m just going to tell you, is not going to allow you, unfortunately, in my own humble opinion, allow you to attract the quality individuals you are looking for to perform that kind of service at Highline. And I would be happy to come down and talk to you in more detail so we don’t take up any more of the committee’s time.

Ian: The dilemma that we find ourselves in is that no one else is picking up these patients. We don’t have the capability and no one else is picking them up. That’s the dilemma.

Dr. Dean: I wouldn’t argue with that. I understand, as I said, we, Harborview, has charity care in spades as you guys do.

Ian: So my concern is the rulemaking would prevent us from trying to serve that population but no one else is willing to pick up that population.

Vicki: Having seen a program, even if there are two providers (unintelligible) and you have new two providers that want to come in, you cannot sustain even an emergent program. Think about that Dr. Dean, your two providers are there 24/7 and that’s tough.

Dr. Dean: Again, and we probably should take this off-line, but even a program that does 200, then you start hiring interventional cardiologists who are fairly expensive to do minimal numbers of case volumes, and there are other states, just throwing this out there, that have dealt with the acute caseload without spreading out the availability of intervention, but have done a very good job by modern technology to try to get patients to centers where they can be taken care of. The state of Washington has gone in a different direction but fast forward ten years, and I’ll probably be retired at that point, but I think you are going to be having the same conversation because I don’t foresee that this is going to be a growth industry and the more places that provide this service, the more difficulty you are going to have at having (a) adequate volumes, and (b) attracting people to come to those places because what you just mentioned – call schedules, low volumes, etc. But it is what it is if you design a system like this. (01:03:35)

Chris: Dr. Dean, we had two interventional cardiologists practicing here in Burien, we recruited them out of Everett. They came down to Burien and practiced. They left because they couldn’t get their numbers. We’ve been successful in recruiting one interventionalist, who is there now to replace one of them, we have another one coming in June, and we’ve started building our intervention program between St. Francis and Highline to deal with the numbers, the procedures by doctors and the number of procedures by institution.
Dr. Dean: I don’t want to try to argue the point, and you are making the point, though, and that is that years ago this was a growth industry and everybody needed PCI sites all over. And it’s not anymore. And if you take basically a fixed number of procedures and divide it by more access, you’re going to wind up with the same problem, and again, that’s another conversation. I don’t want to come across as the bad guy, I don’t have the answer to this but my concern that trying to “fix this” by changing the rule is likely to result in the same problem because you don’t have a significantly increasing “n” to divide amongst the growing number of practitioners if you try to attract people, and again, it’s a quandary, I don’t have an answer for it. I’m just pointing out that we’re going to have this conversation ten years from now.

Jody: And all CHI Franciscan is asking for is the opportunity to put forth an application that UW Medicine can comment on. You can raise these issues. If after reviewing the data, the case, the financials, the quality, if you don’t believe that Highline can operate a quality program I would urge UW Medicine to comment on it, but right now we can’t put forth that application.

Cary: The department will never know if what you are saying is true because they can’t look at the application.

Ian: I understand the economics of it and I know that Lipitor does work as they say, and that’s a good thing. I think for our kind of dog in this hunt is really about there are just so many patients that don’t have access, those programs are not (unintelligible - picking that up?), not providing that access. The whole group of patients that just because they are socio-economic they are underserved populations, they just aren’t getting any care. That’s the dilemma that I see here. Because I’m new I see it in a lot of different areas where there’s just no access to care. And so, what we’re just asking is can we have a different dimension of looking at the rules to include access to underserved populations? And, how do we go about that? Because I’m sure your area isn’t the only area that has this, I’m sure there are other areas in Eastern Washington, or Southern Western Washington, I just don’t know the area that well…..

Jody: Again, our suggested rule is that every other standard has to be met. You can’t come in if you think you are going to do 20, you have to be able to demonstrate you can do more than that…

Frank: When you look at the PCI data from the state, at least, there clearly is a shrinking market. We hit a high water mark in 2010 of around 15,000 PCIs, the most recent data that the state prepared is close to COAPs, it’s around 11,500 or so. And so, this is not a growing market, it’s a shrinking one and carving it up as Dr. Dean mentioned simply means that all the providers have a smaller share of a shrinking pie. So, I would recommend that we really think about that, and think about the need for exceptions language in a market where it’s not growing, in fact, it’s shrinking.

Ian: (Unintelligible - one could say?), from the outside that you’ve already carved up the market, but there’s parts of the market that no one is capturing, and those patients are
not getting care, they don’t have the access to physicians, people aren’t picking them up, they can’t get to Seattle or people don’t want to treat those patients so you already carved up the market so the question is, have you left parts of the market underserved? And how are you going to deal with that?

**Frank:** Exactly. And in the rulemaking initiative of 2008, we were very careful about “carving up the market” and defining planning areas as a roll-up of the existing planning areas that we currently have, and it was a very deliberate choice based on the literature and the clinical outcomes information that we so chose to do that, to roll them up and aggregate them…

**Ian:** Let’s say a planning area has 40,000 patients and 20,000 of those are coming from outside of that planning area and the other 20 are coming within so you think you are taking care of the whole population but 20,000 are not getting service. That’s the issue that…

**Jody:** (Unintelligible) put together for Cherry Hill?

**Frank:** Cherry Hill didn’t have an issue.

**Jody:** Whatever the campus was, First Hill….

**Ian:** My point is that the methodology may be masking a bigger problem and that is that you have places that are underserved. Whether its behavioral health or PCIs, you’ve got a lot of populations that just are just not getting…

**Steve:** Jody, I’m not sure if I heard you…were you quoting some proposed rule language because, I just have a question, are you guys still proposing this language about people “people living in a catchment area,” “the hospital demonstrates (1) people living in its catchment area because of socioeconomic,” da da da. Are you providing different language or are you…

**Jody:** I’ve got some…we had notice yesterday…so the issue of the language will be around what I read, which we would like folks to comment on (01:10:07) that the applicant has the burden to demonstrate health disparities, health inequities, and/or lack of access or availability in the population that is served. If the department finds the burden is met, even absent numeric need, a CoN may be granted assuming all other standards are met.

**Steve:** Number 1, we would like a chance to review that language, and number 2, are you withdrawing the language that was in the original petition?

**Jody:** I don’t know that we’re withdrawing anything from the original petition, this is a discussion around the petition.

**Steve:** Right, but in the petition you proposed language…
Jody: That has been refined, correct.

Dr. Dean: That’s not the language as I recall it.

Jody: Yesterday we were told we had an opportunity to present and we’re trying to get the right people around the table to do this issue justice, again, we would like to come back in a month if you want to have a technical group that we can work with to support the specific language like we did on the numeric need we are glad to do that.

Steve: I’m going to put on my CoN lawyer pontificating hat and ask us to look at the big picture. We’ve only had personal opinions about the efficacy of CoN law. The focus of the CoN program is, in general, to allocate scarce resources and to keep control of healthcare costs of the residents of Washington. And it’s also to make sure that residents get the healthcare they need. But the whole issue of outpatient resources is particularly (unintelligible) when it comes to tertiary health services. Which is what this is. And let’s face it, CHI Franciscan already tried to go about this by getting this pulled out of the tertiary services, definition of tertiary services, and the department decided that no, PCI is a tertiary service and will remain a tertiary service. I’m not being critical of that, but we went through that process. And maybe this is just another attempt to get some sort of relief for Highline, which is fine, people do that, my clients do that. But, I think we have to keep in mind as we move forward here, that the issue is with tertiary services, that it is important that there be proper allocation of services. And of course, access is always an issue, but since we’ve been talking about the consensus document of 2014, the consensus document does weigh in on this whole issue of access, and I may be accused of picking and choosing here, but in the consensus document they say that, “hospitals justify the creation of new PCI centers without onsite surgery by stating that they improve access for geographically underserved 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 the PCI expertise, increase costs for the overall health system and have not been shown to improve access. If the transfer time is less than 30 minutes, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital….The development of PCI facilities within a 30 minute emergency transfer time to an established facility is therefore strongly discouraged.”

Jody: What if there is no provider within 30 minutes?

Steve: Within 30 minutes, okay, well let’s look at that kind of data. We’re talking about access. I think this idea about balkanizing Certificate of Need determination based upon particular populations, no matter how sympathetic we are or may be to those populations is going to undercut the entire purpose of the CoN program.

Jody: Then what we can do, is Steve, I’d love for you to be on my committee…

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Steve: I’m not suggesting that we have a committee…

Jody: EMS has the data, King County EMS has the data about travel times out of that community to the next (unintelligible – appropriate?) hospital and I’d love to share that with you. I do think a committee would be helpful, so we can bring this back and get this taken care of.

Ian: I’m not a lawyer, but it’s always been about patient care. And we have to do that responsibility (01:14:36). But how responsible are we if we have a rulemaking that excludes a large population that needs this care? And no one that has these programs are willing to take them on? That’s the issue here from my…it’s fundamental.

(Many people peaking at once).

Cary: The department can’t consider it without raising the opportunity for the exception.

Steve: Here is the access issue for the state of Washington. We’ll consider it.

Jody: So how do we want to…

Ian: How would you like us to do that, obviously that’s a recommendation, I’m not sure I know the rules here. What would you like us to do?

Kathy: Well, it sounds like we should probably schedule another meeting, at some point. We’d like to talk about it internally before we schedule another meeting.

Ian: Is there anything we can do to support that? Or just, you need to talk about it internally and let us know…

Jan: Well, I think that we’ve certainly heard your arguments regarding when to do some exception language and we’ll take a look at that and certainly be interested in other people’s opinions…

Ian: We’d be happy to come back after your determination. We’d just love to be able to present that in maybe three or four weeks with the two of us here and maybe some others who can provide a better reflection of what’s going on than I can because I’m fairly new….

Jody: The problem I’m seeing and I’ll be very honest with you is that you are asking us to write a Certificate of Need application. Right now we’re only open heart surgery. Open heart surgery has an exception. You can do less than 250, which was the threshold to get in, if you can document, I think there’s three things. There hasn’t been any abuse of those rules, there hasn’t been. We’re not asking to put forth a Certificate of Need application right now, we’re asking for consideration to be able to do (unintelligible) applicable (unintelligible). This is a travesty.
Dr. Dean: I think this group is asking to have another conversation about this.

Jody: We would love to put the data together but it’s not going to be enough. It’s not, every time you’re going to say we want to see that. Meanwhile, we’re slowing down rules for….

Dr. Dean: I don’t know how you predict the future. I’d love to know.

Jody: Well then Certificate of Need couldn’t exist because it’s all about predicting the future.

Ian: And what we’d love is an opportunity to come whenever it’s appropriate. We have the data, we’d love to share the data but we’re going to focus on access and patient care. It doesn’t matter about the future if you are dying today. We want to take care of those patients that need care today. I understand the shrinking economics of healthcare, I understand that it’s a consideration, but our focus is based upon our mission, our patients being cared for today, are they getting the right level of care, we don’t want to provide any level that’s inappropriate or more than what they need, but we do believe that in this one instance we have the need to demonstrate to you all that there is a hole in this system and we need to figure out how to (unintelligible). We just want that opportunity.

Jody: We’re asking for parity with every other Certificate of Need methodology. Every other methodology.

Steve: I would just make one more legal comment. I stated this in the first meeting, and the department is going to want to consult their own counsel, but I believe that this is a significant legislative rule because it’s changing the qualifications for (unintelligible). And as such, you have to go through a certain process and I’m just reminding the department that they need to follow procedures in 34.05.328 regarding legislative rules which includes considering alternative language and which includes conducting a cost benefit analysis before changing the rule. This is not something where we can just throw out the language and say go ahead and adopt it. This is a different type of rule. It’s different in character than the 200 vs 50 issue which does not go to the essence of the granting of a Certificate of Need. This is a significant legislative rule.

Ian: And we’ll be happy to testify under those when it comes to….

Kathy: Just to let you know, this is not a hearing…

Ian: I know, it’s my first though.

Kathy: It’s a meeting.

Frank: If we were going to have another meeting to discuss this if that’s what the department chose to do, it would be very helpful to have their language, their proposed
language so that as Bart said many months ago, we need something to tie exceptions language to. This isn’t a one-off thing that Highline wants, just by itself. Very likely, if we approve exceptions language, it’s there, and we need to understand definitively what it’s tied to and how it’s defined because I don’t think this is going to be a one-off proposal. It’s going to be something that would be out there in the rules, and others will likely to use it over time.

**Steve:** I ask that, at a minimum, that Jody provide that language to the department and that the department distribute that with the draft rules, because right now we’re working with language that appears to no longer be valid. I mean, the language of the petition appears to have changed.

**Kathy:** Right. Alright, any other conversation about the exception language?

**Ian:** I would just end by saying thank you, I appreciate it, this is my first meeting so I didn’t know what to expect. I do know that the intent of the CoN is not to prevent people from getting in, it’s just how (unintelligible) so I appreciate it.

**Kathy:** No other comments?

**Jody:** When will the department finish its internal discussion?

**Jan:** Probably within the next week or so.

**Jody:** Then we’ll set up a meeting after that?

**Jan:** We’ll (unintelligible).

**Dennis:** I would have a more general comment, not specific to their petition. If we’re ready to move on to that.

**Kathy:** I think we might be.

**Dennis:** On March 14, Virginia Mason Memorial submitted a petition for rules under RCW 85.050.033, something close to that, that requests the department to enter into rulemaking and our first meeting on that March petition was in August. There have been subcommittee meetings and now this is the second large stakeholder meeting, and the PCI Certificate of Need WAC 240-310-755 safety standards shall be re-evaluated every three years. It’s been seven or eight years since that. In the interest of a separate petition from exception language that has for the most part been considered as two separate topics at the two meetings we’ve had, there was only a subcommittee meeting on the volume standard of Memorial’s, and the department has provided draft language reflective of the consensus document and reflective of the petition, I would ask consideration, maybe not consideration, I would ask that the department move this volume standard petition forward so that it’s not further delayed. I’m very mindful, I’m being honest, that the window to submit a Certificate of Need application is in
November. At the current rate, we won’t be ready for November when we submitted the application in March of last year, thinking we would hit November of 2016 and now we’re 13 months later. It doesn’t feel like we’re moving forward in a timely manner and while I won’t say there was no opposition to the petition in compliance to the volume standards, I can hear opposition. And I would respectfully request the department to move forward to the CR 102 phase, and I’m just a pharmacist…

Frank: I think the application submission period has passed. It’s January, it’s already passed.

Dennis: I mean November of this year.


Dennis: The bottom line is that the next window to apply is rapidly coming based on the pace of the work we’ve done in the last 13 months.

Cary: Imagine how we feel on the pace of the exception language.

Dennis: I’ve been working on this for seven years.

Steve: Well, we have no objection, I know there was a technical reason why the two petitions were joined. I wasn’t quite sure what it was. But we don’t have any objection to the minimum volumes at all. We don’t think that should be held up, the minimum volumes.

Kathy: We can discuss that internally, as well.

Dennis: While I appreciate being corrected, I will read what is in the rule, the letter of intent should be submitted on the first working day of the last working day of November of every calendar year. So you have to submit a letter of intent in November to be able to then submit an application in January.

Frank: Your rules are reading different than mine.

Dennis: I have them printed off the department’s state’s website.

Frank: I think its January. Doesn’t matter.

Dennis: Bottom line is…

Kathy: You are ready to move forward.

Dennis: I respectfully request that we move forward to a CR 102.
**Presentation – Brief Overview of Rulemaking Process**

**Kathy:** Well, since we’re talking about process, some of you may have already seen this is in some of the other workshops that I’ve facilitated, but this is a brief overview of the rulemaking process. Want to let you know that for Department of Health rulemaking for non-complex, non-controversial rules can take anywhere from 18 months to two years. Based on the collaborative nature and the standards that we have to adhere to, that are dictated by statute, RCW 34.05.

(Referring to slide deck). So, here is a very brief overview of that rulemaking process. There are three stages, preproposal statement of inquiry which is a CR 101 that essentially opens up the rule set for discussion and stakeholdering. We accept comment and work collaboratively with organizations to develop rule sets and gather data so that we can develop effective rule sets that kind of stand the test of time. Next phase is the CR 102 proposed rulemaking, and that’s where there is an actual, formal rulemaking hearing. Everything leading up to that is informal. We do take formal comment once the CR 102 is filed and then we have an actual hearing, and that’s statutorily required, I believe it’s 20 days, it can happen no sooner than 20 days after filing the CR 102. After the CR 102 the department considers all of the comments that have been received, and whether or not we’re going to make any changes to the rule set that was proposed as part of the CR 102. And then the rule becomes final with the filing of the CR 103, or 30 days after the filing of the CR 103. So each of these phases consists of specific tasks and processes. This is kind of a chart of where we are right now in this process, and we’re still working on stakeholder work. We’ve got quite a ways to go, though, until we get to the CR 103. I don’t mean to scare you, Dennis, but we’re closer to the CR 102 than we were before. This gives you sort of a flow chart of how this all works. The rule drafting and analysis sort of speaks to what Steve was talking about with the significant analysis and that’s required under RCW 34.05.328. It’s not required for every rule set but for any sort of legislative, significant rulemaking it is. Typically, CoN falls under that for any rule set that we do.

(Referring to slide). So these are just a listing of some of the tasks and responsibilities the department has consistent with RCW 34.05.310, part of the APA, stage 1 of the rulemaking process. I’m not going to read through every piece of this, but this is where we’re doing sort of the initial legwork of rulemaking, and we don’t want to rush through this. We could end up with a really ineffective, not good rule set if we don’t edit properly. This is also where we start gathering information to develop the significant analysis under 34.05.328, and decide whether or not we need to do a small business economic impact statement consistent with RCW 19.85.

Next phase is standard rulemaking, that’s the CR 102 phase. We draft the CR 102 and filing that document actually opens the formal comment process and establishes the date and time of the public hearing. We take testimony at the public hearing, it does go on the record. We don’t provide any feedback, it just offers stakeholders and other interested parties an opportunity to comment on the rules.
And then we move into the final phase of rulemaking. We compile all of the comments that were received at the CR 102 hearing, decide whether any of those comments are going to sort of change the rules as they were presented in the 102. We also prepare what’s called a concise explanatory statement that includes all of the comments received at the 102 hearing and describes whether or not the department adopted that comment into the rule, thereby changing the rule, or if we didn’t adopt that comment, why we didn’t. So sometimes, for a concise explanatory statement, we can have a ten-page document depending on how controversial the rule was. If the department adopts the rules as they are proposed, we file the rulemaking order and the rule typically becomes effective 31 days after that.

(Referring to slide) This is just another very simple flow chart of the rulemaking process, offered in a different form just depending on how you take your information in. And then a comment we often get, why does rulemaking take so long? We have waiting periods that we have to adhere to that are set by law. Public involvement and deliberative dialogue take a lot of time, especially with Certificate of Need. No two rule sets are exactly alike, so some are very complex, some are controversial, they require a significant amount of time to develop. And, our DOH internal review process is lengthy. Even though we create rule sets over here in Health Systems Quality Assurance, everything is approved by the Secretary’s Office and reviewed before we actually put it out there in the CR 103. So we have several layers of review, not only internally, but though our AG and the Office of the Secretary. Here are additional resources (referring to slide), and I’ll send this slide deck out if you want to click on any of these resources and find out more about rulemaking activity. There’s also a link to the Certificate of Need rulemaking website. I navigated everyone there at the meeting on August 3, but I know that was a while back. Questions?

**Conclusion**

**Kathy:** Before we close, round table. Any other comments or questions?

Patty Seib: No  
Jonathan Seib: No  
Dennis Hoover: No  
Vicki Eastridge: No  
Chris Thomson: No  
Steve Pentz: I thought it was very productive.  
Frank Fox: No  
Ian Worden: Thank you for the opportunity. Appreciate it.  
Cary Evans: No  
Jody Carona: No  
Nancy Tyson: No  
Jan Sigman: No  
Dr. Larry Dean: Thank you as well.  
Zosia: Thank you  
Karen Nidermayer: No
Kathy: All right, we'll be in touch with everyone.

**END**